

Selection Criteria:

Product Name:	REMDESIVIR		
Product Active Ingredient:			
Active Ingredient:			
Active Moiety:			
FDA Received Date:	From:	01-Apr-2020	To: 03-Aug-2020
MedDRA® Version* :	23.0		
Total Cases**:	2163		
Number of Pages:	859		

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. "MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

** "Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting. Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.
Health Prof	Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Mfr Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
503B Facility	Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).

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Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products.
Product	Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Comp.	Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.
OTC	Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Mfr	The manufacturer of the product, as indicated in the report.

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01-May-2020	17731692	NON-EXPEDITED		OT	US-SA-2020SA110743			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Aspartate Aminotransferase Increased; Blood Calcium Decreased; Blood Potassium Decreased; Gastrointestinal Haemorrhage	Lovenox			S	Subcutaneous	100 Mg, Bid		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Dexmedetomidine			C	Unknown	Unk		Not Reported
	Apixaban			C	Unknown	Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Docusate Sodium			C	Unknown	Unk		Not Reported
	Fluticasone Furoate;Vilanterol			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Hydrocodone			C	Unknown	Unk		Not Reported
	Insulin Aspart			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Loratadine			C	Unknown	Unk		Not Reported
	Polyethylene Glycol			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	Unk		Not Reported
	Inula Helenium Root;Senna Alexandrina Leaf			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

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Pantoprazole	C	Unk	Not Reported
Multivitaminum	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17770443	DIRECT	Y	OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Hyperhidrosis; Hypotension; Infusion Related Reaction; Infusion Site Reaction; Nausea; Vomiting	Remdesivir	Y		S	Intravenous drip		30 MIN	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17770487	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Disease Progression; Hypertension; Oxygen Saturation Decreased	Remdesivir	Y		S	Intravenous drip			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17770490	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Endotracheal Intubation	Remdesivir			S				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Methylprednisolone			C				Not Reported

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11-May-2020	17770498	DIRECT	Y	DE			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Pulseless Electrical Activity; Ventricular Fibrillation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17770540	DIRECT	Y	OT			48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17770559	DIRECT	Y				79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770551	DIRECT	Y	OT			72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir Acetaminophen Allopurinol Aspirin Digoxin			S C C C C	Intravenous drip	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported Not Reported	

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Famotidine	C	Not Reported
Metoprolol Succinate	C	Not Reported
Warfarin	C	Not Reported

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12-May-2020	17774804	DIRECT	Y	HO			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17774838	DIRECT	Y	DE			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Cardio-Respiratory Arrest; Dialysis; Pneumonia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17774848	DIRECT	Y	HO			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Oliguria	Remdesivir			S	Intravenous drip			Gilead
	Vancomycin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Etomidate			C				Not Reported
	Succinylcholine			C				Not Reported
	Fentanyl			C				Not Reported
	Naloxone			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Norepinephrine			C				Not Reported
	Inhaled Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Aspirin Chewable			C				Not Reported

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Bisacodyl Suppository	C	Not Reported
Gabapentin	C	Not Reported
Insulin Lispro	C	Not Reported
Propofol	C	Not Reported
Senna	C	Not Reported
Iv Furosemide 40 Mg X 1	C	Not Reported
Hydroxychloroquine Or Placebo	C	Not Reported
Enoxaparin	C	Not Reported
Heparin	C	Not Reported
Metolazone 10 Mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17774850	DIRECT	Y	OT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Covid-19 Pneumonia; Haemodynamic Instability; Hypotension; Renal Tubular Necrosis; Respiratory Failure; Weight Decreased	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Diazepam			C				Not Reported
	Docusate			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Heparin 7,500 Units Sq			C				Not Reported
	Insulin Lispro			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17774851	DIRECT	Y	HO			54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead

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13-May-2020	17775263	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered; Product Label Confusion	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17776492	DIRECT	Y				76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clinical Trial Participant; Thrombocytopenia	Remdesivir			S				Not Reported
	Aspirin			C				Not Reported
	Amlodipine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Torsemide			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Atorvastatin			C				Not Reported

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13-May-2020	17781018	DIRECT	Y	DE			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

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13-May-2020	17781025	DIRECT	Y				41 YR	Male	USA

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Blood Creatinine Increased; Chest X-Ray Abnormal; Clinical Trial Participant; Oxygen Consumption Increased; Product Use In Unapproved Indication; White Blood Cell Count Increased	Remdesivir Fentanyl Hydralazine Piperacillin-Tazobactam Pantoprazole Enoxaparin Propofol			S C C C C C C				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784372	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clinical Trial Participant; Diarrhoea; Nausea; Product Use In Unapproved Indication; Vomiting	Remdesivir Acetaminophen Amlodipine Ascorbic Acid Finasteride Gabapentin Guaifenesin/Codeine Heparin Lisinopril Ondansetron Pantoprazole Propranolol Saline Nasal Spray Zinc Sulfate Combivent Respimat			S C C C C C C C C C C C C C C	Intravenous drip	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17790333	DIRECT	Y				71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Chills; Clinical Trial Participant;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

Electrocardiogram
Change; Hypotension;
Infusion Related Reaction;
Mental Status Changes;
Nausea; Product Use In
Unapproved Indication;
Pulse Abnormal

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14-May-2020	17790340	DIRECT	Y	OT			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Clinical Trial Participant; Product Use In Unapproved Indication; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17790341	DIRECT	Y	OT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Product Label Confusion; Product Preparation Error	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Furosemide			S	Intravenous bolus			Not Reported
	Bumetanide			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Docusate			C				Not Reported
	Epoprostenol Inhalation			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Lorazepam			C				Not Reported
	Maraviroc			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
Propofol			C				Not Reported	
Vasopressin			C				Not Reported	

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Vecuronium

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17791132	DIRECT	Y	DE			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500mg			C				Not Reported
	Atorvastatin 20mg Tab			C				Not Reported
	Azithromycin 500mg Iv			C				Not Reported
	Ceftriaxone 1gm Iv Daily			C				Not Reported
	Cholecalciferol 4,000 Units Daily			C				Not Reported
	Doxycycline 100mg Iv Q12h			C				Not Reported
	Enoxaparin 40mg Daily			C				Not Reported
	Furosemide 20mg Once			C				Not Reported
	Hydroxychloroquine 400mg			C				Not Reported
	Irbesartan 75mg Daily			C				Not Reported
	Potassium 20meq Once			C				Not Reported
	Zinc Sulfate 440mg Daily			C				Not Reported
	Acetaminophen 650mg Q4h Prn			C				Not Reported
Fentanyl 50mcg Q2h Prn			C			Not Reported		
Dexmedetomidine Infusion			C			Not Reported		
Heparin Infusion			C			Not Reported		
Insulin Lispro			C			Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792090	EXPEDITED (15-DAY)		OT	CH-SA-2020SA124099		61 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Exfoliative Generalised; Eosinophilia; Rash Erythematous	Ceftriaxone			S				Not Reported
	Clarithromycin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Amlodipine (Salt Not Specified)			S		5 Mg		Not Reported
	Oxazepam			S		Unk		Not Reported
	Lasix			S		Unk		Sanofi

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Lasix	S	Unk	Sanofi
Lasix	S	Unk	Sanofi
Clexane	S	40 Mg	Sanofi
Clexane	S	40 Mg	Sanofi
Lorazepam	S	Unk	Not Reported
Paracetamol	S	Unk	Not Reported
Paracetamol	S	Unk	Not Reported
Quetiapine Fumarate	S	Unk	Not Reported
Esomeprazole Magnesium	S	Unk	Not Reported
Esomeprazole Magnesium	S	Unk	Not Reported
Haldol	S	Unk	Not Reported
Remdesivir	S	Unk	Not Reported
Diamox [Acetazolamide]	C	Unk	Not Reported
Diamox [Acetazolamide]	C	Unk	Not Reported
Diamox [Acetazolamide]	C	Unk	Not Reported
Distraneurin	C		Not Reported
Heparine	C	Unk	Not Reported
Novorapid	C		Not Reported
Ipramol	C	Unk	Not Reported
Lexotanil	C	Unk	Not Reported
Movicol	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Nozinan	C	Unk	Not Reported
Antibiotics For Otic And Nasal Use	C	Unk	Not Reported
Antibiotics For Otic And Nasal Use	C	Unk	Not Reported
Antibiotics For Otic And Nasal Use	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Dexdor	C	Unk	Not Reported
Dexdor	C	Unk	Not Reported

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Dexdor	C	Unk	Not Reported
Sintenyl	C	Unk	Not Reported
Sintenyl	C	Unk	Not Reported
Dormicum	C	Unk	Not Reported
Dormicum	C	Unk	Not Reported
Dormicum	C	Unk	Not Reported
Noradrenaline	C	Unk	Not Reported
Noradrenaline	C	Unk	Not Reported
Noradrenaline	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Rocuronium	C	Unk	Not Reported
Tracrium	C	Unk	Not Reported
Tracrium	C	Unk	Not Reported
Tracrium	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792126	DIRECT	Y	DE			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792128	DIRECT	Y	OT			59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Hypotension; Infusion Related Reaction	Remdesivir			S	Intravenous drip	Other Frequency:X1		Gilead

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(Loading Dose);

Apap 500 Mg Po Q6hr Prn	C	Not Reported
Pain/Fever		
Ascorbic Acid 1500 Mg Po Daily	C	Not Reported
Cefepime 1 G Ivpb Q12hr	C	Not Reported
L-Thyroxine 175 Mcg Po Daily	C	Not Reported
Lorazepam 0.5 Mg Po Tid Prn	C	Not Reported
Anxiety		
Ondansetron 4 Mg Iv Push Q6hr	C	Not Reported
Prn N/V		
Vancomycin 1.5 G Ivpb Q12hr	C	Not Reported
Zinc Sulfate 220 Mg Po Daily	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792132	DIRECT	Y	DE			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Refusal Of Treatment By Relative	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792142	DIRECT	Y	HO			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792175	DIRECT	Y	HO			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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15-May-2020	17794224	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0467265		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797263	DIRECT	Y	OT			66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Poor Quality Product Administered; Product Storage Error	Remdesivir	Y		S	Intravenous (not otherwise specified)		6 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797264	DIRECT	Y				57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Blood Creatinine Increased; Fluid Overload	Remdesivir			S	Intravenous drip			Gilead	
	Cefepime			C				Not Reported	
	Lactobacillus			C				Not Reported	
	Aspirin			C				Not Reported	
	Fentanyl Continuous Drip			C				Not Reported	
	Dextometomedine			C				Not Reported	
	Propofol			C				Not Reported	
	Heparin Subcutaneous			C				Not Reported	
	Famotidine			C				Not Reported	
	Methylpredinosolone			C				Not Reported	
	Humalog			C				Not Reported	
	Humulin Nph			C				Not Reported	
	Venelex			C				Not Reported	
	Ocean Mist			C				Not Reported	

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Refresh		C					Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797623	DIRECT	Y	OT			66 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hypotension	Remdesivir				S	Intravenous drip			Gilead
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797878	DIRECT	Y	OT			71 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir				S				Gilead
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797266	DIRECT	Y	OT			46 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Seizure	Remdesivir				S	Intravenous bolus			Gilead
	Ascorbic Acid				C				Not Reported
	Atorvastatin				C				Not Reported
	Enoxaparin				C				Not Reported
	Famotidine				C				Not Reported
	Insulin				C				Not Reported
	Melatonin				C				Not Reported
	Methylprednisolone				C				Not Reported
	Zinc				C				Not Reported
	Fentanyl				C				Not Reported
	Norepinephrine				C				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797267	DIRECT	Y	OT			41 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Convalescent Plasma For Covid-19 Tocilizumab Or Placebo/Covacta Study	S C C							Gilead Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797268	DIRECT	Y	OT			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Coronary Artery Stenosis; Depressed Level Of Consciousness; Hemiparesis; Mental Status Changes; Renal Ischaemia	Remdesivir Remdesivir Convalescent Plasma For Covid-19			S S C	Intravenous bolus Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797269	DIRECT	Y	OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Function Test Abnormal	Remdesivir Cefepime Vancomycin			S C C	Intravenous drip			Gilead Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797270	DIRECT	Y				46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Liver Function Test Increased; Therapy Interrupted	Remdesivir Benzonatate Ceftriaxone Clonazepam Doxycycline			S C C C C				Not Reported Not Reported Not Reported Not Reported Not Reported

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Enoxaparin	C	Not Reported
Furosemide	C	Not Reported
Methylprednisolone	C	Not Reported
Omeprazole	C	Not Reported
Ropinirole	C	Not Reported
Topiramate	C	Not Reported
Ziprasidone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797271	DIRECT	Y				70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797281	DIRECT	Y				57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797285	DIRECT	Y				52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Hypertension; Therapy Change	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Digoxin			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
Nebivolol			C				Not Reported	

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Hydroxychloroquine			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17797292	DIRECT	Y	OT			70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Protein Total Increased; Renal Tubular Necrosis; Sepsis	Remdesivir			S	Intravenous drip	Other Frequency:Once, Then 100mg;		Gilead	
	Heparin/Enoxaparin Subcutaneous			C				Not Reported	
	Aspirin 81 Mg			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Ondansetron			C				Not Reported	
	Levothyroxine 150 Mcg			C				Not Reported	
	Tocilizumab 400 Mg			C				Not Reported	
	Ethacrynic Acid			C				Not Reported	
	Metoprolol			C				Not Reported	
	Tradipitant			C				Not Reported	
Trimethobenzamide 200 Mg Injection			C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17798027	DIRECT	Y	RI			70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir (Gs-5734)	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir (Gs-5734)	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17798044	DIRECT	Y	HO			60 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cardiac Failure; Coagulopathy; Organ Failure; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17801712	DIRECT	Y	OT			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798196	DIRECT	Y	OT			23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Liver Function Test Increased; Therapy Cessation	Remdesivir 200 Mg			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Dextromethorphan			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin			C				Not Reported
	Ibuprofen			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C				Not Reported
	Albuterol Hfa			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798574	DIRECT	Y	OT			23 YR	Male	USA

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Drug Ineffective; Liver Function Test Increased; Therapy Cessation	Remdesivir 200 Mg			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C		Not Reported		
	Dextromethorphan			C		Not Reported		
	Benzonatate			C		Not Reported		
	Enoxaparin			C		Not Reported		
	Aspirin			C		Not Reported		
	Ibuprofen			C		Not Reported		
	Vitamin C			C		Not Reported		
	Zinc Sulfate			C		Not Reported		
	Hydroxychloroquine			C		Not Reported		
Prednisone			C	Not Reported				
Albuterol Hfa			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801700	DIRECT	Y	OT			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Abnormal	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801703	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801706	DIRECT	Y	DE, LT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; General Physical Health	Remdesivir	Y		S	Intravenous (not otherwise specified)		3 DAY	Gilead

Deterioration; Oxygen Saturation Decreased	Cefepime 2g Iv Q12h	C	otherwise specified)	Not Reported
	Ascorbic Acid 1500mg Iv Q6h	C		Not Reported
	Thiamine 200mg Iv Q12h	C		Not Reported
	Doxycycline 100mg Po Bid	C		Not Reported
	Methylprednisolone 60mg Iv Q12h	C		Not Reported
	Pantoprazole 20mg Po Q24h	C		Not Reported
	Sertraline 100mg Po Q24h	C		Not Reported
	Methylprednisolone 60mg Iv Q24h	C		Not Reported
	Tamsulosin 0.4mg Po Q24h	C		Not Reported
	Zinc Capsule 50mg Po Q24h	C		Not Reported
	Ipratropium Inh 2 Puffs Po Q6h	C		Not Reported
	Enoxaparin 30mg Sc Q12h	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801710	DIRECT	Y	OT			43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Test Positive; Vomiting	Remdesivir			S	Intravenous drip			Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Glargine			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone			C				Not Reported
	Prochloroperazine			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801711	DIRECT	Y	OT			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported

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18-May-2020	17801746	DIRECT	Y	OT			84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Hypotension; Respiratory Failure; Tachypnoea; Urine Output Decreased; White Blood Cell Disorder	Remdesivir Vancomycin Furosemide			S C C				Gilead Not Reported Not Reported	
18-May-2020	17801755	DIRECT	Y	OT			77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Liver Function Test Increased; Product Use In Unapproved Indication; Renal Replacement Therapy	Remdesivir			S	Intravenous drip			Not Reported	
18-May-2020	17801760	DIRECT	Y				53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Differential White Blood Cell Count Abnormal; Leukopenia; Lymphocyte Percentage Increased; Neutrophil Percentage Decreased; Product Use In Unapproved Indication	Remdesivir Ascorbic Acid 1500mg Po Bid Cholecalciferol 50mcg Po Q24h Zinc Capsule 50mg Po Q24h Magnesium Oxide 420mg Po Bid Insulin Glargine 12 Units Sc Qhs Insulin Aspart Sliding Scale Tid			S C C C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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Ac
Senna 17.2mg Po Daily
Enoxaparin 30mg Sc Q12h

C
C

Not Reported
Not Reported

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18-May-2020	17801796	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine Or Matching Placebo			C				Not Reported
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801801	DIRECT	Y	OT			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypovolaemia; Renal Tubular Necrosis	Remdesivir Injection (For Use Under Eua)			S	Intravenous drip			Gilead
	Remdesivir Injection (For Use Under Eua)			S	Intravenous drip			Gilead
	Vancomycin 2g Iv Q12			C				Not Reported
	Vancomycin 1g Iv Q12			C				Not Reported
	Vancomycin 1g Iv X 1			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Pregabalin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801805	DIRECT	Y	OT			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous bolus	Other Frequency:200mg X 1 100mg X4;		Gilead
	Cefepime			C				Not Reported

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Methylprednisolone	C	Not Reported
Azithromycin	C	Not Reported
Hydroxychloroquine	C	Not Reported
Furosemide	C	Not Reported
Carvedilol	C	Not Reported
Docusate	C	Not Reported
Folic Acid	C	Not Reported
Neurontin	C	Not Reported
Clopidogrel	C	Not Reported
Pantoprazole	C	Not Reported
Mvi	C	Not Reported
Heparin Drip	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801809	DIRECT	Y	HO			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801815	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Swelling; Throat Irritation	Remdesivir	Y		S				Not Reported
	Amlopidine			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Lisinopril			C				Not Reported
	Nystatin Oral Susp			C				Not Reported

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Percocet	C	Not Reported
Pantoprazole	C	Not Reported
Sitagliptin	C	Not Reported
Zinc	C	Not Reported
Vitamin D	C	Not Reported
Vitamin C	C	Not Reported
Aspirin	C	Not Reported
Metformin	C	Not Reported
Methylprednisolone	C	Not Reported
Dipridamole	C	Not Reported
Empagliflozin	C	Not Reported
Insulin Lispro	C	Not Reported
Letrozole	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801819	DIRECT	Y	HO			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Discomfort; Infusion Related Reaction; Nausea; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;	20 MIN	Gilead
	Albuterol Inhaler			C				Not Reported
	Atorvastatin			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Lisinopril			C				Not Reported
	Pantoprazole			C				Not Reported
	Tiotropium			C				Not Reported
	Norco 5			C				Not Reported
	Tussionex			C				Not Reported
	Ondansetron			C				Not Reported
	Prochlorperazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801824	DIRECT	Y	OT			46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported
	Zinc			C				Not Reported

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Quetiapine	C	Not Reported
Methylprednisolone	C	Not Reported
Melatonin	C	Not Reported
Levetiracetam	C	Not Reported
Atorvastatin	C	Not Reported
Ascorbic Acid	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801829	DIRECT	Y	HO			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Hypoxia	Remdesivir			S	Intravenous bolus			Gilead
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801885	DIRECT	Y	OT			34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Pressure Increased; Body Temperature Increased; Heart Rate Increased; Hyperhidrosis; Nausea; Oxygen Saturation Decreased; Respiratory Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801892	DIRECT	Y	OT			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Ceftriaxone			C				Not Reported

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Famotidine	C	Not Reported
Heparin	C	Not Reported
Insulin	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Azithromycin	C	Not Reported
Tocilizumab	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801899	DIRECT	Y				52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Dose Omission	Remdesivir			S	Intravenous bolus			Gilead
	Tocilizumab 760mg			C				Not Reported
	Convalescent Serum			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801905	DIRECT	Y	HO			15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous bolus			Gilead
	Cosyntropin			C				Not Reported
	Cefepime			C				Not Reported
	Melatonin			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Mercaptopurine			C				Not Reported
	Azithromycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801912	DIRECT	Y	LT			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Azotaemia; Continuous Haemodiafiltration; Glomerular Filtration Rate Decreased	Remdesivir Enoxaparin Famotidine	Y	S C C	Intravenous bolus	Gilead Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17802626	DIRECT	Y	DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Covid-19; Dyspnoea; General Physical Health Deterioration; Hypotension; Liver Function Test Abnormal; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased; Pneumonia Staphylococcal; Pyrexia; Renal Function Test Abnormal; Sars-Cov-2 Test Positive	Convalescent Plasma Remdesivir Dapsone Linezolid Vancomycin Piperacillin/Tazobactam			S S C C C C	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802614	DIRECT	Y	LT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802618	DIRECT	Y	OT			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Continuous Haemodiafiltration; Inadequate Haemodialysis; Renal Impairment	Remdesivir	S	Intravenous drip	2 DAY	Gilead
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802638	DIRECT	Y	DE			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacteraemia; Cardiac Arrest; Covid-19; Disease Complication; Pneumonia Pseudomonal; Respiratory Failure	Remdesivir			S	Intravenous bolus			Gilead
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Carvedilol			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lactobacillus Acidophilus			C				Not Reported
	Lansoprazole			C				Not Reported
	Lorazepam			C				Not Reported
	Meropenem			C				Not Reported
	Metoclopramide			C				Not Reported
	Multivitamin			C				Not Reported
	Oxycodone			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported
	Potassium Chloride			C				Not Reported
	Neutra-Phos			C				Not Reported
	Senna			C				Not Reported
	Vancomycin			C				Not Reported
	Hydromorphone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802944	DIRECT	Y	DE			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oxygen Saturation	Remdesivir			S	Intravenous (not			Gilead

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Decreased; Renal Failure					otherwise specified)				
	Hydroxychloroquine Or Matching Placebo (Orchid Trial)		C						Not Reported
	Convalescent Plasma		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802952	DIRECT	Y	DE			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Leviteracetam			C				Not Reported
	Oxcarbazepine			C				Not Reported
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Lispro			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17805154	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0466529		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Hypotension; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17805179	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0467261		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806590	DIRECT	Y	OT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
	Amolodipine			C				Not Reported	
	Atracurium			C				Not Reported	
	Carvedilol			C				Not Reported	
	Famotidine			C				Not Reported	
	Heparin			C				Not Reported	
	Lidocaine Patch			C				Not Reported	
	Midazolam			C				Not Reported	
	Multivitamin			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Atracurium			C				Not Reported	
	Fentanyl			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806639	DIRECT	Y	LT			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Haemodynamic Instability; Pneumothorax; Pulmonary Embolism; Sepsis; Shock	Remdesivir			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806644	DIRECT	Y	OT			45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Bisacodyl Suppository			C				Not Reported	

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Bumetanide 1mg Inj	C	Not Reported
Ceftriaxone 2g Inj	C	Not Reported
Chlorhexidine 0.12% Swish	C	Not Reported
Enoxaparin 100mg	C	Not Reported
Fentanyl 100mcg/Hr	C	Not Reported
Ipratropium-Albuterol Neb	C	Not Reported
Lactated Ringer Infusion	C	Not Reported
Potassium Phosphate 15mmol Bolus	C	Not Reported
Propfol Infusion 40mcg/Kg/Min	C	Not Reported
Rocuronium 10m/MI Infusion	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806653	DIRECT	Y	LT			29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Caesarean Section; Foetal Heart Rate Abnormal; Haemodynamic Instability; Respiratory Failure	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806658	DIRECT	Y	OT			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Condition Aggravated; Haemodialysis	Remdesivir Eua			S				Not Reported
	Amlodipine 5mg			C				Not Reported
	Ascorbic Acid 1000mg			C				Not Reported
	Ceftriaxone 1g			C				Not Reported
	Doxycycline 100mg			C				Not Reported
	Furosemide 40mg			C				Not Reported
	Heparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806695	DIRECT	Y	OT			75 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Creatinine Increased; Body Temperature Increased; Infusion Related Reaction	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Doxazosin			C				Not Reported
	Hydralazine			C				Not Reported
	Lorazepam			C				Not Reported
	Combivent Respimat			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Levothyroxine			C				Not Reported
Zinc Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806699	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Septic Shock	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Norepinephrine			C				Not Reported
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806709	DIRECT	Y	RI			54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806721	DIRECT	Y	DE, LT, OT			72 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Fluid Overload; Hypoxia; Respiratory Disorder; Shock	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Bensonatate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Normosol-R			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Iopamidol			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Melatonin			C				Not Reported
	Metaclopramide			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
Morphine			C				Not Reported	
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806725	DIRECT	Y	DE, OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Acute Kidney Injury; Cardiac Arrest; Hypernatraemia; Metabolic Acidosis; Paralysis; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomidine Drip			C				Not Reported
	Enoxaparin 100 Mg Subq Q12h			C				Not Reported
	Insulin			C				Not Reported
	Methylprednisolone 60 Mg Iv Q12h			C				Not Reported
	Lorazepam 2 Mg Iv Q4h Prn			C				Not Reported
	Levophed Infusion			C				Not Reported
Methylprednisolone 40 Mg Iv			C				Not Reported	

Q12h									
Dopamine Infusion			C						Not Reported
Epinephrine Infusion			C						Not Reported
Phenylephrine Infusion			C						Not Reported
Epoprostenol For Inhalation			C						Not Reported
Sodium Bicarb 150 Meq/Swi 11 At 150 MI/Hr			C						Not Reported
Vancomycin			C						Not Reported
Piperacillin/Tazobactam			C						Not Reported
Heparin Low Intensity Infusion			C						Not Reported
Amiodarone Iv			C						Not Reported
Ketamine Infusion			C						Not Reported
Morphine Infusion			C						Not Reported
Rocuronium Infusion			C						Not Reported
Tocilizumab 800 Mg Iv X1 Dose			C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806729	DIRECT	Y	DE			92 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806734	DIRECT	Y	DE			96 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Abnormal; Renal Failure; Respiratory Failure	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg			C				Not Reported
	Cefepime 1 Gram			C				Not Reported
	Ergocalciferol 50,000 Units			C				Not Reported
	Hydromorphone 0.2 Mg Iv			C				Not Reported
	Methylprednisolone 40 Mg Injection			C				Not Reported
	Pantoprazole 40 Mg Tablet			C				Not Reported
	Senna 17.2 Mg			C				Not Reported
	Sodium Chloride 0.9% Neb			C				Not Reported

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Zinc Sulfate 220 Mg	C	Not Reported
Mirtazapine 7.5 Mg	C	Not Reported
Morphine 4 Mg/ML Injection	C	Not Reported
Torsemide 20 Mg	C	Not Reported
Norepinephrine 8 Mg / 250 ML	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806736	DIRECT	Y	DE			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Clinical Trial Participant; Product Use In Unapproved Indication; Pulseless Electrical Activity; Tachycardia	Remdesivir Eua	Y		S				Not Reported
	Amikacin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Vasopressin			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Diphenhydramine			C				Not Reported
	Docusate			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Robitussin Dm			C				Not Reported
	Insulin Lispro			C				Not Reported
	Tocilizumab			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Montelukast			C				Not Reported
	Pantoprazole			C				Not Reported
Vancomycin			C				Not Reported	
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806739	DIRECT	Y	OT			46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Cholelithiasis; Clinical Trial Participant; Product Use In Unapproved Indication; Sepsis; Shock; Transaminases Increased
Remdesivir
S
Intravenous (not otherwise specified)
Other Frequency:Once;
Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806745	DIRECT	Y	OT			40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17806790	DIRECT	Y	OT			49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline Phosphatase Increased; Blood Pressure Decreased; Body Temperature Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Desvenlafaxine			C				Not Reported
	Epoetin Alfa			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methadone			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pregabalin			C				Not Reported
	Azithromycin			C				Not Reported
	Hydroxychloroquine			C				Not Reported

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19-May-2020	17807091	DIRECT	Y	DE			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17807562	DIRECT	Y	RI			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Creatinine Increased; Blood Pressure Systolic Increased; Glomerular Filtration Rate Decreased; Increased Bronchial Secretion; Oxygen Saturation Decreased; Po2 Decreased	Remdesivir 100 Mg/20 MI Iv (Eua Drug)			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Apap			C				Not Reported
	Ca/Vit D			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Quetiapine			C				Not Reported
	Morphine			C				Not Reported
	Pravastatin			C				Not Reported
	Ezetimibe			C				Not Reported
	Fluoxetine			C				Not Reported
	Memantine			C				Not Reported
	Rivaroxaban			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Calcitonin			C				Not Reported
	Kcl			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17807632	DIRECT	Y	DE			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (Euc) (Remdesivir (Eua))			S				Not Reported

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20-May-2020	17807338	DIRECT	Y				8 YR	Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Product Formulation Administered; Product Use Issue		Remdesivir				S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2020	17807340	DIRECT					62 YR	Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Pneumomediastinum		Remdesivir				S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2020	17807341	DIRECT	Y	OT			54 YR	Male	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased		Remdesivir		Y		S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2020	17807897	DIRECT	Y	OT			59 YR	Female	USA	
<u>Preferred Term</u>		<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Transaminases Increased		Remdesivir 200mg		Y		S	Intravenous (not otherwise specified)			Gilead
		Remdesivir 100mg		Y		S	Intravenous (not otherwise specified)			Gilead
		Remdesivir 100mg		Y		S				Gilead

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Remdesivir 100mg	Y	S	Gilead
Hydromorphone		C	Not Reported
Acetaminophen		C	Not Reported
Zofran		C	Not Reported
Vitd3		C	Not Reported
Titralac		C	Not Reported
Seroquel		C	Not Reported
Calcium Gluconate		C	Not Reported
Lasix		C	Not Reported
Lovenox		C	Not Reported
Miralax		C	Not Reported
Benadryl		C	Not Reported
Levophed		C	Not Reported
Magnesium Sulfate		C	Not Reported
Potassium Chloride		C	Not Reported
Clozaril		C	Not Reported
Propofol		C	Not Reported
Amidate		C	Not Reported
Quellcin		C	Not Reported
Fentanyl		C	Not Reported
Versed		C	Not Reported
Humulin		C	Not Reported
Humalog		C	Not Reported
Ancef		C	Not Reported
Protonix		C	Not Reported
Flagyl		C	Not Reported
Rocephin		C	Not Reported
Vancomycin		C	Not Reported
Zenpep		C	Not Reported
Prilosec		C	Not Reported
Potassium Bicarbonate		C	Not Reported
Zemuron		C	Not Reported
Convalescent Plasm		C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810951	DIRECT	Y				58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead

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20-May-2020	17810957	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810962	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Remdesivir Iv	Y		S	Intravenous drip			Gilead
	Insulin Aspart Sliding Scale			C				Not Reported
	Metoprolol Injection			C				Not Reported
	Cisatracurium Injection			C				Not Reported
	Norepinephrine Injection			C				Not Reported
	Propofol Injection			C				Not Reported
	Fentanyl Injection			C				Not Reported
	Vasopressin Injection			C				Not Reported
	Vancomycin Injection			C				Not Reported
	Cefepime Injection			C				Not Reported
	Enoxaparin Injection			C				Not Reported
	Pantoprazole Injection			C				Not Reported
	Tocilizumab Injection			C				Not Reported
	Digoxin Injection			C				Not Reported
	Melatonin Tablet			C				Not Reported
	Aspirin 325mg Tablet			C				Not Reported
Furosemide Injection			C				Not Reported	
Metolazone Tablet			C				Not Reported	
Insulin Glargine			C				Not Reported	
Atorvastatin Tablet			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810969	DIRECT	Y	OT			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Blood Bilirubin Increased Remdesivir S Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810975	DIRECT	Y	HO, OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir Remdesivir			S C				Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810977	DIRECT	Y	OT			21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemofiltration	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Stat Dose;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810978	DIRECT	Y				77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Haemofiltration	Remdesivir Tocilizumab Linezolid Enoxaparin Vitamin C Thiamine Pepcid Zinc Precedex			S C C C C C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Fentanyl	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Cisatracurium	C	Not Reported

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20-May-2020	17810988	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment; Renal Injury	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810994	DIRECT	Y	OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Infusion Related Reaction	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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20-May-2020	17811012	DIRECT	Y	OT			35 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Renal Impairment; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine 10 Mg Daily			C				Not Reported
	Ascorbic Acid 500 Mg Po Bid			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dextrose 5% Iv, 100 Ml/Hr			C				Not Reported
	Diphenhydramine 25 Mg Iv X 1			C				Not Reported
	Doxycycline 100 Mg Po Bid			C				Not Reported
	Doxycycline Suspension 100 Mg Po Bid			C				Not Reported
	Enoxaparin 40 Mg Sq Bid			C				Not Reported
	Famotidine 20 Mg Bid			C				Not Reported

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Fentanyl Iv Infusion	C	Not Reported
Furosemide Iv 20 Mg X1 Then 40 Mg Bid	C	Not Reported
Hydralazine 10 Mg Iv Q4h Prn	C	Not Reported
Regular Insulin Infusion	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Ketamine Infusion	C	Not Reported
Methylprednisolone Iv	C	Not Reported
Montelukast	C	Not Reported
Ondansetron	C	Not Reported
Tocilizumab Iv	C	Not Reported

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20-May-2020	17811020	DIRECT	Y	DE			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefazolin			C				Not Reported
	Cisatracurium			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lansoprazole			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vancomycin			C				Not Reported
	Vecuronium			C				Not Reported
	Angiotensin li			C				Not Reported
	Hydromorphone			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported

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20-May-2020	17811029	DIRECT	Y	OT			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Melatonin			C				Not Reported
	Nebivolol			C				Not Reported
	Valsartan			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811036	DIRECT	Y				66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811043	DIRECT	Y	OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead
	Amlodipine			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported

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Duo-Neb	C	Not Reported
Linezolid	C	Not Reported
Morphine	C	Not Reported
Pantoprazole	C	Not Reported
Acetaminophen	C	Not Reported
Fentanyl	C	Not Reported
Midazolam	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811050	DIRECT	Y	DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Respiratory Failure; Septic Shock; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811056	DIRECT	Y	OT			71 YR	Male	AFG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Platelet Count Decreased	Remdesivir	Y		S	Intravenous drip			Gilead
	Flomax			C				Not Reported
	Vitamin C 1000mg			C				Not Reported
	Zinc 220			C				Not Reported
	Allopurinol 300mg			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonatate			C				Not Reported
	Ceftriazone 1gm			C				Not Reported
	Dipyridamole			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Zestoretic			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Prednisone			C				Not Reported

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20-May-2020	17811063	DIRECT	Y				49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811080	DIRECT	Y	DE			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ventricular Fibrillation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Albumin 5% 25g			C				Not Reported
	Bumetanide 1mg Q12h			C				Not Reported
	Calcium 500mg With Vit D 5mcg 2 Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Enoxaparin 80mg Bid			C				Not Reported
	Furosemide 20mg Once			C				Not Reported
	Norepinephrine 4mg/250ml Infusion			C				Not Reported
	Oxycodone 5mg Q6h			C				Not Reported
	Pantoprazole 40mg Q12h			C				Not Reported
	Propofol Infusion 25mcg/Kg/Min			C				Not Reported
	Psyllium 58.6% Packet			C				Not Reported
	Ribavirin 600mg Q8h			C				Not Reported
	Sertraline 150mg Daily			C				Not Reported
	Vitamin D 2000 Units Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811088	DIRECT	Y	OT			27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir Via Emergency Use Authorization			S	Intravenous drip			Not Reported

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Aminotransferase Increased; Blood Alkaline Phosphatase Increased;	Covid-19 Convalescent Plasma	C	Not Reported
Haemofiltration; Liver Function Test Increased; Renal Impairment; Right Ventricular Dysfunction	Tocilizumab 400 Mg Iv In 100 MI Nacl	C	Not Reported
	Tocilizumab 400 Mg Iv In 100 MI Nacl	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811092	DIRECT	Y	HO, LT, OT			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Erythema; Rash Macular	Remdesivir			S				Gilead
	Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Vancomycin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Tocilizumab Or Placebo			C				Not Reported
	Furosemide			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Albuterol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811136	DIRECT	Y	DS, HO, LT, OT			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Movement Disorder; Hypoxia; Lung Infiltration; Miosis; Pyrexia; Respiratory Distress; Tachycardia; Unresponsive To Stimuli; Unresponsive To Stimuli	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen 650mg Po Q4h Prn			C				Not Reported
	Azithromycin 500mg Po Daily			C				Not Reported
	Enoxaparin 40mg Subq Daily			C				Not Reported
	Famotidine 20mg Po Daily			C				Not Reported
	Ondansetron 4mg Iv Q6h Prn			C				Not Reported

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20-May-2020	17811139	DIRECT	Y	HO, LT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oxygen Saturation Decreased; Respiratory Distress	Remdesivir Albuterol Cyclobenzaprine Aspirin Ec Doxycycline Atorvastatin Pyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Zinc Ondansetron Diphenhydramine Amiodarone Famotidine			S C C C C C C C C C C C C C C				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811147	DIRECT	Y	DS, HO, LT			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carotid Artery Occlusion; Ischaemic Stroke	Remdesivir Acetaminophen Aspirin Azithromycin Ceftriaxone Furosemide Hydroxychloroquine Or Placebo Magnesium Sulfate Potassium Bicarbonate Enoxaparin			S C C C C C C C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811158	DIRECT	Y	DE			60 YR	Male	ALB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Oxygen Saturation Decreased	Remdesivir			S		Other Frequency:Loading Dose;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17812033	DIRECT	Y				63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Rash; Tachycardia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812217	DIRECT	Y	DE			71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Failure; Hypertension; Hypotension; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812224	DIRECT	Y	DE			41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Lung Disorder; Pulmonary Embolism; Sudden Death	Remdesivir Remdesivir			S C	Intravenous bolus			Gilead Not Reported	

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21-May-2020	17812243	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Sarilumab			C				Not Reported
	Apixaban			C				Not Reported
	Furosemide			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Sennosides			C				Not Reported
	Bisacodyl			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Hydralazine			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Docusate			C				Not Reported
	Metoprolol			C				Not Reported
	Ropinorole			C				Not Reported
	Tamsulosin			C				Not Reported
	Carbidopa/Levodopa			C				Not Reported
	Losartan			C				Not Reported
	Paroxetine			C				Not Reported
	Finasteride			C				Not Reported
	Pantoprazole			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812244	DIRECT	Y	DE			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Morphine Pca			C				Not Reported
	Levetiracetam			C				Not Reported
	Enoxaparin			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Folic Acid			C				Not Reported

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Finasteride	C	Not Reported
Terazosin	C	Not Reported
Pantoprazole	C	Not Reported
Aspirin	C	Not Reported
Atorvastatin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812245	DIRECT	Y	OT			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812248	DIRECT	Y				67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Poor Quality Product Administered; Product Storage Error	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812559	DIRECT	Y	OT			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperhidrosis; Hypotension; Vomiting	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Precedex			C				Not Reported
	Diltiazem			C				Not Reported
	Docusate			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Furosemide			C				Not Reported
Haloperidol			C				Not Reported	

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Hyalazine	C	Not Reported
Lantus	C	Not Reported
Insulin Lispro	C	Not Reported
Lactobacillus	C	Not Reported
Lorazepam	C	Not Reported
Magnesium Oxide	C	Not Reported
Methylprednisolone	C	Not Reported
Potassium Chloride	C	Not Reported
Lyrica	C	Not Reported
Seroquel	C	Not Reported
Terazosin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812562	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812592	DIRECT	Y				69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Zosyn			C				Not Reported
	Levophed			C				Not Reported
	Sinemet			C				Not Reported
	Dilaudid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Actemra			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812596	DIRECT	Y	OT			74 YR	Female	USA

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Supraventricular Tachycardia	Remdesivir			S				Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812599	DIRECT	Y				39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Throat Irritation	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813534	EXPEDITED (15-DAY)			US-GILEAD-2020-0467788		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction; Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17815405	DIRECT	Y	OT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17815427	DIRECT	Y				69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Increased; Condition Aggravated	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:X1 Then100mg Q24h;	5 DAY	Not Reported	
	Acetaminophen			C				Not Reported	
	Amlodipine			C				Not Reported	

Apixaban	C	Not Reported
Aspirin (Enteric Coated) 81 Mg Daily	C	Not Reported
Atorvastatin	C	Not Reported
Benzotropine	C	Not Reported
Carvedilol	C	Not Reported
Divalproex	C	Not Reported
Famotidine	C	Not Reported
Guaifenesin + Codeine Prn	C	Not Reported
Tamsulosin	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin, Regular (Sliding Scale)	C	Not Reported
Ipratropium And Albuterol Inhalation	C	Not Reported
Loratadine	C	Not Reported
Methylprednisolone Sodium Succinate	C	Not Reported
Montelukast	C	Not Reported
Morphine, Intravenous (Prn)	C	Not Reported
Ibrutinib	C	Not Reported
Pantoprazole	C	Not Reported
Quetiapine (And I Ran Out Of Room: Zosyn)	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17815613	DIRECT	Y	RI			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Dialysis	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17763474	EXPEDITED (15-DAY)		HO	US-ROCHE-2594510		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Unknown			Not Reported

Increased; Deep Vein Thrombosis; Intentional Product Use Issue; Off Label Use	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enoxaparin	C		Not Reported
	Oxygen	C		Not Reported
	Loperamide	C		Not Reported
	Lovenox [Enoxaparin Sodium]	C		Not Reported
	Zosyn	C		Not Reported
	Tylenol	C		Not Reported
	Vancomycin	C		Not Reported
	Zithromax	C		Not Reported
	Calcium Gluconate	C		Not Reported
	Potassium Chloride	C		Not Reported
	Cholecalciferol	C		Not Reported
	Melatonin	C		Not Reported
	Multivitamin And Mineral	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815622	DIRECT	Y	DE			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest; Pulseless Electrical Activity; Respiratory Failure	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Chloride 0.9% Iv Solution			C				Not Reported
	Hydralazine			C				Not Reported
	Morphine			C				Not Reported
	Vecuronium			C				Not Reported
	Epinephrine Drip			C				Not Reported
	Phenylephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
Sodium Bicarbonate Drip			C			Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815629	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Dialysis	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Duoneb			C				Not Reported
	Pantoprazole			C				Not Reported
	Sodium Chloride 0.9% Iv Solution			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815634	DIRECT	Y	OT			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disseminated Intravascular Coagulation; General Physical Health Deterioration; Hypotension; Hypothermia; Infusion Related Reaction	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Duoneb			C				Not Reported
	Pantoprazole			C				Not Reported
	Valacyclovir			C				Not Reported
	Acetaminophen			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815658	DIRECT	Y	DE			59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Acute Kidney	Remdesivir			S	Intravenous bolus			Gilead

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Injury; Blood Lactic Acid
Increased; Cardio-
Respiratory Arrest;
Haemoglobin Decreased;
Hypotension; White Blood
Cell Count Increased

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22-May-2020	17815906	DIRECT		DE, HO			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Disseminated Intravascular Coagulation; Hypoxia; Paralysis; Renal Failure; Shock	Remdesivir			S				Not Reported
	Naloxone			C				Not Reported
	Norepinephrine			C				Not Reported
	Inhaled Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Aspirin Chewable			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Lasix			C				Not Reported
	Enoxaparin			C				Not Reported
	Heparin			C				Not Reported
	Metolazone			C				Not Reported
	Etomidate			C				Not Reported
Succinylcholine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816199	DIRECT	Y				44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered; Product Dispensing Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Albuterol Nebulizer			C				Not Reported
	Carvedilol			C				Not Reported
	Cefepime			C				Not Reported
	Furosemide			C				Not Reported

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Heparin	C	Not Reported
Hydrocortisone	C	Not Reported
Norepinephrine	C	Not Reported
Vancomycin	C	Not Reported

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22-May-2020	17816200	DIRECT	Y	DE			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Prolactin Increased; Cardiac Failure Congestive; Lung Disorder; Oxygen Saturation Decreased	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)		4 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816201	DIRECT	Y	DE			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Dialysis; Metabolic Acidosis; Pneumonia Viral	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816202	DIRECT	Y	OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not			Gilead

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otherwise specified)

Cefepime	C	Not Reported
Doxycycline	C	Not Reported
Enoxaparin 40 Mg Bid	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816203	DIRECT	Y	OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased	Remdesivir Eua			S				Not Reported
	Doxycycline			C				Not Reported
	Zosyn			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816204	DIRECT	Y	HO			82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Disease Progression	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816205	DIRECT	Y	OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Renal Impairment	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Acetaminophen-Hydrocodone			C				Not Reported
	Albuterol-Ipratropium			C				Not Reported
	Apixaban			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Baclofen			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Midazolam			C				Not Reported
	Ferrous Sulfate			C				Not Reported

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Fluconazole	C	Not Reported
Fluconazole	C	Not Reported
Folic Acid	C	Not Reported
Furosemide	C	Not Reported
Heparin	C	Not Reported
Meropenem	C	Not Reported
Tocilizumab	C	Not Reported
Vancomycin	C	Not Reported
Norepinephrine	C	Not Reported
Propfol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816206	DIRECT	Y	LT, OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once Once Load;	5 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816207	DIRECT	Y	DE			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Metoprolol			C				Not Reported
	Albuterol 2 Mg/5ml Syrup			C				Not Reported
	Cholecalciferol			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Acetaminophen			C				Not Reported
	Risperidone			C				Not Reported
	Mirtazipine			C				Not Reported
	Trazodone			C				Not Reported
	Risperidone			C				Not Reported
	Rosuvastatin			C				Not Reported
	Rivaroxaban			C				Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole			C				Not Reported

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22-May-2020	17816208	DIRECT		HO			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension	Remdesivir			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816211	DIRECT	Y				78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Hallucination, Visual; Intensive Care Unit Delirium	Remdesivir Lorazepam Iv 0.25 Mg Gabapentin 100 Mg Requip 1 Mg			S C C C	Intravenous drip	Other Frequency:Once;			Gilead Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816477	DIRECT	Y	OT			75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other F			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816490	DIRECT	Y	OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Desc;			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816502	DIRECT	Y	OT			87 YR	Male	USA

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Liver Function Test Increased; Sars-Cov-2 Test Positive	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816556	DIRECT	Y	HO, OT			84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Covid-19	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Atorvastatin			C				Not Reported	
	Diltiazem			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Furosemide			C				Not Reported	
	Insulin			C				Not Reported	
	Metoprolol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Lorazepam			C				Not Reported	
	Fentanyl			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816562	DIRECT	Y	OT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816575	DIRECT	Y	HO			43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased; Blood	Remdesivir	Y		S	Intravenous drip			Gilead	
	Furosemide 40 Mg Iv			C				Not Reported	

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Creatinine Increased; Norepinephrine C Not Reported
Renal Impairment; Septic Shock

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816997	DIRECT	Y	HO			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis	Remdesivir Solution For Injection			S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Acetaminophen			C				Not Reported
	Nicotine Patch			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817002	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication; Renal Replacement Therapy; Respiratory Failure; Shock	Remdesivir Under Emergency Use Authorization (Eua).			S	Intravenous (not otherwise specified)			Gilead
	Fentanyl Infusion			C				Not Reported
	Insulin Regular (Humulin R)			C				Not Reported
	Sliding Scale							
	Propofol Infusion			C				Not Reported
	Enoxaparin (Lovenox)			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Norepinephrine (Levophed)			C				Not Reported
	Vasopressin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817004	DIRECT	Y	OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Clinical Trial Participant; Hepatic Enzyme Increased; Product Use In Unapproved Indication Remdesivir S Intravenous (not otherwise specified) Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818831	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0468218		96 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17819757	DIRECT	Y	RI			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication; Renal Replacement Therapy	Remdesivir (Eua) 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir (Eua) 100 Mg vial	Y		S	Intravenous (not otherwise specified)	Every 24 Hr		Gilead
	Norepinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clonazepam			C				Not Reported
	Desmopressin			C				Not Reported
	Docusate			C				Not Reported
	Dopamine			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported

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Ketamine	C	Not Reported
Insulin	C	Not Reported
Midodrine	C	Not Reported
Phenylephrine	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Sennosides	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17822985	DIRECT	Y	OT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous drip			Gilead
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17822988	DIRECT	Y				44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17822990	DIRECT	Y	OT			35 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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Therapy Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17822997	DIRECT	Y	OT			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Continuous Haemodiafiltration; Respiratory Failure; Thrombosis In Device; Urine Output Decreased	Remdesivir			S	Intravenous bolus	Other Frequency:Once, Then;		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Convalescent Plasma			C				Not Reported	
	Tocilizumab Or Placebo Trial			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17823220	DIRECT	Y	RI			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Acute Kidney Injury	Remdesivir (Eua) 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir (Eua) 100 Mg Vial	Y		S			Intravenous (not otherwise specified)		Gilead
	Albumin			C				Not Reported	
	Albuterol			C				Not Reported	
	Bumetanide			C				Not Reported	
	Caffeine Citrate			C				Not Reported	
	Chlorothiazide			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Famotidine			C				Not Reported	
	Furosemide			C				Not Reported	
	Gabapentin			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Insulin Regular			C				Not Reported	
	Lactulose			C				Not Reported	
	Magnesium Sulfate			C				Not Reported	
	Methylprednisolone			C				Not Reported	
	Metolazone			C				Not Reported	

Midazolam	C	Not Reported
Midodrine	C	Not Reported
Oxycodone	C	Not Reported
Piperacillin/Tazobactam	C	Not Reported
Potassium Chloride	C	Not Reported
Quetiapine	C	Not Reported
Rocuronium	C	Not Reported
Vancomycin	C	Not Reported
Dexmedetomidine	C	Not Reported
Epoprostenol	C	Not Reported
Heparin	C	Not Reported
Hydromorphone	C	Not Reported
Ketamine	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Vasopressin	C	Not Reported
Acetaminophen	C	Not Reported
Fentanyl	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17822998	DIRECT	Y				50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Hypoaesthesia; Pruritus	Remdesivir Eua	Y		S	Intravenous drip			Gilead
	Ceftriaxone (Rocephin) 1,000 Mg In 0.9 % Sodium Chloride (Ns) 50 MI Ad			C				Not Reported
	Enoxaparin (Lovenox) (Conc: 40 Mg/ 0.4 MI) Injection 40 Mg			C				Not Reported
	Benzonatate (Tessalon Perles) Capsule 100 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin (Conc: 10-100 Mg/5 MI) (Robitussin Dm) Sy			C				Not Reported
	Ondansetron (Zofran) (Conc: 2 Mg/MI) Injection 4 Mg			C				Not Reported
	Polyethylene Glycol 3350 (Miralax) Packet 17 G			C				Not Reported
	Promethazine (Phenergan) 6.25 Mg In 0.9 % Sodium Chloride			C				Not Reported

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(Ns) 50 MI I Sennosides-Docusate Sodium (8.6-50 Mg/Tab) (Senna Plus) Tablet 2 Table	C	Not Reported
Simvastatin (Zocor) Tablet 40 Mg	C	Not Reported
Tramadol (Ultram) Tablet 50 Mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823000	DIRECT	Y	OT			85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pain	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823003	DIRECT	Y	DE			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospice Care	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823009	DIRECT	Y	OT			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Atracurium			C				Not Reported	
	Midazolam			C				Not Reported	
	Furosemide			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823018	DIRECT	Y	HO, OT			49 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir Injection Remdesivir			S C	Intravenous drip			Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823020	DIRECT	Y	LT			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Hyperkalaemia	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823021	DIRECT	Y	DE, DS			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Failure	Remdesivir Tocilizumab	Y		S C	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823024	DIRECT	Y				64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (5 Mg/MI Injection Concentrate) Ascorbic Acid 500 Mg Tab Azithromycin 500 Mg Ivpb Benzonatate 100 Mg Cap Ceftriaxone 1 Gm Ivpb Enoxaparin Inj Methylprednisolone 40 Mg Iv Zinc Sulfate 220 Mg Cap			S C C C C C C C	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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23-May-2020	17823028	DIRECT	Y	OT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Nephropathy Toxic	Remdesivir	Y		S	Intravenous bolus	Other Frequency:X1;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823098	DIRECT	Y	LT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Dialysis; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hepatic Failure; Hyperkalaemia; Hypovolaemic Shock; Metabolic Acidosis; Renal Failure; Shock Haemorrhagic	Remdesivir Aspirin Diltiazem Insulin Lispro Methylprednisolone Protonix Atarax Lovenox Ativan Fentanyl Versed Ketamine			S C C C C C C C C C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17823103	DIRECT	Y	LT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatine Increased; Dialysis; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hepatic Failure;	Remdesivir Aspirin Diltiazem Insulin Lispro Methylprednisolone			S C C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported Not Reported

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Hypovolaemic Shock;	Protonix	C	Not Reported
Liver Function Test	Atarax	C	Not Reported
Increased; Shock	Lovenox	C	Not Reported
Haemorrhagic	Ativan	C	Not Reported
	Ketamine	C	Not Reported
	Versed	C	Not Reported
	Ativan	C	Not Reported
	Fentanyl	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823031	DIRECT	Y				62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Plavix			C				Not Reported
	Lovenox			C				Not Reported
	Fentanyl			C				Not Reported
	Hydralazine			C				Not Reported
	Humalog			C				Not Reported
	Levophed			C				Not Reported
	Omeprazole			C				Not Reported
	Propofol			C				Not Reported
	Humulin			C				Not Reported
	Ativan			C				Not Reported
	Versed			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vecuronium			C				Not Reported
	Keppra			C				Not Reported
	Solumedrol			C				Not Reported
	Tylenol			C				Not Reported
	Melatonin			C				Not Reported
	Nitroglycerin			C				Not Reported
	Crestor			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823035	DIRECT	Y				31 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hepatic Enzyme Increased	Eua Remdesivir	Y	S	Intravenous (not otherwise specified)	Not Reported
	Lovenox		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823037	DIRECT	Y	OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823040	DIRECT	Y	OT			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin Regular			C				Not Reported
	Lactulose			C				Not Reported
	Levothyroxine			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Quetiapine			C				Not Reported
	Senna			C				Not Reported
	Vasopressin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823060	DIRECT	Y	OT			81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hypotension	Remdesivir	S	Intravenous drip	Other Frequency:Once Then 100 Mgx4;	30 MIN	Gilead
	Bisoprolol 5 Mg	C				Not Reported
	Diltiazem Er 30 Mg	C				Not Reported
	Hydralazine 25 Mg	C				Not Reported
	Losartan 100 Mg	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823067	DIRECT	Y	DE			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Disorder	Convalescent Plasma			S	Intravenous (not otherwise specified)	Other Frequency:2 Units Given Once;		Versiti Blood Centers
	Remdesivir (Eua)			S				Not Reported
	Tocilizumab			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823073	DIRECT	Y	HO			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823078	DIRECT	Y	DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C				Not Reported
	Fentanyl			C				Not Reported
	Methylprednisolone			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular			C				Not Reported

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Vancomycin	C	Not Reported
Daptomycin	C	Not Reported
Labetalol	C	Not Reported
Duoneb Nebulizer	C	Not Reported
Atorvastatin	C	Not Reported
Bupropion	C	Not Reported
Cefepime	C	Not Reported
Cisatracurium	C	Not Reported
Dexmedetomidine	C	Not Reported
Enoxaparin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823118	DIRECT	Y	OT			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Heparin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Selinexor			C				Not Reported
	Senna			C				Not Reported
	Trazodone			C				Not Reported
	Zinc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17823125	DIRECT	Y	OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Lactic Acid Decreased; Renal Injury; Respiratory Rate Increased; Septic Shock; Tachypnoea; Urinary Casts	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Apixaban 5 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported

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Cisatracurium Infusion	C	Not Reported
Propofol Infusion	C	Not Reported
Fentanyl Infusion	C	Not Reported
Tocilizumab 400 Mg	C	Not Reported
Unfractionated Intravenous Heparin	C	Not Reported
Piperacillin/Tazobactam 4.5 Grams Q6h	C	Not Reported
Vancomycin 1250 Mg Q12h	C	Not Reported
Tradipitant/Placebo	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820923	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA130868			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Nph Insulin			C		Unk		Not Reported
	Insulin Human;Insulin Human Injection, Isophane			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Sitagliptin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823157	DIRECT	Y	OT			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hepatic Enzyme Increased	Remdesivir	Y	S	Intravenous drip	Gilead
	Albuterol Hfa 90mcg/Puff		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823162	DIRECT	Y	OT			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S				Not Reported
	Zosyn			C				Not Reported
	Doxycycline			C				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823167	DIRECT	Y	OT			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Hydroxychloroquine			C				Not Reported
	Propofol			C				Not Reported
	Hydromorphone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823171	DIRECT	Y				59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823177	DIRECT	Y	OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823181	DIRECT	Y	OT			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypopnoea; Infusion	Remdesivir			S				Not Reported
Related Reaction; Rash;	Allopurinol 100 Mg Tablet			C				Not Reported
Rash Pruritic; Respiratory	Carvedilol 12.5 Mg Tablet			C				Not Reported
Distress; Wheezing	Enoxaparin 40 Mg			C				Not Reported
	Subcutaneous							
	Famotidine 20mg Tablets			C				Not Reported
	Insulin Glargine Subcutaneous			C				Not Reported
	Insulin Lispro Subcutaneous			C				Not Reported
	Multivitamin Oral Tablet			C				Not Reported
	Polyethylene Glycol 17 G Packet			C				Not Reported
	Senna-Docusate 8.6 Mg-50 Mg			C				Not Reported
	Tablet							
	Tamoxifen 20 Mg Tablets			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823188	DIRECT	Y				60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase	Remdesivir			S				Not Reported
Increased; Aspartate	Albuterol Inhaler			C				Not Reported
Aminotransferase	Amlodipine 5 Mg Tablet			C				Not Reported
Increased	Benzonatate 200mg Capsules			C				Not Reported
	Docusate 100 Mg Capsule			C				Not Reported
	Senna Tablets			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Subcutaneous							
	Famotidine 20mg Tablets			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro Subcutaneous			C				Not Reported
	Levothyroxine 50mcg Tablet			C				Not Reported
	Rosuvastatin 20 Mg Tablet			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823195	DIRECT	Y	DE			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Encephalopathy; Hypoxia; Respiratory Distress; Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Zosyn			C				Not Reported
	Insulin Lispro & Insulin Glargine			C				Not Reported
	Albuterol			C				Not Reported
	Combivent			C				Not Reported
	Amlodipine			C				Not Reported
	Precedex			C				Not Reported
	Lovenox			C				Not Reported
	Gabapentin			C				Not Reported
	Seebri			C				Not Reported
	Levothyroxine			C				Not Reported
	Ativan			C				Not Reported
	Lopressor			C				Not Reported
	Dulera			C				Not Reported
Percocet			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823212	DIRECT	Y	OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17823217	DIRECT	Y				89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Administration Site Extravasation	Remdesivir			S	Intravenous drip		5 DAY	Gilead

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26-May-2020	17792758	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2020191603		61 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Exfoliative Generalised; Eosinophilia; Rash Erythematous	Nexium			S	Unknown	Unk		Unknown
	Nexium			S	Unknown	Unk		Unknown
	Temesta (Lorazepam)			S	Unknown	Unk		Pfizer
	Zithromax			S	Unknown	Unk		Pfizer
	Amlodipine Besilate			S	Unknown	Unk		Pfizer
	Haldol			S	Unknown	Unk		Not Reported
	Quetiapine			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	Unk		Not Reported
	Lasix [Furosemide Sodium]			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Clarithromycine			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Anxiolit			S	Unknown	Unk		Not Reported
	Clexane			S	Unknown	40 Mg		Not Reported
	Clexane			S	Unknown	40 Mg		Not Reported
	Dafalgan			S	Unknown	Unk		Not Reported
	Dafalgan			S	Unknown	Unk		Not Reported
	Solu-Medrol			C	Unknown	Unk		Not Reported
	Diamox [Acetazolamide]			C	Unknown	Unk		Not Reported
Diamox [Acetazolamide]			C	Unknown	Unk		Not Reported	
Diamox [Acetazolamide]			C	Unknown	Unk		Not Reported	
Distraneurin [Clomethiazole]			C	Unknown	Unk		Not Reported	
Novorapid			C	Unknown	Unk		Not Reported	
Ipramol			C	Unknown	Unk		Not Reported	

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Heparine [Heparin Sodium]	C	Unknown	Unk	Not Reported
Lexotanil	C	Unknown	Unk	Not Reported
Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch Morphine	C	Unknown	Unk	Not Reported
Nozinan [Levomepromazine Hydrochloride]	C	Unknown	Unk	Not Reported
Dexdor	C	Unknown	Unk	Not Reported
Dexdor	C	Unknown	Unk	Not Reported
Dexdor	C	Unknown	Unk	Not Reported
Sintenyl	C	Unknown	Unk	Not Reported
Sintenyl	C	Unknown	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unknown	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unknown	Unk	Not Reported
Dormicum [Midazolam Maleate]	C	Unknown	Unk	Not Reported
Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
Noradrenaline [Norepinephrine]	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Rocuronium [Rocuronium Bromide]	C	Unknown	Unk	Not Reported
Tracrium	C	Unknown	Unk	Not Reported
Tracrium	C	Unknown	Unk	Not Reported
Tracrium	C	Unknown	Unk	Not Reported
Colistin	C	Unknown	Unk	Not Reported
Colistin	C	Unknown	Unk	Not Reported
Colistin	C	Unknown	Unk	Not Reported

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Tobramycin	C	Unk	Not Reported
Tobramycin	C	Unk	Not Reported
Tobramycin	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822479	EXPEDITED (15-DAY)		OT	DE-ABBVIE-20K-062-3416492-00			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Liver Disorder; Multiple Organ Dysfunction Syndrome; Renal Failure	Kaletra			S	Oral			Not Reported
	Remdesivir			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823907	DIRECT	Y	OT			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Dyspnoea	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823998	DIRECT	Y	DE			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824003	DIRECT	Y	OT			43 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824009	DIRECT	Y	OT			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Amiodarone 360 Mg/200 MI			C				Not Reported
	Milrinone 20 Mg/100 MI			C				Not Reported
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824025	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Pneumonia; Renal Failure	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824060	DIRECT	Y	DE			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Total;		Gilead
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methocarbamol			C				Not Reported

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Methylprednisolone Sodium	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Pregabalin	C	Not Reported
Propofol	C	Not Reported
Vancomycin	C	Not Reported
Vasopressin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824081	DIRECT	Y				38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetylcysteine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftaroline			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Regular			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Senna			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824084	DIRECT	Y				59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Acetylcysteine			C				Not Reported
	Atorvastatin			C				Not Reported
	Citalopram			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported

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Protonix	C	Not Reported
Tiotropium	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824086	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Albuterol Ipratropium			C				Not Reported
	Famotidine			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Insulin Lispro			C				Not Reported
	Epoprostenol			C				Not Reported
	Asprin			C				Not Reported
	Acetaminophen			C				Not Reported
	Norepinephrine			C				Not Reported
	Heparin Drip			C				Not Reported
	Methylprednisone			C				Not Reported
	Midodrine			C				Not Reported
	Ampicillin Sulbactam			C				Not Reported
	Metolazone			C				Not Reported
	Ketamine Drip			C				Not Reported
	Hydromorphone Drip			C				Not Reported
	Cisatracurium Drip			C				Not Reported
	Furosemide			C				Not Reported
	Potassium			C				Not Reported
	Acetazolamide			C				Not Reported
	Oxycodone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824087	DIRECT	Y	HO, OT			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Burning Sensation; Clinical Trial Participant; Condition Aggravated;	Remdesivir			S				Gilead

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Covid-19 Pneumonia;
Product Use In
Unapproved Indication;
Respiratory Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824088	DIRECT	Y				85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clinical Trial Participant; Decreased Appetite; Product Use In Unapproved Indication	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824089	DIRECT	Y	DE			82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Miralax			C				Not Reported
	Lorazepam			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dilaudid			C				Not Reported
	Guiafenesin			C				Not Reported
	Aspirin			C				Not Reported
	Acetaminophen			C				Not Reported
	Mylanta Suspension			C				Not Reported
Methylprednisolone			C			Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824090	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Clinical Trial Participant; Remdesivir Y S Intravenous drip Gilead
Ischaemic Stroke; Product
Use In Unapproved
Indication; Vertebral Artery
Occlusion

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824149	DIRECT	Y	RI			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824205	DIRECT	Y				67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Procedural Hypotension	Remdesivir			S				Gilead
	Azithromycin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	D5/Ns			C				Not Reported
	Fentanyl			C				Not Reported
	Gemfibrozil			C				Not Reported
	Heparin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Sodium Phosphate			C				Not Reported
	Zinc Sulfate			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824219	DIRECT	Y	HO, OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Dyspnoea	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824509	DIRECT	Y	HO, OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Pneumonia; Sepsis	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824895	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Bumetanide			C				Not Reported
	Chlorothiazide			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Lidocaine Patch			C				Not Reported
	Metronidazole			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
Vecuronium			C				Not Reported	
Zinc Sulfate			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824899	DIRECT	Y	HO			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Therapy Cessation	Remdesivir Eua	Y		S	Intravenous bolus			Gilead
	Chlorhexidine 0.12% Solution			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Ipratropium-Albuterol			C				Not Reported
	Multivitamin			C				Not Reported
	Rocuronium			C				Not Reported
	Sennosides-Docusate			C				Not Reported
	Hydromorphone			C				Not Reported
	Lorazepam			C				Not Reported
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824926	DIRECT	Y	OT			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Inflammatory Marker Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen Tab			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine Iv			C				Not Reported
	Metoprolol Iv			C				Not Reported
	Potassium & Sodium Phosphates Packet			C				Not Reported
	Potassium Chloride Tab			C				Not Reported
	Vancomycin Iv			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824932	DIRECT	Y	OT			69 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Levothyroxine			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Propofol			C				Not Reported
Succinylcholine			C			Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824939	DIRECT	Y	DE			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824944	DIRECT	Y	DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Dyspnoea; Emphysema; Interstitial Lung Disease; Respiratory Failure; Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Albuterol			C				Not Reported
	Brovana			C				Not Reported
	Anoro Ellipta			C				Not Reported
	Lasix			C				Not Reported
	Prednisone			C				Not Reported

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Insulin	C	Not Reported
Protonix	C	Not Reported
Atorvastatin	C	Not Reported
Metformin	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824950	DIRECT	Y	OT			46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Voriconazole Iv			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluconazole			C				Not Reported
	Fluticasone Nasal Spray			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Senna			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Sodium Chloride 0.9% W/ 20 Meq Kcl			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Iopamidol			C				Not Reported
	Ondansetron			C				Not Reported
	Promethazine W/ Codeine			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824956	DIRECT	Y	OT			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased;	Remdesivir			S	Intravenous drip			Gilead
Dose Calculation Error;	Ascorbic Acid Po			C				Not Reported
Glomerular Filtration Rate	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported

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Decreased; Incorrect Dose Administered By Product; Sepsis	Cholecalciferol Cimetidine Po Furosemide Ivp And Gtt Zinc Gluconate Po Cisatricurium Epoprostenol Inhaled Fentanyl Infusion Vent Sedation Propofol	C C C C C C C C	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824960	DIRECT	Y	HO			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824966	DIRECT	Y	LT, OT			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Dialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Albumin 25 Gm Infusion			C				Not Reported
	Famotidine 20 Mg Po			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Furosemide 40 Mg Iv			C				Not Reported
	Enoxaparin 40 Mg Sq			C				Not Reported
	Insulin Infusion			C				Not Reported
	Cisatracurium Infusion			C				Not Reported
	Meropenem			C				Not Reported
	Simvastatin 20 Mg			C				Not Reported

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		Vitamin D 2000 Units			C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
26-May-2020	17824970	DIRECT	Y	OT			56 YR	Male	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Daily After 200mg;		Gilead			
	Ascorbic Acid Po 1000mg Bid			C				Not Reported			
	Atorvastatin 10mg Po Daily			C				Not Reported			
	Ceftriaxone 1gm liv Daily			C				Not Reported			
	Clopidogrel 75mg Po Daily			C				Not Reported			
	Enoxaparin 90mg Sq Q12hrs			C				Not Reported			
	Famotidine 20mg Iv Daily			C				Not Reported			
	Insulin Lispro Sq Sliding Scale			C				Not Reported			
	Loratadine 10mg Po Daily			C				Not Reported			
	Methylprednisolone 125mg Iv Q12hrs			C				Not Reported			
	Zinc 220mg Oral Bid			C				Not Reported			
	Norco 5/325mg Po Q6hrs Prn			C				Not Reported			
	Fentanyl Variable Rate Continuous Iv			C				Not Reported			
	Norepinephrine Variable Rate Continuous Iv			C				Not Reported			
	Propofol Variable Rate Continuous Iv			C				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
26-May-2020	17824973	DIRECT	Y	OT			41 YR	Male	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Asthenia; Chromaturia; Fatigue; Therapy Cessation	Remdesivir	Y		S				Not Reported			
	Azithromycin			C				Not Reported			
	Cefepime			C				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
26-May-2020	17824977	DIRECT	Y				55 YR	Male	USA		

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash; Rash Maculo-Papular	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Stribild			C		Not Reported		
	Prezista			C		Not Reported		
	Lovenox			C		Not Reported		
	Solumedrol			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824979	DIRECT	Y	DE			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S			Intravenous (not otherwise specified)	Gilead
	Azithromycin 250mg Iv			C			Not Reported	
	Potassium Chloride Er 40meq Oral			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824984	DIRECT	Y	OT			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C		Not Reported		
	Acetaminophen 325 Mg			C		Not Reported		
	Aspirin 81mg Ec			C		Not Reported		
	Enoxaparin 40mg Sc Bid			C		Not Reported		
	Pantoprazole 40mg Po Qday			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824989	DIRECT	Y	DE			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Arrhythmia; Creatinine	Remdesivir Solution	S						Gilead
Renal Clearance	Modafinil	C						Not Reported
Decreased;	Trazodone	C						Not Reported
Encephalopathy;	Quetiapine	C						Not Reported
Respiratory Failure;								
Sudden Cardiac Death								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824990	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Remdesivir	Y		S	Intravenous drip			Gilead
Aminotransferase	Tocilizumab			C				Not Reported
Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824991	DIRECT	Y	OT			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Remdesivir	Y		S	Intravenous bolus			Gilead
Aminotransferase	Bisacodyl			C				Not Reported
Increased; Blood Alkaline	Lansoprazole			C				Not Reported
Phosphatase Increased;	Metoclopramide			C				Not Reported
Liver Function Test	Polyethylene Glycol			C				Not Reported
Increased	Sennosides-Docusate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824992	DIRECT	Y	HO			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir Injection			S	Intravenous drip			Gilead
	Remdesivir For Injection, Lyophilized Powder, 100 Mg Vial			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824993	DIRECT	Y				79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Administration Site Extravasation	Remdesivir			S	Intravenous drip		5 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825230	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA135575			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported
	Fenofibrate			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	Unk		Not Reported
	Sodium Chloride			C	Unknown	Unk		Not Reported
	Sitagliptin			C	Unknown	Unk		Not Reported
	Midazolam			C	Unknown	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
Nph Insulin			C	Unknown	Unk		Not Reported	
Insulin Human;Insulin Human Injection, Isophane			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826568	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0467857		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826584	EXPEDITED (15-DAY)			US-GILEAD-2020-0467774			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Storage Error	Remdesivir			S	Unknown	Unk		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17827902	DIRECT	Y	DS, HO, LT			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crystal Nephropathy; Hydronephrosis; Renal Tubular Necrosis; Respiratory Disorder; Urine Analysis Abnormal	Remdesivir Acetaminophen Duonebs Amiodarone 150mg Iv Bolus Once Azithromycin 500mg Iv Once Cefepime 2gm Iv Potassium Chloride 20meq Iv Tocilizumab 400mg Iv			S C C C C C C C		Intravenous drip		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17827908	DIRECT	Y	OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Condition Aggravated; Enteritis	Remdesivir Atorvastatin Lovenox Imodium Losartan Pantoprazole Phosphorus Toradol			S C C C C C C		Intravenous (not otherwise specified)		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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Lopressor	C	Not Reported
Metoprolol	C	Not Reported
Aspirin	C	Not Reported
Diltiazem	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17827943	DIRECT	Y	DE			53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Bradycardia; Cardio- Respiratory Arrest; Hypotension; Respiratory Failure	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17827959	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Remdesivir			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17828102	DIRECT	Y				85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gallbladder Disorder; Hepatic Enzyme Increased	Remdesivir 100 Mg/20 MI			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17828289	DIRECT	Y				81 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased	Remdesivir (Eua) 100 Mg Vial			S	Intravenous (not otherwise specified)	Intravenous (not otherwise specified)		Gilead
	Remicade Inj 100mg Vial			S			Intravenous (not otherwise specified)	
	Acetaminophen			C				Not Reported
	Acetazolamide			C				Not Reported
	Azithromycin			C				Not Reported
	Cellralxone			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Nph			C				Not Reported
	Lansoprazole			C				Not Reported
	Linolid			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
Pantoprazole			C				Not Reported	
Polyethylene Glycol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828748	DIRECT	Y	OT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828807	DIRECT	Y	OT			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829752	DIRECT	Y	OT			49 YR	Prefer not to disclose	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Injection	Y		S	Intravenous drip		3 DAY	Gilead
	Acetaminophen 500 Mg			C				Not Reported
	Albuterol 90 Mcg Hfa			C				Not Reported
	Ascorbic Acid 500 Mg			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Dexamethasone 20 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin Cr 30-600			C				Not Reported
	Docusate 100 Mg			C				Not Reported
	Docusate-Senna 50/8.6 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Guaifenesin 100/5			C				Not Reported
	Loperamide 2mg/15ml			C				Not Reported
	Ondansetron 4mg/2ml			C				Not Reported
	Zinc Sulfate 220mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829758	DIRECT	Y	OT			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Ischaemic Hepatitis; Multi-Organ Disorder; Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829764	DIRECT	Y				46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine	Remdesivir Injection			S	Intravenous (not	Other Frequency:Once;		Gilead

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Phosphokinase Increased; Therapy Cessation	Remdesivir	S	otherwise specified) Intravenous (not otherwise specified)	6 DAY	Gilead
	Atorvastatin 40 Mg Tablet	C			Not Reported
	Ceftriaxone 1 Gm Injection	C			Not Reported
	Enoxaparin 100 Mg Injection	C			Not Reported
	Furosemide 40 Mg Injection	C			Not Reported
	Hydromorphone 1 Mg Injection	C			Not Reported
	Hydroxychloroquine 200 Mg Tablet	C			Not Reported
	Lorazepam 2 Mg Injection	C			Not Reported
	Meropenem 1 Gm Injection	C			Not Reported
	Pantoprazole 40 Mg Injection	C			Not Reported
	Potassium Chloride Injection	C			Not Reported
	Topiramate 100 Mg Tablet	C			Not Reported
	Vancomycin 1 Gm Injection	C			Not Reported
	Propofol 10 Mg/ML Injection	C			Not Reported
	Sodium Bicarbonate Injection	C			Not Reported
	Vecuronium Injection	C			Not Reported
	Acetaminophen Tablet	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830125	EXPEDITED (15-DAY)			US-GILEAD-2020-0468001		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dose Omission	Remdesivir			S	Unknown	200 Mg		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830843	EXPEDITED (15-DAY)		OT	CH-JNJFOC-20200514694		61 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Erythematous	Haldol			S	Unknown			Janssen
	Ceftriaxone			S	Unknown			Not Reported
	Clarithromycine			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported

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Remdesivir	S	Unknown	Not Reported
Amlodipine	S	Unknown	Not Reported
Anxiolit	S	Unknown	Not Reported
Clexane	S	Unknown	Not Reported
Clexane	S	Unknown	Not Reported
Dafalgan	S	Unknown	Not Reported
Dafalgan	S	Unknown	Not Reported
Lasix /00032601/	S	Unknown	Not Reported
Lasix /00032601/	S	Unknown	Not Reported
Lasix /00032601/	S		Not Reported
Nexium /01479302/	S	Unknown	Not Reported
Nexium /01479302/	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Temesta /00273201/	S	Unknown	Not Reported
Diamox /00016901/	C		Not Reported
Diamox /00016901/	C		Not Reported
Diamox /00016901/	C		Not Reported
Distaneurin /00027501/	C		Not Reported
Novorapid	C		Not Reported
Ipramol	C		Not Reported
Heparine /00027701/	C		Not Reported
Lexotanil	C		Not Reported
Movicol	C		Not Reported
Morphine	C		Not Reported
Nozinan /00038601/	C		Not Reported
Solu-Medrol	C		Not Reported
Dexdor	C		Not Reported
Dexdor	C		Not Reported
Dexdor	C		Not Reported
Sintenyl	C		Not Reported
Sintenyl	C		Not Reported
Dormicum /00036201/	C		Not Reported
Dormicum /00036201/	C		Not Reported
Dormicum /00036201/	C		Not Reported
Noradrenaline /00127501/	C		Not Reported
Noradrenaline /00127501/	C		Not Reported

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Noradrenaline /00127501/	C	Not Reported
Propofol	C	Not Reported
Propofol	C	Not Reported
Propofol	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Tracrium	C	Not Reported
Tracrium	C	Not Reported
Tracrium	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17831674	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468136		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Digoxin			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Methylprednisolon [Methylprednisolone]			C		Unk		Not Reported
	Nebivolol			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833395	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir	Y		S	Intravenous drip			Gilead

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27-May-2020	17833398	DIRECT	Y				41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833410	DIRECT	Y	OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir Injection	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported
	Loperamide			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Chloride			C				Not Reported
	Multivitamin			C				Not Reported
	Ondansetron			C				Not Reported
Dextromethorphan-Guaifenesin			C				Not Reported	
Zinc Sulfate			C				Not Reported	
Docusate-Senna			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833414	DIRECT	Y	OT			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Acute Respiratory Failure;	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amiodarone Infusion			C				Not Reported

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Alanine Aminotransferase Increased; Aspartate Aminotransferase	Ceftriaxone	C	Not Reported
Increased; Blood Alkaline Phosphatase Increased;	Dobutamine Infusion	C	Not Reported
Blood Bilirubin Increased;	Doxycycline Iv	C	Not Reported
Blood Creatinine Increased; Hypoxia;	Enoxaparin 40mg Q12	C	Not Reported
Shock; Viral	Famotidine 20mg Iv Q12	C	Not Reported
Cardiomyopathy	Fentanyl Infusion	C	Not Reported
	Hydrocortisone 50mg Iv Q6hr	C	Not Reported
	Midazolam Infusion	C	Not Reported
	Norepinephrine Infusion	C	Not Reported
	Phenylephrine Infusion	C	Not Reported
	Propofol Infusion	C	Not Reported
	Sodium Bicarbonate Inusion	C	Not Reported
	Vasopressin Infusion	C	Not Reported
	Digoxin Bolus Iv	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833420	DIRECT	Y	DE			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833421	DIRECT	Y	OT			24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epigastric Discomfort; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Iohexol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833426	DIRECT	Y	DE			51 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Decreased; Cardiac Arrest; Lethargy; Pneumothorax; Respiratory Failure	Remdesivir Solution			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Aztreonam			C				Not Reported
	Bisacodyl			C				Not Reported
	Buspirone			C				Not Reported
	Carbidopa-Levodopa			C				Not Reported
	Celebrex			C				Not Reported
	Clonazepam			C				Not Reported
	Digoxin			C				Not Reported
	Depakote			C				Not Reported
	Lovenox			C				Not Reported
	Fentanyl			C				Not Reported
	Guaifenesin Er			C				Not Reported
	Metoprolol			C				Not Reported
	Propofol			C				Not Reported
	Risperidone			C				Not Reported
	Dexmedetomidine Additive			C				Not Reported
Epinephrine			C				Not Reported	
Fentanyl			C				Not Reported	
Vancomycin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833433	DIRECT	Y	OT			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported

Budesonide-Formoterol	C	Not Reported
Ceftriaxone	C	Not Reported
Cholecalciferol	C	Not Reported
Dexamethasone	C	Not Reported
Docusate-Senna	C	Not Reported
Enoxaparin	C	Not Reported
Insulin Lispro	C	Not Reported
Insulin Glargine	C	Not Reported
Linagliptin	C	Not Reported
Lisinopril	C	Not Reported
Pantoprazole	C	Not Reported
Polyethylene Glycol	C	Not Reported
Selinexor	C	Not Reported
Tramadol	C	Not Reported
Zinc Sulfate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833438	DIRECT	Y				43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia	Remdesivir			S	Intravenous bolus		10 DAY	Gilead
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Acetylcysteine Inh. Solution 20%			C				Not Reported
	Albuterol-Ipratropium Inh. Solution			C				Not Reported
	Amlodipine			C				Not Reported
	Enteral Nutrition (Vital Hp)			C				Not Reported
	Famotidine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Lispro			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833450	DIRECT	Y				52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased Remdesivir S Intravenous (not otherwise specified) Other Frequency:Once; Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833453	DIRECT	Y	OT			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir	Y		S	Intravenous bolus		1 DAY	Gilead
	Acetaminophen Prn			C				Not Reported
	Albuterol Hfa Mdi			C				Not Reported
	Ascorbic Acid (Vitamin C) 1000mg Po Tid			C				Not Reported
	Bisacodyl Supp Daily Prn			C				Not Reported
	Enoxaparin 40mg Subq Q12hr			C				Not Reported
	Guaifenesin/Codeine Prn Cough			C				Not Reported
	Tussionex Po Bid			C				Not Reported
	Solu-Medrol 40mg Iv Q12hr			C				Not Reported
	Morphine Iv Prn			C				Not Reported
	Sodium Chloride Iv Solution			C				Not Reported
	Thiamine 100mg Tablet Po Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Chlorhexidine Swish/Spit Bid			C				Not Reported
	Famotidine 20mg Po Bid			C				Not Reported
	Mupirocin 2% Ointment Nasal Bid			C				Not Reported
Thiamine 100mg Iv Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833459	DIRECT	Y	OT			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Glomerular Filtration Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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27-May-2020	17833468	DIRECT	Y	OT			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pyrexia	Remdesivir			S				Not Reported
	Atorvastatin			C				Not Reported
	Bumetanide			C				Not Reported
	Carvedilol			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported
	Melatonin			C				Not Reported
	Meropenem			C				Not Reported
	Warfarin			C				Not Reported
Heparin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833473	DIRECT	Y				44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C			Not Reported	
	Aztreonam			C			Not Reported	
	Levaquin			C			Not Reported	
	Pravastatin			C			Not Reported	
	Sirolimus			C			Not Reported	
	Prednisone			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833477	DIRECT		OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Embolism	Remdesivir			S	Intravenous (not			Not Reported

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833483	DIRECT	Y	DE			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Arrest	Remdesivir Covid-19 Convalescent Plasma	Y		S C	Intravenous drip	Other Frequency:Once;		Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833489	DIRECT	Y	DE			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Diarrhoea; Malaise; Pyrexia	Remdesivir Acetaminophen Apixaban Ceftriaxone Chlorhexidine Oral Solution Enoxaparin Furosemide Gabapentin Insulin (Lispro, Regular) Lactated Ringers Latanoprost Drops Magnesium Sulfate Metoprolol Tartrate Metronidazole Modafinil Mometasone/Formoterol Montelukast Morphine Potassium Chloride Sertraline Sodium Chloride 0.9% Infusion Vancomycin			S C	Intravenous bolus			Gilead Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833490	DIRECT	Y	DE			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Acute Respiratory Failure; Cough; Dyspnoea; Hypoxia; Renal Impairment; Sepsis	Remdesivir			S	Intravenous bolus			Gilead
	Albuterol			C				Not Reported
	Aspirin			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine Oral Solution			C				Not Reported
	Normosol-R			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone Iv			C				Not Reported
	Triad Paste Wound Dressing			C				Not Reported
	Insulin (Glargine, Regular)			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lactulose			C				Not Reported
	Magnesium Sulfate Iv			C				Not Reported
	Melatonin			C				Not Reported
	Metronidazole			C				Not Reported
	Midazolam			C				Not Reported
	Midodrine			C				Not Reported
	Morphine Sulfate			C				Not Reported
Norepinephrine			C				Not Reported	
Pantoprazole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833492	DIRECT		OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

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27-May-2020	17833505	DIRECT	Y	OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; General Physical Health Deterioration;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
Haemoglobin Decreased;	Amiodarone			C				Not Reported
Intestinal Dilatation;	Albumin			C				Not Reported
Intestinal Ischaemia;	Cyanocobalamin			C				Not Reported
Lactic Acidosis; Neutrophil Count Decreased; Platelet Count Decreased; Septic Shock; Supraventricular Tachycardia; Tissue Infiltration	Folic Acid			C				Not Reported
	Heparin Sq			C				Not Reported
	Enoxaparin Sq			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Midodrine			C				Not Reported
	Multivitamin			C				Not Reported
	Nicotine Transdermal			C				Not Reported
	Thiamine			C				Not Reported
	Dobutamine Infusion			C				Not Reported
	Epinephrine Infusion			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Ketamine Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Phenylephrine Infusion			C				Not Reported
	Vasopressin Infusion			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833510	DIRECT	Y	OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Albumin			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Cefepime			C				Not Reported

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Enoxaparin	C	Not Reported
Furosemide	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Levofloxacin	C	Not Reported
Methylprednisolone	C	Not Reported
Pantoprazole	C	Not Reported
Sertraline	C	Not Reported
Vancomycin	C	Not Reported
Fentanyl	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833527	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)		4 DAY	Not Reported
	Sinemet			C				Not Reported
	Fentanyl			C				Not Reported
	Reglan			C				Not Reported
	Midodrine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Pepcid			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833532	DIRECT	Y	OT			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S				Gilead

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27-May-2020	17833533	DIRECT	Y				64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Not Reported
	Zithromax			C				Not Reported
	Rocephin			C				Not Reported
	Lovenox			C				Not Reported
	Solumedrol			C				Not Reported
	Humalog			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833539	DIRECT	Y	HO			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Headache; Heart Rate Increased; Migraine; Myalgia; Pain; Pruritus; Rash Papular	Remdesivir Injection	Y		S	Iontophoresis	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833545	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833603	DIRECT	Y	HO, LT			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Bacterial Infection; White Blood Cell Count Increased	Remdesivir	S	Not Reported
	Aspirin 81mg	C	Not Reported
	Atorvastatin 10mg	C	Not Reported
	Famotidine 20mg	C	Not Reported
	Furosemide 20mg	C	Not Reported
	Lorazepam 2mg	C	Not Reported
	Sodium Chloride	C	Not Reported
	Vancomycin	C	Not Reported
	Heparin	C	Not Reported
	Insulin Aspart	C	Not Reported
	Insulin Detemir	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833610	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Pyrexia; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin Ec			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzotropine			C				Not Reported
	Carvedilol			C				Not Reported
	Divalproex			C				Not Reported
	Donepezil			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular Human			C				Not Reported
	Ipratropium/Albuterol Inhalation			C				Not Reported
	Loratadine			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported
	Montelukast			C				Not Reported
	Ibrutinib			C				Not Reported
	Pantoprazole			C				Not Reported
	Also: Quetiapine, Tamsulosin,			C				Not Reported

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Zinc Sulfate, & Zosyn

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27-May-2020	17833630	DIRECT	Y				66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833637	DIRECT	Y	DE			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir For Eua	Y		S				Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833642	DIRECT	Y	LT			26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Pulseless Electrical Activity; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported

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27-May-2020	17833647	DIRECT	Y				42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Tremor	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead	
	Enoxaparin			C				Not Reported	
	Insulin Glargine (Lantus)			C				Not Reported	
	Insulin Lispro			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833652	DIRECT	Y	HO, OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Increased; Liver Disorder; Prothrombin Time Prolonged	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Unknown	
	Actemra			C				Not Reported	
	Plaquinil			C				Not Reported	
	Ceftiraxone			C				Not Reported	
	Doxycycline			C				Not Reported	
	Vancomycin			C				Not Reported	
	Vit C			C				Not Reported	
	Torseamide			C				Not Reported	
	Cardizem			C				Not Reported	
	Lipitor			C				Not Reported	
	Protonix			C				Not Reported	
	Metoprolol XI			C				Not Reported	
	Prednisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833668	DIRECT	Y				40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	

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27-May-2020	17833677	DIRECT	Y	DE			77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dyspnoea; Hypoxia; Lethargy; Respiratory Disorder	Remdesivir			S				Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833720	DIRECT	Y				57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833738	DIRECT	Y				1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Product Formulation Administered; Product Dispensing Error; Product Use Issue; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833753	DIRECT		DE			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19	Remdesivir Remdesivir			S C				Gilead Not Reported	

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27-May-2020	17833766	DIRECT		OT			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir Remdesivir			S C					Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17839011	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir Remdesivir			S C	Intravenous drip				Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833859	DIRECT	Y	OT			78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Lethargy; Oxygen Saturation Decreased; Palpitations; Tremor; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once (Loading Dose;			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834192	DIRECT	Y	OT			92 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;	Remdesivir Remdesivir			S C					Gilead Not Reported

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Glomerular Filtration Rate
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834582	DIRECT	Y	DE			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Ipratropium			C				Not Reported
	Metoprolol			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin			C				Not Reported
	Diltiazem			C				Not Reported
	Fentanyl			C				Not Reported
	Morphine			C				Not Reported
	Allopurinol			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Lorazepam			C				Not Reported
	Furosemide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834588	DIRECT	Y	DE, OT			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Febrile Neutropenia; Respiratory Failure	Remdesivir			S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834593	DIRECT	Y	LT			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir Atorvastatin	Y	S C	Intravenous bolus	Gilead Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834597	DIRECT	Y	DE			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Condition Aggravated; Hypotension; Inflammatory Marker Increased; Ventricular Fibrillation	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen 650mg Tablet			C				Not Reported
	Cefepime 2g Ivpb			C				Not Reported
	Dexmedetomidine 1.4mg/Kg/Hr Infusion			C				Not Reported
	Enoxaparin 40mg Bid			C				Not Reported
	Etomidate 20mg Once			C				Not Reported
	Fentanyl 100mcg Once			C				Not Reported
	Insulin Glargine 5 Units Bid			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Lorazepam 1mg Inj Once			C				Not Reported
	Insulin Regular Sliding Scale			C				Not Reported
	Midazolam 5mg Inj Once			C				Not Reported
	Propofol Infusion			C				Not Reported
	Rocuronium Infusion			C				Not Reported
	Vancomycin 1250mg Q6h			C				Not Reported
Magnesium Oxide 400mg Bid			C				Not Reported	
Potassium Chloride 40meq Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834603	DIRECT	Y	DS			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Decreased; Blood Urea Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:1 Time & 100 Daily;		Gilead
	Lovenox 40mg			C				Not Reported
	Docusate With Senna			C				Not Reported
	Famotidine			C				Not Reported

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Lantus	C	Not Reported
Insulin Lispro	C	Not Reported
Lisinopril	C	Not Reported
Acetaminophen	C	Not Reported
Fentanyl Drip	C	Not Reported
Lactated Ringers	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834607	DIRECT		DE			92 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834613	DIRECT	Y	DE			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Hypoxia	Remdesivir	Y		S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834623	DIRECT	Y	OT			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported

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Linezolid	C	Not Reported
Meropenem	C	Not Reported
Lorazepam	C	Not Reported
Phenylephrine	C	Not Reported
Propofol	C	Not Reported

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28-May-2020	17834646	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834651	DIRECT	Y	DE			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participant; Liver Function Test Increased; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication; Shock	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Norepinephrine Infusion			C		Not Reported		
	Phenylephrine Infusion			C		Not Reported		
	Vasopressin Infusion			C		Not Reported		
	Epinephrine Infusion			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834885	DIRECT	Y	DE			83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clinical Trial Participant; Product Use In Unapproved Indication; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C		Not Reported		
	Piperacillin/Tazobactam			C				Not Reported

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28-May-2020	17834887	DIRECT	Y	DE			66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palliative Care; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Convalescent Plasma			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834892	DIRECT	Y	OT			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Dysphagia; Headache; Product Use In Unapproved Indication	Remdesivir			S				Not Reported	
	Convalescent Plasma			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834894	DIRECT	Y	OT			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S				Not Reported	
	Amlodipine			C				Not Reported	
	Ibuprofen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834895	DIRECT	Y	OT			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead	

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28-May-2020	17834911	DIRECT	Y				54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Valproic Acid			C				Not Reported	
	Hydroxychloroquine			C				Not Reported	
	Azithromycin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834946	DIRECT	Y	OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Morphine			C				Not Reported	
	Duoneb			C				Not Reported	
	Dextrose 50%			C				Not Reported	
	Sodium Chloride Flush			C				Not Reported	
	Sodium Chloride 250 MI			C				Not Reported	
	Potassium Chloride			C				Not Reported	
	Magnesium Sulfate			C				Not Reported	
	Dexmedetomidine			C				Not Reported	
	Zinc Sulfate			C				Not Reported	
	Cefepime			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Metoprolol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Bumetanide			C				Not Reported	
	Methylprednisolone			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Chlorothiazide			C				Not Reported	
	Vancomycin			C				Not Reported	
	Insulin Detemir			C				Not Reported	
	Tocilizumab			C				Not Reported	

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28-May-2020	17834965	DIRECT	Y	OT			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834973	DIRECT	Y	OT			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834979	DIRECT	Y				84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Platelet Count Increased; White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acyclovir 400 Mg Po Bid			C				Not Reported
	Allopurinol 300 Mg Po Daily			C				Not Reported
	Aspirin 325 Mg Po Daily			C				Not Reported
	Cholecalciferol 2000 Units Po Daily			C				Not Reported
	Furosemide 20 Mg Po Bid			C				Not Reported
	Levothyroxine 88 Mcg Po Daily			C				Not Reported
	Meropenem 1 Gram Iv Q12h			C				Not Reported
	Ruxolitinib			C				Not Reported
	Heparin Iv Infusion			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835864	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468283		38 YR	Female	USA

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Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17837791	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GILEAD-2020-0469042		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hydronephrosis; Necrosis; Renal Impairment; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Duoneb			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838503	DIRECT	Y	OT			57 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Renal Impairment	Remdesivir			S	Intravenous drip			Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Midazolam			C				Not Reported
	Rocuronium			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838778	DIRECT	Y	OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin Tablet			C				Not Reported
	Ceftriaxone Injection			C				Not Reported
	Enoxaparin Injection			C				Not Reported
	Furosemide Injection			C				Not Reported
	Guaifenesin Tablet			C				Not Reported
	Hydroxychloroquine Tablet			C				Not Reported
	Lansoprazole Capsule			C				Not Reported
	Levothyroxine Tablet			C				Not Reported
	Methylprednisolone Injection			C				Not Reported
	Pantoprazole Tablet			C				Not Reported
	Vancomycin Injection			C				Not Reported
	Propofol Injection			C				Not Reported
	Acetaminophen Tablet			C				Not Reported
	Alprazolam Tablet			C				Not Reported
Lorazepam Injection			C			Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838938	DIRECT	Y				33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir	Y		S	Intravenous drip			Gilead

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Aminotransferase
Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838945	DIRECT	Y	OT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838949	DIRECT	Y				90 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838954	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir	Y		S	Intravenous drip			Gilead
	Fenatnyl			C				Not Reported
	Nimbex			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Cetrixone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17838955	DIRECT	Y	OT			63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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Acute Kidney Injury; Ischaemic Hepatitis; Transaminases Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;	Gilead
	Azithromycin	C			Not Reported
	Ceftriaxone	C			Not Reported
	Dexamethasone	C			Not Reported
	Enoxaparin	C			Not Reported
	Famotidine	C			Not Reported
	Fentanyl	C			Not Reported
	Insulin Glargine	C			Not Reported
	Insulin Lispro	C			Not Reported
	Phenylephrine	C			Not Reported
	Piperacillin/Tazobactam	C			Not Reported
	Propofol	C			Not Reported
	Rocuronium	C			Not Reported
	Zinc Sulfate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838959	DIRECT	Y	HO, LT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838962	DIRECT	Y				73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S	Oral			Gilead
	Cefepime			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Aripiprazole			C				Not Reported
	Gabapentin			C				Not Reported
	Mirtazapine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin			C				Not Reported

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Famotidine	C	Not Reported
Prazosin	C	Not Reported
Tamsulosin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838968	DIRECT	Y				82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased	Remdesivir Eliquis 2.5mg Q12h	Y		S	Intravenous drip			Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838972	DIRECT	Y	LT			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ventricular Tachycardia	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838976	DIRECT	Y				71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Hypotension; Infusion Site Extravasation; Infusion Site Reaction; Nausea	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838982	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate	Remdesivir			S	Intravenous drip			Gilead

Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838987	DIRECT	Y				91 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838988	DIRECT	Y	OT			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838991	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838994	DIRECT	Y				77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Glomerular Filtration Rate Decreased Remdesivir S Intravenous drip Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17838997	DIRECT	Y				32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839001	DIRECT	Y	LT, OT			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead
	Rocuronium			C				Not Reported
	Sodium Bicarbonate 50 Meq			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Drip			C				Not Reported
	Morphine			C				Not Reported
	Propofol			C				Not Reported
	Zosyn			C				Not Reported
	Azithromycin			C				Not Reported
	Bumex			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839004	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
White Blood Cell Count Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported

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Allopurinol	C	Not Reported
Amiodarone	C	Not Reported
Aspirin	C	Not Reported
Atorvastatin	C	Not Reported
Cardidopa-Levodopa	C	Not Reported
Diltiazem	C	Not Reported
Enoxaparin	C	Not Reported
Furosemide	C	Not Reported
Hydrocodone-Acetaminophen	C	Not Reported
Insulin Aspart	C	Not Reported
Insulin Glargine	C	Not Reported
Methylprednisolone	C	Not Reported
Metoprolol Tartrate	C	Not Reported
Sertraline	C	Not Reported
Topiramate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839023	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ventricular Fibrillation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839025	DIRECT	Y				54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839026	DIRECT	Y	DE			88 YR	Female	AFG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Hypoxia; Skin Discolouration	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Aztreonam			C				Not Reported

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	Ceftriaxone				C				Not Reported
	Pumozyne				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839552	DIRECT	Y	HO, RI, OT			94 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenia	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17839768	DIRECT	Y				32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839763	DIRECT	Y				76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Tachycardia	Remdesivir Injection			S	Intravenous bolus	Other Frequency:200mg X1;		Gilead	
	Amlodipine			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Metoprolol XI			C				Not Reported	
	Prazosin			C				Not Reported	
	Probenecid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839790	DIRECT	Y	DE			81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dialysis; Renal Failure; Tachypnoea	Remdesivir	S	Intravenous bolus	Gilead
	Acetaminophen	C		Not Reported
	Amlodipine	C		Not Reported
	Aspirin	C		Not Reported
	Atorvastatin	C		Not Reported
	Benzonatate	C		Not Reported
	Normosol-R	C		Not Reported
	Enoxaparin	C		Not Reported
	Fentanyl	C		Not Reported
	Furosemide	C		Not Reported
	Guaifenesin/Codeine	C		Not Reported
	Heparin	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Hydromorphone	C		Not Reported
	Insulin (Glargine, Lispro And Regular)	C		Not Reported
	Labetolol	C		Not Reported
	Lactated Ringers	C		Not Reported
	Levothyroxine	C		Not Reported
	Lidocaine/Epinephrine	C		Not Reported
	Lorazepam	C		Not Reported
	Magnesium Sulfate	C		Not Reported
	Morphine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839798	DIRECT	Y	DE			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Haemodialysis;	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
Pneumothorax; Pseudomonal Bacteraemia	Convalescent Plasma Tocilizumab Or Matching Placebo			C C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839805	DIRECT	Y	DE			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Fluid Overload; Hypotension	Remdesivir Solution	S	Intravenous (not otherwise specified)	Gilead
	Convalescent Plasma	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839841	DIRECT	Y	OT			48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Hot; Flushing; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once Then 100mg X4;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839991	DIRECT	Y	OT			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840013	DIRECT	Y	DE			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840020	DIRECT	Y	OT			34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase	Remdesivir			S				Not Reported

Increased; Aspartate
Aminotransferase
Increased; Blood Alkaline
Phosphatase Increased;
Hyperhidrosis; Liver
Function Test Increased;
Therapy Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840027	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Dialysis; Disease Progression	Remdesivir	Y		S				Gilead
	Aspirin			C				Not Reported
	Atovastatin			C				Not Reported
	Calcium Citrate/Vitamin D			C				Not Reported
	Cefazolin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Hydrocortisone			C				Not Reported
	Lansoprazole			C				Not Reported
	Naloxegol			C				Not Reported
	Multivitamin			C				Not Reported
	Tacrolimus			C				Not Reported
	Tenofovir			C				Not Reported
	Atracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
Norepinephrine			C				Not Reported	
Propofol			C				Not Reported	
Vasopressin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840033	DIRECT	Y	OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Continuous	Remdesivir			S	Intravenous (not			Gilead

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Haemodiafiltration;
Creatinine Renal
Clearance Decreased;
Endotracheal Intubation;
Renal Impairment;
Therapy Cessation

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840034	DIRECT	Y	DE			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest; Cardio-Respiratory Arrest; Pulse Absent; Shock	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840052	DIRECT	Y	OT			55 YR	Male	XQZ

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Hydromorphone			C				Not Reported
	Fluoxetine			C				Not Reported
	Fentanyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Heparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840058	DIRECT	Y	OT			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine	Remdesivir			S	Intravenous bolus			Gilead

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Increased; C-Reactive Protein Increased; Fibrin D Dimer Increased;	Acetylcysteine 20% Oral Solution	C							Not Reported
Glomerular Filtration Rate Decreased; Haematuria;	Aztreonam	C							Not Reported
Interleukin Level Increased; Seizure	Furosemide	C							Not Reported
	Levofloxacin	C							Not Reported
	Tocilizumab	C							Not Reported
	Acetaminophen	C							Not Reported
	Albuterol	C							Not Reported
	Atropine 1% (Orally)	C							Not Reported
	Clopidogrel	C							Not Reported
	Docusate	C							Not Reported
	Heparin Subq	C							Not Reported
	Levothyroxine	C							Not Reported
	Midazolam	C							Not Reported
	Norepinephrine	C							Not Reported
	Pantoprazole	C							Not Reported
	Propofol	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840084	DIRECT	Y				79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use	Remdesivir	Y		S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840087	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Hypoxia; Respiratory Failure; Severe Acute Respiratory Syndrome	Remdesivir 100mg/20 MI			S	Intravenous (not otherwise specified)	Intravenous (not otherwise specified)		Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carbidopa-Levodopa			C				Not Reported
	Donepezil			C				Not Reported
	Enoxaprin			C				Not Reported

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Etomidate	C	Not Reported
Lispro	C	Not Reported
Insulin	C	Not Reported
Metoprolol	C	Not Reported
Montelukast	C	Not Reported
Solifenecin	C	Not Reported
Acetaminophen	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840213	DIRECT	Y	DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Distributive Shock; Drug Ineffective	Remdesivir 100mg/20 MI Eua			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Frequency 4x		Gilead
	Colace			C				Not Reported
	Eliquis			C				Not Reported
	Humalog			C				Not Reported
	Insulin			C				Not Reported
	Lantus			C				Not Reported
	Pepcid			C				Not Reported
	Miralax			C				Not Reported
	Seroquel			C				Not Reported
	Singulair			C				Not Reported
	Zofran			C				Not Reported
	Acetaminophen			C				Not Reported
	Piperacillin Tazobactam			C				Not Reported
	Azithromycin			C				Not Reported
	Diclofenac			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Exmedetomidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840266	DIRECT	Y	OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Blood Bilirubin Increased; Blood Creatinine Increased; Dehydration; Hypotension; Transaminases Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Fentanyl Drip		C		Not Reported
	Norepinephrine Drip		C		Not Reported
	Rocuronium Drip		C		Not Reported
	Furosemide Ivp X1		C		Not Reported
	Gabapentin		C		Not Reported
	Lovenox		C		Not Reported
	Famotidine		C		Not Reported
	Lactated Ringers		C		Not Reported
	Acetaminophen		C		Not Reported
Ketamine		C		Not Reported	
Propofol		C		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840269	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide Iv			C				Not Reported
	Furosemide Po			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841424	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468719		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Norepinephrine			C		2-10 Mcg/Min		Not Reported
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Azithromycin			C				Not Reported
	Bumetanide			C				Not Reported

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Ceftriaxone	C		Not Reported
Clonazepam	C		Not Reported
Desmopressin	C		Not Reported
Docusate	C		Not Reported
Enoxaparin	C		Not Reported
Epoprostenol	C		Not Reported
Famotidine	C		Not Reported
Fentanyl	C		Not Reported
Furosemide	C		Not Reported
Heparin	C		Not Reported
Hydromorphone	C		Not Reported
Ketamine	C		Not Reported
Insulin	C		Not Reported
Midodrine	C		Not Reported
Phenylephrine	C	25-50 Mcg/Min	Not Reported
Propofol	C		Not Reported
Rocuronium	C		Not Reported
Sennosides	C		Not Reported
Dopamine	C	1-7 Mcg/Kg/Min	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841427	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468705		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin Aspart			C				Not Reported
	Metoprolol			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Vasopressin			C				Not Reported
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Tocilizumab			C				Not Reported
	Digoxin			C				Not Reported

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Melatonin	C	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Not Reported
Furosemide	C	Not Reported
Metolazone	C	Not Reported
Insulin Glargine	C	Not Reported
Atorvastatin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842483	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468473		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydromorphone			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran [Ondansetron]			C				Not Reported
	Vitamin D3			C				Not Reported
	Titralac [Calcium Carbonate]			C				Not Reported
	Seroquel			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Miralax			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Levophed			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Clozaril			C				Not Reported
	Propofol			C				Not Reported
	Amidate [Etomidate]			C				Not Reported
	Quelicin			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported
	Humuline Regular			C				Not Reported
	Humalog			C				Not Reported
	Ancef [Cefazolin Sodium]			C				Not Reported

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Protonix [Omeprazole]	C	Not Reported
Flagyl [Metronidazole]	C	Not Reported
Rocephin [Ceftriaxone]	C	Not Reported
Vancomycin	C	Not Reported
Zenpep	C	Not Reported
Prilosec [Omeprazole]	C	Not Reported
Potassium Bicarbonate	C	Not Reported
Zemuron	C	Not Reported
Levaquin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842537	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468948		85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17844971	DIRECT	Y				71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Not Reported
	Prenisone`			C				Not Reported
	Augmentin			C				Not Reported
	Sertraline			C				Not Reported
	Apixiban			C				Not Reported
	Apriso			C				Not Reported
	Divalproex			C				Not Reported
	Cetirizine			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydroxyzine			C				Not Reported
	Loperamide			C				Not Reported
	Metoprolol Succinate XI			C				Not Reported
	Omeprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Spirolactone			C				Not Reported
	Tamsulosin			C				Not Reported
	Metoprol Tartrate			C				Not Reported

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	Zosyn Saline				C C					Not Reported Not Reported
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29-May-2020	17844976	DIRECT	Y	HO			27 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead		
	Setraline			C				Not Reported		
	Melatonin			C				Not Reported		
	Acetaminophen			C				Not Reported		
	Enoxaparin			C				Not Reported		
	Ketorolac			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-May-2020	17844978	DIRECT	Y	OT			61 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Atrial Fibrillation; Heart Rate Irregular	Remdesivir			S	Intravenous (not otherwise specified)			Gilead		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-May-2020	17844983	DIRECT	Y				47 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Disease Progression; Hyperhidrosis; Hypotension	Remdesivir	Y		S	Parenteral			Gilead		
	Lovenox			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-May-2020	17844998	DIRECT	Y	HO			77 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

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Acute Kidney Injury Remdesivir S Intravenous drip Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845001	DIRECT	Y	OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Creatinine Increased; International Normalised Ratio Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845002	DIRECT	Y	DS			33 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Quadripareisis	Remdesivir			S	Intravenous drip	Other Frequency:X1 Loading Dose;		Gilead
	Senna			C				Not Reported
	Melatonin			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Doxycycline Iv			C				Not Reported
	Clindamycin Iv			C				Not Reported
	Dexamethasone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Glycolax			C				Not Reported
	Peridex			C				Not Reported
	Acetaminophen Po			C				Not Reported
	Precedex			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Acyclovir Iv			C				Not Reported
	Etomidate			C				Not Reported
	Omnipaque			C				Not Reported
	Lorazepam			C				Not Reported
	Midazolam			C				Not Reported

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Rocuronium	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845005	DIRECT	Y				23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845007	DIRECT	Y	OT			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous drip			Gilead
	Osmolite 1.5 Cal Liquid			C				Not Reported
	Atorvastatin 10mg At Bedtime			C				Not Reported
	Chlorhexidine Mouthwash			C				Not Reported
	Doxepin 10mg			C				Not Reported
	Ensure Clinical Health			C				Not Reported
	Erythromycin Opth Ointment Twice Daily			C				Not Reported
	Furosemide 40mg Iv Once			C				Not Reported
	Heparin In D5w 25000 Unit Bag			C				Not Reported
	Propofol 1000mg Titration			C				Not Reported
	Sodium Chloride 0.9% @ 50ml/Hr			C				Not Reported
	Acetaminophen 325mg Tablet			C				Not Reported
	Lorazepam 1mg Injection Once			C				Not Reported
	Noepinephrine 4mg In 500ml			C				Not Reported
	Dextrose 5%							
	Hydroxychloroquine 200mg			C				Not Reported
	Insulin Lispro Per Sliding Scale			C				Not Reported
	Levothyroxine 137mcg Per Dose			C				Not Reported
	Methylprednisolone 125mg Iv Every 6 Hrs			C				Not Reported
	Omega 3 Fatty Acid 2000mg Twice Daily			C				Not Reported

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Pantoprazole 40mg Iv Twice Daily	C	Not Reported
Propranolol 40mg Twice Daily	C	Not Reported
Sertraline 25mg Daily	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845012	DIRECT	Y	HO, OT			44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; Therapy Interrupted; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cobicistat/ Elvitegravir/Emtracitabine			C				Not Reported
	Atorvastatin			C				Not Reported
	Doxycycline			C				Not Reported
	Omnipaque			C				Not Reported
	Ceftriaxone			C				Not Reported
	Norepinephrine			C				Not Reported
	Cisatracurium			C				Not Reported
	Cholecalciferol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Folic Acid			C				Not Reported
	Multivitamin			C				Not Reported
	Codeine-Guifenesin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845018	DIRECT	Y	LT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Therapy Interrupted	Remdesivir	Y		S				Gilead
	Azithromycin			C				Not Reported
	Duoneb			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Budesonide			C				Not Reported
	Chlorhexadine			C				Not Reported
	Enoxaparin			C				Not Reported
	Lasix			C				Not Reported
	Lantus			C				Not Reported

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Lactobacillus	C	Not Reported
Methylprednisolone	C	Not Reported
Oxycodone	C	Not Reported
Pantoprazole	C	Not Reported
Zosyn	C	Not Reported
Cisatracurium	C	Not Reported
Dexmedetomidine	C	Not Reported
Fentanyl	C	Not Reported
Propofol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845059	DIRECT	Y	DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus	Other Frequency:X1;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Kaletra 400/100 Mg Bid Po			C				Not Reported
	Ivermectin 9mg Po Q48h X2			C				Not Reported
	Doses							
	Actemra 400mg X1			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845065	DIRECT	N	DE			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Acidosis; Acute	Remdesivir			S	Intravenous drip			Gilead
Kidney Injury; Blood Creatinine Increased;	Remdesivir			S	Intravenous drip			Gilead
Blood Pressure Systolic Decreased; Bronchitis;	Convalescent Plasma			C				Not Reported
Hypotension; Multiple Organ Dysfunction Syndrome; Oliguria;	Azithromycin			C				Not Reported
Pneumonia; Renal Impairment; Respiratory Failure; Sepsis	Medrol			C				Not Reported
	Amlodopine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Ceftriaxone			C				Not Reported
	Lovenox			C				Not Reported
	Insulin Lispro			C				Not Reported
	Zosyn			C				Not Reported

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Vacomycin	C	Not Reported
Versed	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Vasopressin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845068	DIRECT	Y				61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation; Peripheral Swelling	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17846418	DIRECT	Y	RI, OT			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17846473	DIRECT	Y	RI, OT			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Creatine Phosphokinase Increased; Blood Lactate	Remdesivir 100mg/20ml Vial			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead

Dehydrogenase
Increased; C-Reactive
Protein Increased;
Hypotension; Right
Ventricular Systolic
Pressure Increased;
Serum Ferritin Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845070	DIRECT	Y	DE, HO, LT			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;		Gilead	
	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Acetaminophen			C				Not Reported	
	Amlodipine			C				Not Reported	
	Anastrozole			C				Not Reported	
	Ascorbic Acid			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Azithromycin			C				Not Reported	
	Cefepime			C				Not Reported	
	Clopidogrel			C				Not Reported	
	Combivent Respimat			C				Not Reported	
	Compazine			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Clonidine			C				Not Reported	
	Coreg			C				Not Reported	
	Cyanocobalamin			C				Not Reported	
	Docusate Senna			C				Not Reported	
	Donepezil			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Famotidine			C				Not Reported	
	Ferrous Sulfate			C				Not Reported	
	Folic Acid			C				Not Reported	
	Gabapentin			C				Not Reported	

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30-May-2020	17845071	DIRECT	Y	HO			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Cerebrovascular Accident; Mental Status Changes	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Loading/Once Daily;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Loading/Once Daily;		Gilead
	Venlafaxine			C				Not Reported
	Topamax			C				Not Reported
	Namenda			C				Not Reported
	Imdur			C				Not Reported
	Neurontin			C				Not Reported
	Breo Ellipta			C				Not Reported
	Pepcid			C				Not Reported
	Aspirin			C				Not Reported
	Cardizem			C				Not Reported
	Levetiracetam			C				Not Reported
	Combivent			C				Not Reported
	Heparin			C				Not Reported
	Dextrose			C				Not Reported
	Morphine			C				Not Reported
	Rocephin			C				Not Reported
	Zithromax			C				Not Reported
	Nystatin			C				Not Reported
	Cardizem			C				Not Reported
	Tylenol			C				Not Reported
	Eliquis			C				Not Reported
	Sodium Chloride			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845076	DIRECT	Y	OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Bradycardia	Remdesivir	Y		S	Intravenous bolus				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845081	DIRECT	Y	OT			69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Laryngeal Oedema; Periorbital Swelling; Peripheral Swelling; Peripheral Swelling	Remdesivir	Y		S	Intravenous bolus				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845085	DIRECT	Y	OT			69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845113	DIRECT	Y	OT			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Related Reaction; Nausea	Remdesivir			S	Intravenous (not otherwise specified)		7 DAY		Gilead
	Remdesivir			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845123	DIRECT	Y	OT			55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)				Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845128	DIRECT					48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Product Preparation Error; Product Preparation Error	Remdesivir			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17845130	DIRECT	Y	HO, OT			70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Methylprednisolone			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Lisinopril			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17846348	DIRECT		HO				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Pain	Remdesivir (Eua)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17846639	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469017		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Famotidine			C		Unk		Not Reported	

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31-May-2020	17845136	DIRECT	Y				63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Chronic Kidney Disease	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir (Eua)			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17845140	DIRECT	Y				57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage; Thrombocytopenia	Remdesivir			S	Intravenous drip			Not Reported	

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01-Jun-2020	17846453	DIRECT	Y				61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Lopinavir/Ritonavir			C				Not Reported	
	Losartan			C				Not Reported	
	Metformin Er			C				Not Reported	
	Tocilizumab			C				Not Reported	
	Aspirin			C				Not Reported	
	Cefuroxime			C				Not Reported	
	Famotidine			C				Not Reported	
	Gabapentin			C				Not Reported	
	Guaifenesin			C				Not Reported	
	Hydrocholorthiazide			C				Not Reported	
	Heparin			C				Not Reported	

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01-Jun-2020	17846476	DIRECT	Y				39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C			Not Reported	
	Lovenox			C			Not Reported	
	Ondansetron			C			Not Reported	
	Tramadol			C			Not Reported	
Acetaminophen			C			Not Reported		

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01-Jun-2020	17846480	DIRECT	Y				51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dose Omission	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846502	DIRECT	Y	HO			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846513	DIRECT		OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hyperphosphataemia	Remdesivir	S	Intravenous (not otherwise specified)	Not Reported
	Ceftriaxone	C		Not Reported
	Docusate Sodium	C		Not Reported
	Etomidate	C		Not Reported
	Famotidine	C		Not Reported
	Furosemide	C		Not Reported
	Insulin Detemir	C		Not Reported
	Insulin Humalog	C		Not Reported
	Magnesium Sulfate	C		Not Reported
	Metolazone	C		Not Reported
	Metoprolol	C		Not Reported
	Senna Liquid	C		Not Reported
	Bumetanide Drip	C		Not Reported
	Fentanyl Drip	C		Not Reported
	Heparin Infusion	C		Not Reported
	Insulin Human Regular	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846521	DIRECT		OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombocytosis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C				Not Reported
	Docusate Sodium			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Insulin Detemir			C				Not Reported
	Insulin Humalog			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Metolazone			C				Not Reported
	Metoprolol			C				Not Reported
	Senna Liquid			C				Not Reported
	Bumetanide Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Heparin Infusion			C				Not Reported
	Insulin Human Regular			C				Not Reported

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01-Jun-2020	17846712	DIRECT	N	DE			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19	Remdesivir 5mg/MI Concentrated Solution	Y		S	Intravenous (not otherwise specified)	Other Dose:200mg/40ml; Frequency: 1		Gilead	
	Convalescent Plasma 213 MI			C	Intravenous (not otherwise specified)	Dose Or Amount: 100/Mg/20ml Frequency: 2		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847828	EXPEDITED (15-DAY)			US-GILEAD-2020-0468846		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error; Product Storage Error	Remdesivir			S	Unknown	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17848017	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469288		79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Blood Urea Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Tocilizumab			C				Not Reported	
	Cefepime			C				Not Reported	
	Azithromycin			C				Not Reported	
	Fentanyl			C				Not Reported	
	Midazolam			C				Not Reported	
	Propofol			C				Not Reported	
	Albumin			C				Not Reported	
	Famotidine			C				Not Reported	
	Aspirin 81			C				Not Reported	

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Furosemide	C	Not Reported
Enoxaparin	C	Not Reported
Insulin	C	Not Reported
Cisatracurium	C	Not Reported
Meropenem	C	Not Reported
Simvastatin	C	Not Reported
Vitamin D [Colecalciferol]	C	Not Reported

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01-Jun-2020	17848022	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0469201		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Endotracheal Intubation	Remdesivir			S	Unknown	Unk		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Lorazepam			C				Not Reported
	Sodium Chloride			C				Not Reported
	Vancomycin			C				Not Reported
	Heparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported
	Norepinephrine			C				Not Reported
	Ceftriaxone			C				Not Reported

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01-Jun-2020	17848028	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469174		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported

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Cefepime	C	Unk	Not Reported
Chlorhexidine	C	Unk	Not Reported
Normosol R	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Hydrocortisone	C	Unk	Not Reported
Triad	C	Unk	Not Reported
Insulin Glargine	C	Unk	Not Reported
Insulin Regular Hm	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Lactulose	C	Unk	Not Reported
Magnesium Sulfate	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Metronidazole	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Midodrine	C	Unk	Not Reported
Morphine Sulfate	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Phenylephrine	C	Unk	Not Reported
Potassium Chloride	C		Not Reported
Prismasate Bk0/3.5	C		Not Reported
Primasol Bgk	C		Not Reported
Propofol	C		Not Reported
Simvastatin	C		Not Reported
Sodium Bicarbonate	C		Not Reported
Vancomycin	C		Not Reported
Zolpidem	C		Not Reported

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01-Jun-2020	17848039	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469173		82 YR	Female	USA

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Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Lactated Ringers			C		Unk		Not Reported
	Latanoprost			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Metoprolol Tartrate			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported
	Modafinil			C		Unk		Not Reported
	Mometasone			C		Unk		Not Reported
	Formoterol			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Sertraline			C		Unk		Not Reported
	Sodium Chloride 0.9%			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

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01-Jun-2020	17848077	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-		71 YR	Male	USA

0468738

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Flomax [Tamsulosin Hydrochloride]			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Benzonatate			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dipyridamole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Zestoretic			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported

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01-Jun-2020	17849181	DIRECT	Y	OT			36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Nausea; Vomiting	Remdesivir Eua			S				Not Reported
	Convalescent Plasma			C				Not Reported
	Zinc Sulfate			C				Not Reported

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01-Jun-2020	17849209	DIRECT	Y	OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Culture Positive; International Normalised Ratio Increased; Staphylococcal Infection	Remdesivir			S	Intravenous (not otherwise specified)		5 DAY	Not Reported	
	Warfarin			C				Not Reported	
	Vancomycin			C				Not Reported	
	Amlodipine			C				Not Reported	
	Aspirin			C				Not Reported	
	Carvedilol			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Pravastatin			C				Not Reported	
	Terazosin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849214	DIRECT	Y	OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Oxybutin			C				Not Reported	
	Losartan			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Potassium			C				Not Reported	
	Gabapentin			C				Not Reported	
	Duloxetine			C				Not Reported	
	Lorazepam			C				Not Reported	
	Rocuronium			C				Not Reported	
	Melatonin			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Insulin Lispro			C				Not Reported	

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Buspirone	C	Not Reported
Amlodipine	C	Not Reported
Prednisone	C	Not Reported
Propofol	C	Not Reported
Penicillin V Potassium	C	Not Reported
Norepinephrine	C	Not Reported
Hydromorphone	C	Not Reported
Famotidine	C	Not Reported
Lipase-Protease-Amylase	C	Not Reported
Insulin Regular	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849220	DIRECT	Y	OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Betamethasone			C				Not Reported
	Docusate-Senna			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Metoprolol			C				Not Reported
	Polyethylene Glycol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849260	DIRECT	Y	DE			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Oxygen Saturation Decreased; Pulse Absent	Remdesivir			S	Intravenous drip			Gilead
	Plaquenil 200mg			C				Not Reported
	Prazosin 1mg			C				Not Reported
	Proventil Inhaler			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Lactinex Granules			C				Not Reported
	Lasix 40mg/4ml Iv			C				Not Reported
	Lipitor 40mg			C				Not Reported
	Lovenox 40mg			C				Not Reported
	Heparin 25000 Unit/250ml			C				Not Reported

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Protonix 40mg	C	Not Reported
Robitussin Ac Syrup	C	Not Reported
Ascorbic Acid 500mg	C	Not Reported
Vitamin D 2000 Units	C	Not Reported
Zinc Sulfate 200mg	C	Not Reported
Zoloft 100mg	C	Not Reported
Zyloprim 100mg	C	Not Reported
Propofol	C	Not Reported
Vasostrict	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849266	DIRECT	Y	DE			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Palliative Care; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849270	DIRECT	Y	DE			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (200 Mg X 1 Dose Followed By 100 Mg Daily)			S				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Carvedilol			C				Not Reported
	Lovenox			C				Not Reported
	Ivig			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pyridostigmine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849276	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Palliative Care; Therapy Cessation Remdesivir S Intravenous (not otherwise specified) Other Frequency:Once; Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849282	DIRECT	Y	OT			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cells In Urine; Fungal Infection; Glomerular Filtration Rate Decreased; Renal Tubular Necrosis; Urine Analysis Abnormal; White Blood Cells Urine Positive	Remdesivir Eua			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir Eua			S	Intravenous drip			Gilead
	Vancomycin 1.25g Iv Q24hrs			C				Not Reported
	Vancomycin 1.25g Iv Q12hrs			C				Not Reported
	Vancomycin 1g Iv X One Dose			C				Not Reported
	Vancomycin 1g Iv X One Dose			C				Not Reported
	Zosyn 4.5g Iv X One Dose			C				Not Reported
	Zosyn 3.375g Iv Q8hrs Extended Infusion			C				Not Reported
	Midazolam Iv Infusion Continuous			C				Not Reported
	Insulin Iv Infusion Continuous			C				Not Reported
	Fentanyl Iv Infusion			C				Not Reported
	Clonidine 0.2mg Transdermal Patch Q 7 Days			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849287	DIRECT	Y	DE, OT			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Disease Progression; Hypoxia; Myalgia; Pneumonia Staphylococcal; Pyrexia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849288	DIRECT	Y	DE			59 YR	Male	AFG

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Bicarbonate Decreased; Blood Bilirubin Increased; Blood Creatinine Increased; Blood Glucose Decreased; Blood Ph Decreased; Blood Potassium Increased; Blood Sodium Increased; Blood Urea Increased; Cardio-Respiratory Arrest; Glomerular Filtration Rate Decreased; Haematocrit Decreased; Haemoglobin Decreased; Mean Cell Haemoglobin Concentration Decreased; Mean Cell Haemoglobin Decreased; Mean Platelet Volume Increased; Metabolic Acidosis; Oxygen Saturation Decreased; Pco2 Increased; Platelet Count Decreased; Po2 Decreased; Polychromasia; Protein Total Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849289	DIRECT	Y	OT			70 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849304	DIRECT	Y				66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous bolus		4 DAY	Gilead
	Actemra 600 Mg Iv Once			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849309	DIRECT	Y	OT			54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Renal Impairment; Therapy Interrupted	Remdesivir			S	Intravenous drip	Other Frequency:One Time;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Methylprednisolone			C				Not Reported
	Regular Insulin			C				Not Reported
	Cefepime			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported
	Propofol			C				Not Reported
	Heparin			C				Not Reported
D5/Sodium Bicarbonate Drip			C				Not Reported	
Sodium Bicarbonate 50meq Push			C				Not Reported	

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01-Jun-2020	17849315	DIRECT	Y	DE, OT			70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Convalescent Plasma			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849320	DIRECT	Y	DE			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block; Cardiogenic Shock; General Physical Health Deterioration; Hypotension; Lethargy; Malaise; Pulmonary Embolism; Right Atrial Enlargement; Right Ventricular Dysfunction; Right Ventricular Enlargement; Vomiting	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once- Loading Dose;		Gilead	
	Convalescent Plasma			C				Not Reported	
	Azithromycin			C				Not Reported	
	Enoxaparin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849324	DIRECT	Y	DS, OT			55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Oliguria; Prerenal Failure; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead	
	Acetaminophen 650 Mg			C				Not Reported	
	Albuterol			C				Not Reported	
	Azithromycin			C				Not Reported	
	Colchicine			C				Not Reported	
	Fentanyl			C				Not Reported	
	Hydrocortisone 50 Mg Q8h			C				Not Reported	
	Pantoprazole 40 Mg Iv			C				Not Reported	

Piperacillin Tazobactam	C	Not Reported
Prednisone	C	Not Reported
Tocilizumab 800 Mg	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849330	DIRECT	Y	DE			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Infarction; Dysphagia; End Stage Renal Disease; Failure To Thrive; Pneumonia Viral; Respiratory Failure	Remdesivir Zosyn Vancomycin			S C C	Intravenous drip			Gilead Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849357	DIRECT	Y	HO			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849363	DIRECT	Y				41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849368	DIRECT	Y	OT			70 YR	Male	USA

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Acute Kidney Injury; Haemodialysis; Renal Failure; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S		Gilead		
	Simvastatin			C		Not Reported		
	Melatonin			C		Not Reported		
	Levothyroxine			C		Not Reported		
	Propofol			C		Not Reported		
	Norepinephrine			C		Not Reported		
	Insulin Regular			C		Not Reported		
	Insulin Lispro			C		Not Reported		
	Hydrophorphone			C		Not Reported		
	Meropenem			C		Not Reported		
	Prismassol			C		Not Reported		
	Linezoid			C		Not Reported		
	Famotidine			C		Not Reported		
	Heparin			C		Not Reported		
Lisinopril-Hydrochlorothiazide			C	Not Reported				
Diclofenac			C	Not Reported				
Insulin Aspart			C	Not Reported				
Insulin Glargine			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849369	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Supraventricular Extrasystoles; Ventricular Tachycardia	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849373	DIRECT	Y	OT			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead

Cessation	Remdesivir	Y	S	Intravenous bolus	Gilead
	Acetaminophen Prn		C		Not Reported
	Bisacodyl Supp Prn		C		Not Reported
	Chlorhexidine Po Bid		C		Not Reported
	Robitussin Dm Prn		C		Not Reported
	Heparin 7.500 U Subq Tid		C		Not Reported
	Melatonin Prn Insomnia		C		Not Reported
	Menthol Lozenge Prn		C		Not Reported
	Methocarbamol 750mg Po Bid Prn		C		Not Reported
	Bengay Cream Prn		C		Not Reported
	Solu-Medrol 40mg Iv Bid		C		Not Reported
	Bactroban Oint Nasal Bid		C		Not Reported
	Ns Iv Solution		C		Not Reported
	Zofran Po/iv Prn		C		Not Reported
	Pantoprazole		C		Not Reported
	Miralax Daily Prn		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849387	DIRECT	Y	OT			28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Hypotension	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849393	DIRECT	Y	DE			47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Fentanyl Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Levopred Drip			C				Not Reported
	Rocuronium Drip			C				Not Reported
	Vasopressin Drip			C				Not Reported
	Versed Drip			C				Not Reported
	Tpn			C				Not Reported

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Mucomyst 600mg Bid Via Tube	C	Not Reported
Ascobic Acid	C	Not Reported
Cholecalciferol	C	Not Reported
Docusate	C	Not Reported
Regular Insulin	C	Not Reported
Protonix	C	Not Reported
Miralax	C	Not Reported
Selenium	C	Not Reported
Vitamin A	C	Not Reported
Vitamin E	C	Not Reported
Zinc Sulfate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849399	DIRECT	Y	OT			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Hydrocortisone			C				Not Reported
	Lantus			C				Not Reported
	Humalog Slicing Scale			C				Not Reported
	Protonix			C				Not Reported
	Vancomycin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Rucuronium Drip			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17849407	DIRECT	Y				55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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01-Jun-2020	17849442	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Dialysis; Oliguria; Renal Impairment; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17794570	EXPEDITED (15-DAY)		DE, HO, LT, OT	NL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037224		66 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Haematoma Muscle; Lactic Acidosis; Off Label Use; Renal Failure; Respiratory Failure; Subcutaneous Abscess	Apixaban			S	Unknown	Unk		Bristol Myers Squibb
	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram, Qd		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Milligram, Qd		Not Reported
	Nadroparine			S	Unknown	Unk		Not Reported
	Pravastatine [Pravastatin Sodium]			C	Unknown	Unk		Not Reported
	Metoclopramide			C	Unknown	Unk		Not Reported
	Nifedipine			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported
	Oxycodone [Oxycodone Hydrochloride]			C	Unknown	Unk		Not Reported
	Fenoterol;Ipratropium			C	Unknown	Unk		Not Reported
Cotrimaxazol			C	Unknown	Unk		Not Reported	
Valaciclovir			C	Unknown	Unk		Not Reported	

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Allopurinol	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Pantoprazol [Pantoprazole]	C	Unknown	Unk	Not Reported
Flucloxacillin	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849531	DIRECT	Y				64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849543	DIRECT	Y	DE			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849845	DIRECT	Y	HO			23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported
	Bumetanide			C				Not Reported
	Clonazepam			C				Not Reported
	Famotidine			C				Not Reported

Insulin Lispro	C	Not Reported
Dexmedetomidine	C	Not Reported
Dobutamine	C	Not Reported
Fentanyl	C	Not Reported
Methylprednisolone	C	Not Reported
Acetaminophen	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850775	DIRECT	Y	OT			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased; Rales	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Citalopram			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydroxyzine			C				Not Reported
	Lisinopril			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Miralax			C				Not Reported
	Sodium Chloride Infusion			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850817	DIRECT	Y				71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Schedule Of Product Administration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Povidone Iodine			C				Not Reported
	Potassium Chloride, Extended Release			C				Not Reported
	Simvastatin			C				Not Reported

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Insulin Lispro		C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850823	DIRECT	Y	DS, HO, OT			72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis	Remdesivir Vancomycin			S C	Parenteral			Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850829	DIRECT	Y	DS, HO, OT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Urine Output Decreased	Remdesivir Vancomycin Methylprednisolone			S C C	Parenteral			Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850833	DIRECT	Y	HO			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850839	DIRECT	Y	DE, HO, OT			42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Haemodialysis; Renal Impairment	Remdesivir			S	Parenteral			Gilead	

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02-Jun-2020	17850843	DIRECT	Y	DS, HO, OT			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased; Haemodialysis; Urine Output Decreased	Remdesivir Vancomycin			S C	Parenteral			Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850847	DIRECT	Y	OT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase	Remdesivir Vancomycin Enoxaparin Insulin Aspart Acetaminophen Azithromycin Cefepime Ceftriaxone Zyrtec			S C C C C C C C C	Intravenous drip			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850883	DIRECT	Y	OT			77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Musculoskeletal Stiffness	Remdesivir Aspirin Chewable 81 Mg Gabapentin Magnesium Oxide Metoprolol Tartrate Pantoprazole Pravastatin	Y		S C C C C C C	Intravenous drip	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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Rivaroxaban	C	Not Reported
Ropinirole	C	Not Reported
Tamsulosin	C	Not Reported

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02-Jun-2020	17850888	DIRECT	Y	DE, DS, HO, OT			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Haemodialysis; Multiple Organ Dysfunction Syndrome; Renal Impairment; Respiratory Failure	Remdesivir			S	Parenteral			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850892	DIRECT	Y	DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medical Observation	Remdesivir			S	Parenteral			Gilead
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Zosyn			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850895	DIRECT	Y	OT			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850901	DIRECT	Y				79 YR	Female	USA

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Blood Creatinine Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Allopurinol 100mg Po Daily			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Apixaban 5mg Po Bid			C				Not Reported
	Ascorbic Acid 250mg Po Daily			C				Not Reported
	Aspirin Ec 81mg Po Daily			C				Not Reported
	Bumetanide 1mg Po Daily			C				Not Reported
	Famotidine 40mg Po Daily			C				Not Reported
	Ferrous Sulfate 325mg Po Bid			C				Not Reported
	Gabapentin 300mg Po Bid			C				Not Reported
	Levothyroxine 100 Mcg Po Daily			C				Not Reported
	Lidocaine 5% Patch Td Daily			C				Not Reported
	Lisinopril 10mg Po Daily			C				Not Reported
	Multivitamin 1 Tablet Po Daily			C				Not Reported
	Pantoprazole 40mg Po Daily			C				Not Reported
	Acetaminophen 650mg Po Q6h Prn Fever			C				Not Reported
	Guaifenesin 200mg Po Q4h Prn Cough			C				Not Reported
	Iohexol 350mg Iodine/MI Inj: Dose=75ml Once			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850905	DIRECT	Y	LT, OT			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Dehydration; Pulmonary Oedema; Renal Disorder	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:X1. Then 100mg/Day;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850908	DIRECT	Y	DE, OT			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Creatinine Increased; Cardiac Arrest; Hypoxia; Nausea; Respiratory Failure; Vomiting	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
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02-Jun-2020	17850912	DIRECT	Y	HO			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Amlodipine			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported
	Lactated Ringers			C				Not Reported
	Sodium Chloride 0.9%			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850927	DIRECT	Y	OT			47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850931	DIRECT	Y				28 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Liver Function Test Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C		Not Reported		
	Vancomycin			C		Not Reported		
	Cholecalciferol			C		Not Reported		
	Ascorbic Acid			C		Not Reported		
	Methylprednisolone			C		Not Reported		
	Midazolam			C		Not Reported		
	Norepinephrine			C		Not Reported		
	Famotidine			C		Not Reported		
	Topiramate			C		Not Reported		
	Vecuronium			C		Not Reported		
	Thiamine			C		Not Reported		
	Zinc Sulfate			C		Not Reported		
Propofol			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850933	DIRECT	Y	DE, HO, LT			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Pyrexia; Respiratory Distress	Emergency Use Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;		Gilead
	Emergency Use Remdesivir	Y		S			Intravenous (not otherwise specified)	
	Hydralazine			C				Not Reported
	Imdur			C				Not Reported
	Ketorolac			C				Not Reported
	Levemir			C				Not Reported
	Linezolid			C				Not Reported
	Memantine			C				Not Reported
	Novolog			C				Not Reported
	Potassium Chloride			C				Not Reported
	Potassium Phosphate Sodium Phosphate			C				Not Reported
	Percocet			C				Not Reported
	Primidone			C				Not Reported
	Pyridoxine			C				Not Reported

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Vancomycin	C	Not Reported
Vitamin D	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850940	DIRECT	Y	OT			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Connection Issue; Drug Dose Omission By Device; Product Leakage; Product Supply Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17852138	EXPEDITED (15-DAY)		DE, HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2020VAL000437			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Pancreatitis	Furosemide			S	Intravenous (not otherwise specified)	Unk		Validus
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Kardegic			C		Unk		Not Reported
	Coumadine			C		Unk		Not Reported
	Perfalgan			C		Unk		Not Reported
	Triatec /00885601/			C		Unk		Not Reported
	Piperacillin			C		Unk		Not Reported
	Cordarone			C		Unk		Not Reported
	Rovamycine /00074401/			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Heparin AI			C		Unk		Not Reported
	Ciprofloxacin			C		Unk		Not Reported
	Tazobactam			C		Unk		Not Reported

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Solupred /00016217/	C	Unk	Not Reported
Bisoce	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17853588	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469405		76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Brovana			C				Not Reported
	Anoro Ellipta			C				Not Reported
	Lasix [Furosemide]			C				Not Reported
	Prednisone			C				Not Reported
	Insulin			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Atorvastatin			C				Not Reported
	Metformin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Rocephin [Ceftriaxone]			C				Not Reported
	Azithromycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17853597	EXPEDITED (15-DAY)		DE, HO	US-GILEAD-2020-0469416		88 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; General Physical Condition	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
Abnormal; Hypotension; Oxygen Consumption Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17853613	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469516		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C		Unk		Not Reported
	Ipratropium			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Piperacillin / Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854398	DIRECT	Y	OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Cough; Dyspnoea; Hypertension; Malaise	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854534	DIRECT	Y				61 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854539	DIRECT	Y	OT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Condition Aggravated; Dialysis; General Physical Health Deterioration	Remdesivir Remdesivir	Y		S C	Intravenous drip		2 DAY	Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854546	DIRECT	Y	HO			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Remdesivir	Y		S C	Intravenous (not otherwise specified)		5 DAY	Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854552	DIRECT	Y	OT			78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir Cefepime Omnipaque 350 Mg Vancomycin			S C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported	

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02-Jun-2020	17854560	DIRECT	Y	DE			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ejection Fraction Decreased; Glomerular Filtration Rate Abnormal; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854566	DIRECT	Y	OT			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholecystitis; Cholelithiasis; Chronic Kidney Disease; Condition Aggravated; Hepatic Enzyme Increased; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Melatonin			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Lispro			C				Not Reported
	Hydromorphone			C				Not Reported
	Famotidine			C				Not Reported
	Levothyroxine			C				Not Reported
	Atorvastatin			C				Not Reported
	Linezolid			C				Not Reported
	Insulin Glargine			C				Not Reported
	Cefepime			C				Not Reported
	Metolazone			C				Not Reported
	Insulin Isophane			C				Not Reported
	Bumetanide			C				Not Reported
	Losartan			C				Not Reported
	Metformin			C				Not Reported
	Metoprolol Succinate			C				Not Reported
	Pregabalin			C				Not Reported

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Liraglutide			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854573	DIRECT	Y				56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Respiratory Arrest; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17854578	DIRECT	Y	DE			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Morphine Drip			C				Not Reported	
	Norepinepine Drip			C				Not Reported	
	Rocuronium Drip			C				Not Reported	
	Vasopressin Drip			C				Not Reported	
	Versed Drip			C				Not Reported	
	Phenylehprine Drip			C				Not Reported	
	Tpn			C				Not Reported	
	Vancomycin			C				Not Reported	
	Meropenem			C				Not Reported	
	Humalog Sliding Scale			C				Not Reported	
	Ascorbic Acid			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Esomeprazole			C				Not Reported	
	Folic Acid			C				Not Reported	
	Heparin For Crrt			C				Not Reported	
	Selenium			C				Not Reported	
	Vitamin E			C				Not Reported	
	Zinc Sulfate			C				Not Reported	

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02-Jun-2020	17854729	DIRECT	Y	OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Impairment	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17855372	DIRECT	Y	OT			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Impairment	Remdesivir 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir 100mg Vial			S		Intravenous (not otherwise specified)		Gilead	
	Furosemide			C				Not Reported	
	Lovenox			C				Not Reported	
	Unasyn			C				Not Reported	
	Protonix			C				Not Reported	
	Metoprolol			C				Not Reported	
	Keppra			C				Not Reported	
Fentanyl			C				Not Reported		
Versed			C				Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17855700	EXPEDITED (15-DAY)			US-GILEAD-2020-0468459		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error; Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead	

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03-Jun-2020	17855745	DIRECT	Y				66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol			C				Not Reported
	Ipratropium			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Pantoprazole			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17855748	DIRECT	Y	DS, HO, LT, OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ergocalciferol			C				Not Reported
	Heparin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin Glargine			C				Not Reported
	Ketamine			C				Not Reported
	Melatonin			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Succinylcholine			C				Not Reported

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Thiamine	C	Not Reported
Vancomycin	C	Not Reported
Zinc Sulfate	C	Not Reported
Acetaminophen	C	Not Reported
Albumin	C	Not Reported
Insulin Regular	C	Not Reported
Fentanyl	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17856141	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0468702		82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17856201	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468990		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Covid-19; Respiratory Failure; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin Regular Hm			C		Sliding Scale		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17856753	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469662		59 YR	Male	USA

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Acute Kidney Injury; Bronchitis; Hypotension; Multiple Organ Dysfunction Syndrome; Oliguria; Pneumonia; Renal Impairment; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Rocuronium			C				Not Reported
	Azithromycin			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Medrol [Methylprednisolone]			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Zosyn			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Versed			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
Vasopressin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857103	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468777		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albumin			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Bumetanide			C				Not Reported
Caffeine Citrate			C				Not Reported	

Chlorothiazide	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported
Furosemide	C	Not Reported
Gabapentin	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Insulin Regular Hm	C	Not Reported
Lactulose	C	Not Reported
Magnesium Sulfate	C	Not Reported
Methylprednisolone	C	Not Reported
Metolazone	C	Not Reported
Midazolam	C	Not Reported
Midodrine	C	Not Reported
Oxycodone	C	Not Reported
Piperacillin/Tazobactam	C	Not Reported
Potassium Chloride	C	Not Reported
Quetiapine	C	Not Reported
Rocuronium	C	Not Reported
Vancomycin	C	Not Reported
Dexmedetomidine	C	Not Reported
Epoprostenol	C	Not Reported
Heparin	C	Not Reported
Hydromorphone	C	Not Reported
Ketamine	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Vasopressin	C	Not Reported
Acetaminophen	C	Not Reported
Fentanyl	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857107	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469610		81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Renal Failure; Tachypnoea	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported

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Atorvastatin	C		Not Reported
Benzonatate	C		Not Reported
Normosol R	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Guaifenesin/Codeine	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Hydrochlorothiazide	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported
Insulin 2	C		Not Reported
Labetalol	C	Unk	Not Reported
Lactated Ringers	C	Unk	Not Reported
Levothyroxine	C	Unk	Not Reported
Lidocaine	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Magnesium Sulfate	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Convalescent Plasma	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857141	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469657		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Hypoxia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Once		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carbidopa + Levodopa			C				Not Reported

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Donepezil	C	Not Reported
Enoxaparin	C	Not Reported
Lispro Insulin	C	Not Reported
Metoprolol	C	Not Reported
Montelukast	C	Not Reported
Solifenacin	C	Not Reported
Acetaminophen	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857144	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469659		71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Milligram Per Millilitre, Once		Gilead
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Nimbex [Cisatracurium Besilate]			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Insulin			C				Not Reported
	Heparin			C				Not Reported
Famotidine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857171	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469603		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Colace			C				Not Reported
	Eliquis			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Pepcid [Famotidine]			C				Not Reported

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Miralax	C	Not Reported
Seroquel	C	Not Reported
Singulair	C	Not Reported
Zofran [Ondansetron]	C	Not Reported
Acetaminophen	C	Not Reported
Piperacillin/Tazobactam	C	Not Reported
Azithromycin	C	Not Reported
Diclofenac	C	Not Reported
Propofol	C	Not Reported
Norepinephrine	C	Not Reported
Fentanyl	C	Not Reported
Dexmedetomidine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857185	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469616		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17857269	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0468988		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17858737	DIRECT	Y	OT			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir	Y		S				Gilead
	Furosemide			C				Not Reported
	Potassium Chloride			C				Not Reported

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Lactulose	C	Not Reported
Divalproex	C	Not Reported
Cholecalciferol	C	Not Reported
Risperidone	C	Not Reported
Ramelteon	C	Not Reported
Clonazepam	C	Not Reported
Gabapentin	C	Not Reported
Prednisone	C	Not Reported
Piperacillin Tazobactam	C	Not Reported
Lamotrigine	C	Not Reported
Tamsulosin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17858747	DIRECT	Y	OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S		Intravenous (not otherwise specified)		Gilead
	Aripiprazole			C				Not Reported
	Famotidine			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Regular			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium			C				Not Reported
	Propofol			C				Not Reported
	Melatonin			C				Not Reported
	Bupropion			C				Not Reported
	Cetirizine			C				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported
	Sertraline			C				Not Reported
	Trazodone			C				Not Reported
	Ocrelizumab			C				Not Reported

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03-Jun-2020	17858915	DIRECT	Y				58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Therapy Interrupted	Remdesivir			S	Intravenous drip			Gilead	
	Dilaudid Drip			C				Not Reported	
	Propofol Drip			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Jun-2020	17858934	DIRECT	Y				69 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Blood Pressure Decreased; Chills; Heart Rate Decreased; Hyperhidrosis; Infusion Related Reaction; Tremor	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead		
	Acetaminophen			C					Not Reported	
	Albuterol (Proventil) Nebulizer Solution			C					Not Reported	
	Azithromycin (Zithromax) 500 Mg In Ns Ivpb			C					Not Reported	
	Benzonatate (Tessalon) Capsule			C					Not Reported	
	Ceftriaxone (Rocephin) 1 G In Ns Ivpb			C					Not Reported	
	Heparin, Porcine Injection 7,500 Units Subq Tid			C					Not Reported	
	Ipratropium-Albuterol (Combivent) Inhaler			C					Not Reported	
	Methylprednisolone *Pf* (Solu-Medrol) Injection 40 Mg			C					Not Reported	
	Morphine Injection			C					Not Reported	
	Ns			C					Not Reported	
	Ondansetron			C					Not Reported	
	Pravastatin			C					Not Reported	
	Thiamine 100mg Tablet			C					Not Reported	
	Iohexol (Omnipaque) 350 Mg			C					Not Reported	
	Iodine/MI Injection			C					Not Reported	
Quetiapine (Seroquel) Tablet 200 Mg			C			Not Reported				

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03-Jun-2020	17858974	DIRECT	Y	OT			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Amiodarone			C				Not Reported
	Zosyn			C				Not Reported
	Methylprednisolone			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17858982	DIRECT	Y	HO, OT			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir Injection	Y		S	Intravenous bolus			Gilead
	Furosemide			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17858990	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen (Prn)			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atropine			C				Not Reported
	Benzonatate			C				Not Reported
	Bumetanide			C				Not Reported
	D50w (Prn)			C				Not Reported

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Doxycycline --Intravenous	C	Not Reported
Epinephrine--Intravenous Drip	C	Not Reported
Hydromorphone--Intravenous Drip	C	Not Reported
Insulin Glargine	C	Not Reported
Regular Insulin Drip/Sliding Scale	C	Not Reported
Lubricant Eye Ointment (And Also Natural Tears Drops)	C	Not Reported
Methylprednisolone Sodium Succinate	C	Not Reported
Multivitamin Tablet	C	Not Reported
Nebivolol	C	Not Reported
Pantoprazole	C	Not Reported
Propofol--Intravenous Drip	C	Not Reported
Rocuronium	C	Not Reported
Zosyn	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17859011	DIRECT	Y	DE			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Cough; Epistaxis; Haemoptysis; Hypotension; Pulseless Electrical Activity; Respiratory Arrest; Retching	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Rivaroxaban			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17859017	DIRECT	Y	DE			99 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Pressure Decreased; Mental Status Changes; Somnolence	Remdesivir			S	Intravenous bolus			Gilead

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03-Jun-2020	17859024	DIRECT	Y	OT			75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Anuria; Blood Creatinine Increased; Cardiac Dysfunction; Dialysis; International Normalised Ratio Increased; Renal Impairment	Remdesivir				S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir				S	Intravenous bolus			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17859029	DIRECT	Y	OT			86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Ulcer Haemorrhage; Haemoglobin Decreased; Melaena	Remdesivir				S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir				S	Intravenous drip			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17859036	DIRECT	Y	OT			50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
White Blood Cell Count Decreased	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen				C				Not Reported
	Azithromycin				C				Not Reported
	Benzonatate				C				Not Reported
	Ceftriaxone				C				Not Reported
	Hydrocodone/Acetaminophen				C				Not Reported
	0.9% Sodium Chloride				C				Not Reported

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Butalbital-Acetaminophen- Caffeine	C	Not Reported
Ondansetron	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17859043	DIRECT	Y				44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	17859048	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Hypoperfusion; Jugular Vein Thrombosis; Pneumonia; Sepsis	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17793631	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0466952		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Pulseless Electrical Activity; Ventricular Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

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04-Jun-2020	17860016	DIRECT	Y				65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Drug Administration Rate; Infusion Site Haemorrhage; Infusion Site Pain	Remdesivir				S	Intravenous drip	Other Frequency:Once;		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860021	DIRECT	Y	OT			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir Kaletra Actemra Zithromax				S C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860075	DIRECT	Y				48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline Phosphatase Increased	Remdesivir Tocilizumab		Y		S C	Intravenous bolus			Gilead Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860079	DIRECT	Y	OT			27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased;	Remdesivir Ascorbic Acid		Y		S C	Intravenous drip			Gilead Not Reported

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Haemodialysis	Cefepime	C	Not Reported
	Cholecalciferol	C	Not Reported
	Enoxaparin	C	Not Reported
	Fluconazole	C	Not Reported
	Insulin Glargine	C	Not Reported
	Insulin Lispro	C	Not Reported
	Melatonin	C	Not Reported
	Methylprednisolone	C	Not Reported
	Pantoprazole	C	Not Reported
	Propofol	C	Not Reported
	Fentanyl	C	Not Reported
	Insulin Regular	C	Not Reported
	Norepinephrine	C	Not Reported
	Potassium Chloride	C	Not Reported
	Sodium Phosphate	C	Not Reported
	Succinylcholine	C	Not Reported
	Midazolam	C	Not Reported
	Metoprolol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860084	DIRECT	Y	DE			48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Dyspnoea; Hypoxia	Remdesivir			S	Parenteral			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860088	DIRECT	Y	OT			37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860095	DIRECT		DE			74 YR	Female	USA

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Multiple-Drug Resistance; Pneumonia	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860100	DIRECT	Y	HO			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Decreased; Covid-19 Pneumonia; Nephropathy Toxic; Renal Impairment; Renal Ischaemia; Respiratory Failure; Septic Shock	Remdesivir	Y		S	Intravenous drip			Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860412	EXPEDITED (15-DAY)		LT	US-ACS-001698		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sepsis	Meropenem			S	Unknown			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	From 01-Apr-2020 To 09- Apr-2020, The Patient Received Remdesivir 100 Mg Iv		Not Reported
	Chloroquine			C	Unknown			Not Reported
	Metoprolol Tartrate			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Albuterol/Ipratropium			C	Unknown			Not Reported
	Oxycodone			C	Unknown			Not Reported
Fentanyl			C	Unknown			Not Reported	

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Diazepam	C	Unknown	Not Reported
Vancomycin	C	Unknown	Not Reported
Propofol	C	Unknown	Not Reported
Norepinephrine	C	Unknown	Not Reported
Phenylephrine	C	Unknown	Not Reported
Digoxin	C	Unknown	Not Reported
Aspirin	C	Unknown	Not Reported
Diltiazem	C	Unknown	Not Reported
Fluoxetine Hydrochloride	C	Unknown	Not Reported
Insulin	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Amiodarone	C	Unknown	Not Reported
Bupropion Hydrochloride	C	Unknown	Not Reported
Cefazolin	C	Unknown	Not Reported
Enoxaparin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860990	DIRECT	Y	OT			40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Remdesivir			S	Intravenous drip			Not Reported
Aminotransferase	Acetaminophen			C				Not Reported
Increased; Blood Bilirubin	Famotidine			C				Not Reported
Increased	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported
	Propofol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Epoprostenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860994	DIRECT	Y	OT			90 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Lethargy; Mechanical Ventilation; Mental Status Changes; Walking Aid User	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cholecalciferol			C				Not Reported
	Codeine/Guaifenesin			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin			C				Not Reported
	Levetiracetam			C				Not Reported
	Levothyroxine			C				Not Reported
	Multivitamin			C				Not Reported
Pantoprazole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17860999	DIRECT	Y	DE			49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Antibiotic Therapy; Renal Replacement Therapy	Remdesivir Under Emergency Use Authorization	Y		S	Intravesical			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17861003	DIRECT	Y	HO			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Disorder	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Epoprostenol			C				Not Reported

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Fentanyl	C	Not Reported
Heparin Drip	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported

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04-Jun-2020	17861008	DIRECT		OT			30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Methylprednisolone 60mg Iv Q8h			C				Not Reported
	Methylprednisolone 40mg Iv Q8h			C				Not Reported
	Tocilizumab 400mg Ivpd			C				Not Reported
	Acetaminophen 1000mg Ivpb Q6h Prn			C				Not Reported
	Oxycodone/Acetaminophen 5mg/325mg Q6h Prn			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17861033	DIRECT	Y	DE			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Arrest	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetamenophen			C				Not Reported
	Amlodopine			C				Not Reported
	Atorvastatin			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dabigatran			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Guaifenesin			C				Not Reported
	Lantus Insulin			C				Not Reported
	Novolog Insulin			C				Not Reported

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Levothyroxine	C	Not Reported
Magnesium Sulfate	C	Not Reported
Senna S	C	Not Reported
Tiotropium	C	Not Reported
Vancomycin	C	Not Reported

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04-Jun-2020	17861039	DIRECT					48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17861907	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469837		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Acute Kidney Injury; Blood Creatinine Increased; Cardiovascular Disorder; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hyperkalaemia; Hypovolaemic Shock; Metabolic Acidosis; Shock Haemorrhagic	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Protonix [Omeprazole]			C		Unk		Not Reported
	Atarax [Alprazolam]			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Ketamine			C		Unk		Not Reported
	Versed			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17862396	EXPEDITED (15-DAY)			US-GILEAD-2020-0469055		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Dextrose Water				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17862427	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0468936		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Dyspnoea; Feeling Hot	Remdesivir				S	Unknown	Unk		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17862432	EXPEDITED (15-DAY)			US-GILEAD-2020-0468996			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error	Remdesivir				S	Unknown			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17863082	EXPEDITED (15-DAY)			US-GILEAD-2020-0469009		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intercepted Product	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
Dispensing Error; Product Administration Error; Product Dispensing Error	Carvedilol				C		Unk		Not Reported
	Cefepime				C		Unk		Not Reported
	Furosemide				C		Unk		Not Reported
	Heparin				C		Unk		Not Reported

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Hydrocortisone	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17863105	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469189		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albuterol;Ipratropium			C				Not Reported
	Apixaban			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Baclofen			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Midazolam			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Fluconazole			C				Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Meropenem			C				Not Reported
	Tocilizumab			C				Not Reported
	Vancomycin			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17863108	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469179		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Azithromycin	C			Not Reported
	Ceftriaxone	C			Not Reported
	Benzonatate	C			Not Reported
	Enoxaparin	C			Not Reported
	Famotidine	C			Not Reported
	Metoprolol	C			Not Reported
	Potassium Bicarbonate;Sodium Phosphate	C			Not Reported
	Potassium Chloride	C			Not Reported
	Vancomycin	C			Not Reported
	Acetaminophen	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17863182	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469222		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Piperacillin+Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluconazole			C				Not Reported
	Fluticasone			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Senna [Senna Alexandrina Leaf]			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Sodium Chloride			C				Not Reported
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Iopamidol			C				Not Reported
	Ondansetron			C				Not Reported
	Promethazine			C				Not Reported
	Codeine			C				Not Reported

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04-Jun-2020	17863307	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470071		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Prazosin			C		Unk		Not Reported
	Proventil [Salbutamol]			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Lactinex [Lactobacillus Acidophilus]			C		Unk		Not Reported
	Lasix [Furosemide]			C		Unk		Not Reported
	Lipitor [Atorvastatin]			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Protonix [Omeprazole]			C		Unk		Not Reported
	Robitussin A C			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Zoloft			C		Unk		Not Reported
	Zyloprim			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864171	DIRECT	Y	OT			33 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hepatic Enzyme Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Tocilizumab		C		Not Reported
	Colchine		C		Not Reported
	Doxycycline		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864177	DIRECT	Y	HO			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864180	DIRECT	Y				77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Midazolam			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864182	DIRECT	Y	OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased Remdesivir S Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864201	DIRECT	Y	HO			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Alprazolam			C				Not Reported
	Azithromycin			C				Not Reported
	Bupropion			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Iopamidol			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
	Norepinephrine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Propofol			C				Not Reported
Rocuronium			C				Not Reported	
Vancomycin			C				Not Reported	
Vecuronium			C				Not Reported	
Venlafaxine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864223	DIRECT	Y	LT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Oxygen	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported

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Saturation Decreased	Enoxaparin Guaifenesin Ibuprofen	C C C			Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864252	DIRECT	Y	DE			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus	Other Frequency:X1;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Hydroxychloroquin 200mg Po Bid			C				Not Reported
	Actemra 400mg X1			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864258	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864265	DIRECT	Y	DE, HO			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; General Physical Health Deterioration; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous drip			Gilead
	Levophed			C				Not Reported
	Neo-Syneprine			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Versed Drip			C				Not Reported
	Nimbex Drip			C				Not Reported
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Precedex			C				Not Reported

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04-Jun-2020	17864269	DIRECT	Y	OT			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Increased	Remdesivir Azithromycin Ceftriaxone Fentanyl Infusion Midazolam Infusion Propofol	Y		S C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864279	DIRECT	Y	OT			76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864306	DIRECT	Y				25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir	Y		S	Intravenous drip				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17864803	DIRECT	Y	OT			57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension	Remdesivir For Injection 100mg/Vial Zinc	Y		S C	Intravenous (not otherwise specified)				Gilead Not Reported

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Pantoprazole	C	Not Reported
Meropenem	C	Not Reported
Levothyroxine	C	Not Reported
Levetiracetam	C	Not Reported
Hydrocortisone	C	Not Reported
Famotidine	C	Not Reported
Enoxaparin	C	Not Reported
Cipro	C	Not Reported
Azithromycin	C	Not Reported
Ascorbic Acid	C	Not Reported
Dopamine	C	Not Reported
Norepinephrine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865473	DIRECT	Y	OT			28 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Remdesivir			S	Intravenous drip			Gilead
Aminotransferase Increased; Bilirubin Conjugated Abnormal	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Cisatracurium Drip			C				Not Reported
	Sennosides 5 Ml			C				Not Reported
	Docusate 50 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported
	Epoprostenol Inhaled			C				Not Reported
	Famotidine 20 Mg			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Furosemide 40 Mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Insulin Nph			C				Not Reported
	Ketamine Drip			C				Not Reported
	Methylprednisone 60 Mg			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Zosyn 4.5 Grams			C				Not Reported
	Propofol Drip			C				Not Reported
	Timolol Eye Drop			C				Not Reported
	Vancomycin 1.5 Gram			C				Not Reported

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05-Jun-2020	17865479	DIRECT	Y	DE			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865482	DIRECT	Y				29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Delivery System Issue	Remdesivir 100mg Iv In 100ml Ns	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865487	DIRECT	Y	DE			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865494	DIRECT	Y	DE, LT			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Infarction; International Normalised Ratio Increased; Miosis; Respiratory Failure; Thrombocytopenia; Troponin Increased; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Norepinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Dexmedetomidine			C				Not Reported

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Fentanyl	C	Not Reported
Midazolam	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Succinylcholine	C	Not Reported
Argatroban	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865506	DIRECT	Y	DE			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardiac Arrest; Circulatory Collapse; International Normalised Ratio Increased	Remdesivir Amiodarone Drip Cefepime 1g Iv Q24h Norepinephrine Drip Phytonadione 10 Mg Sc Propofol Drip Vancomycin 1g Iv Q12h Vasopressin Drip	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865510	DIRECT	Y	DE, OT			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disseminated Intravascular Coagulation; Dyspnoea; Pulmonary Embolism; Shock	Remdesivir Remdesivir Convalescent Plasma Doxycycline Acetaminophen Ceftriaxone Docusate Sodium Donepezil Enoxaparin Fluoxetine Melatonin Omeprazole			S	Intravenous drip	Other Frequency:Once-Loading Dose;		Gilead
				S	Intravenous drip			Gilead
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported
				C				Not Reported

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Potassium Chloride	C	Not Reported
Propofol	C	Not Reported
Risperidone	C	Not Reported
Senna Tablet	C	Not Reported
Quetiapine	C	Not Reported
Polyethylene Glycol	C	Not Reported
Fentanyl	C	Not Reported
Furosemide	C	Not Reported
Etomidate	C	Not Reported
Succinylcholine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865514	DIRECT		OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide 20mg Ivp X1			C				Not Reported
	Furosemide 40mg Ivp X4			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865519	DIRECT		OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypophosphataemia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Furosemide 20mg Ivp X1			C				Not Reported
	Furosemide 40mg Ivp X4			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865524	DIRECT		OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S				Not Reported
	Acetaminophen 650mg Q4h			C				Not Reported

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05-Jun-2020	17865547	DIRECT	Y				40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Disease Progression	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead	
	Vancomycin Ivpb			C				Not Reported	
	Tocilizumab Ivpb			C				Not Reported	
	Merrem Ivpb			C				Not Reported	
	Azithromycin Ivpb			C				Not Reported	
	Cefepime Ivpb			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865589	DIRECT		OT			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Vancomycin 750mg Iv Once			C				Not Reported	
	Vancomycin 1g Iv Daily			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865594	DIRECT	Y				64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
	Aspirin 81mg Tab Po Daily			C				Not Reported	
	Bumetanide 1mg Po Bid			C				Not Reported	
	Carvedilol 25mg Po Bid			C				Not Reported	
	Clopidogrel 75mg Po Daily			C				Not Reported	
	Isosorbide Mononitrate 30mg Po Daily			C				Not Reported	
	Montelukast 10mg Po Daily			C				Not Reported	
	Pantoprazole 40mg Po Daily			C				Not Reported	
	Pregabalin 75mg Po Tid			C				Not Reported	

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Tramadol 50mg Po Q6h Prn
Pain

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865599	DIRECT		OT			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukocytosis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17865627	DIRECT		DE			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia; Respiratory Arrest; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen 650mg Q4h Prn			C				Not Reported
	Insulin Human Regular Sliding Scale			C				Not Reported
	Norepinephrine Iv Drip			C				Not Reported
	Rocuronium 50mg Iv p X1			C				Not Reported
	Clonazepam 0.5mg Q8h			C				Not Reported
	Valproic Acid 125mg Q6h			C				Not Reported
	Atorvastatin 10mg Daily			C				Not Reported
	Levothyroxine 25mcg Daily			C				Not Reported
	Famotidine 20mg Q12h			C				Not Reported
	Enoxaparin 80mg Q12h			C				Not Reported
	Piperacillin/Tazobactam 3.375g Iv Q6h			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866073	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Decreased; Respiratory Depression	Remdesivir			S	Intravenous bolus			Gilead

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Propofol			S	Intravenous drip		Other Frequency:50-75mcg/Kg/Min;			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866082	DIRECT	Y	OT			94 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Creatinine Renal Clearance Decreased	Remdesivir		Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866086	DIRECT		OT			55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Function Test Abnormal; Renal Impairment	Remdesivir				S	Intravenous (not otherwise specified)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866090	DIRECT	Y	OT			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Reaction	Remdesivir Remdesivir				S C				Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866091	DIRECT		OT			55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir				S	Intravenous (not otherwise specified)			Not Reported
	Norepinephrine Iv Drip				C				Not Reported
	Fentanyl Iv Drip				C				Not Reported

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05-Jun-2020	17866098	DIRECT		HO			67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Hepatitis; International Normalised Ratio Increased; Ischaemic Hepatitis; Liver Function Test Increased; Rhabdomyolysis	Remdesivir Crestor Apixaban				S C C				Gilead Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866101	DIRECT	Y	OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lacunar Infarction; Seizure	Remdesivir		Y		S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866105	DIRECT	Y	OT			50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir Enoxaparin Ceftriaxone Atorvastatin				S C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866451	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469160		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Headache; Myalgia; Rash Remdesivir S Intravenous (not otherwise specified) 200 Mg, Qd Gilead
Papular

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866498	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470010		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Carvedilol			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Losartan			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pyridostigmine			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866546	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470050		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Related Reaction; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17866936	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469248		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Tremor	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Lantus			C		Unk		Not Reported

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Insulin Lispro		C		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868108	EXPEDITED (15-DAY)			US-GILEAD-2020-0469266		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission	Remdesivir			S	Unknown	200 Mg		Gilead	
	Remdesivir			S	Unknown	100 Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868192	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469449		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Albuterol Hfa			C				Not Reported	
	Ascorbic Acid			C				Not Reported	
	Aspirin (E.C.)			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Azithromycin			C				Not Reported	
	Budesonide			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Docusate;Senna			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Linagliptin			C				Not Reported	
	Lisinopril			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Polyethylene Glycol 3350			C				Not Reported	
	Selinexor			C				Not Reported	
	Tramadol			C				Not Reported	
	Zinc Sulfate			C				Not Reported	

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05-Jun-2020	17868685	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Shock	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen Suppositories			C				Not Reported
	Acetaminophen Oral Tablets			C				Not Reported
	Acetylcysteine Po			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	D50w Prn Hypoglycemia			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate (1 Dose For Intubation)			C				Not Reported
	Hydromorphone Drip			C				Not Reported
	Insulin Lispro--Sliding Scale			C				Not Reported
	Ipratropium Inhaler			C				Not Reported
	Methylprednisolone Sodium Succinate (X 1 Dose)			C				Not Reported
	Propofol Drip			C				Not Reported
	Rocuronium (1 Dose For Intubation)			C				Not Reported
	Sodium Chloride Drip			C				Not Reported
	Zosyn 3.375 G Iv			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868686	DIRECT	Y	LT			39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S				Not Reported
	Heparin			C				Not Reported
	Azithromycin			C				Not Reported

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Norepinephrine	C	Not Reported
Acetaminophen	C	Not Reported
Midazolam	C	Not Reported
Cefepime	C	Not Reported
Hydromorphone	C	Not Reported
Bisacodyl	C	Not Reported
Vasopressin	C	Not Reported
Propofol	C	Not Reported
Ipratropium-Albuterol	C	Not Reported
Acetylcysteine	C	Not Reported
Insulin Regular	C	Not Reported
Hydrocortisone Sodium Succinate	C	Not Reported
Famotidine	C	Not Reported
Albuterol	C	Not Reported
Perflutren Lipid Microspheres	C	Not Reported
Chlorhexidine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868688	DIRECT	Y	OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Hyperhidrosis	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868690	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Calcium Gluconate			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Phytonadione			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopression			C				Not Reported

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Piperacillin/Tazobactam			C				Not Reported		
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05-Jun-2020	17868691	DIRECT	Y	DS			44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead	
	Fluconazole			C				Not Reported	
	Hydrochlorothiazide			C				Not Reported	
	Lisinopril			C				Not Reported	
	Amlodipine			C				Not Reported	
	Ferrous Sulfate			C				Not Reported	
	Omeprazole			C				Not Reported	
	Hydrocodone/Acetaminophen			C				Not Reported	
	Cyanocobalamin			C				Not Reported	
	Multivitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868692	DIRECT	Y	DE			70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Respiratory Failure; Shock	Remdesivir Eua			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868694	DIRECT	Y	HO			87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868695	DIRECT	Y	OT			53 YR	Male	USA

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Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868696	DIRECT	Y	OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17868697	DIRECT	Y	DE			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Cardiac Arrest	Remdesivir			S	Intravenous bolus	Other Frequency:Once Loading Dose;	1 DAY	Gilead	
	Acetaminophen			C				Not Reported	
	Artificial Tears			C				Not Reported	
	Aspirin			C				Not Reported	
	Azithromycin			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Desmopressin			C				Not Reported	
	Famotidine			C				Not Reported	
	Fentanyl			C				Not Reported	
	Heparin			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Insulin Nph			C				Not Reported	
	Meropenem			C				Not Reported	
	Methylprednisolone			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17870105	DIRECT	Y				53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Neutropenia; Respiratory Failure	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Route:lv		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17870709	DIRECT	Y	DE			77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Covid-19 Pneumonia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17870830	DIRECT	Y	DE			69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Acute Kidney Injury; Areflexia; Cardiac Arrest; Condition Aggravated; Hypotension; Miosis; Nodal Rhythm; Pulmonary Arterial Pressure Increased; Pulmonary Fibrosis; Pulse Absent; Respiratory Failure; Right Ventricular Dilatation; Right Ventricular Failure; Sinus Bradycardia; Unresponsive To Stimuli	Remdesivir (Eua) (Remdesivir (Eua)) Vancomycin (Vancomycin Hcl 1gm/Vil Inj)			S S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Other Strength:1 Gm/Vil;		Not Reported Not Reported	

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05-Jun-2020	17870880	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Ammonia Increased; Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Lactic Acid Increased; Body Temperature Increased; Candida Test Positive; Chest Pain; Covid-19 Pneumonia; Fluid Overload; Haemodynamic Instability; Hypotension; Interleukin Level Increased; Lung Opacity; Metabolic Acidosis; Oxygen Saturation Decreased; Renal Failure; Septic Shock	Remdesivir Pantoprazole 40mg Atorvastatin 40mg Albuterol Neds Albumin Thiamine 100mg Furosemide 20mg Lantus Multivitamin With Minerals			S S S C C C C C C				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Other Route:lv Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17871070	DIRECT	Y	OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Oxygen Saturation Decreased; Therapy Interrupted	Remdesivir 200mg Remdesivir 100mg Bupropion 300mg 24 Hour Release Tablet Acetaminophen Azltromycin Benzocaine-Menthol Lozenge	Y		S S C C C C		Intravenous (not otherwise specified) Intravenous (not otherwise specified) Oral		Gilead Gilead Not Reported Not Reported Not Reported Not Reported

Bisacodyl	C	Not Reported
Calcium Carbonate	C	Not Reported
Diphenhydramine	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported
Fentanyl	C	Not Reported
Gaulfensin	C	Not Reported
Hydromorphone	C	Not Reported
Melatonin	C	Not Reported
Midazolam	C	Not Reported
Noreplenphrine	C	Not Reported
Nystalin	C	Not Reported
Topical Powder	C	Not Reported
Ondanestron	C	Not Reported
Polyethylene Glycol	C	Not Reported
Potassium Bicarbonate-Citric Acid Effervescent	C	Not Reported
Propofol	C	Not Reported
Senna (Senokot)	C	Not Reported
Sertraline	C	Not Reported
Temazepam	C	Not Reported
Trazodone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2020	17868624	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469292		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dialysis; Off Label Use	Remdesivir			S	Unknown	50 Mg		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2020	17868698	DIRECT	Y	OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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06-Jun-2020	17868699	DIRECT	Y	HO			69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Chest X-Ray Abnormal; Chills; Dyspnoea; Heart Rate Increased; Infusion Related Reaction; Leukocytosis; Pyrexia	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
	Iv Pantoprazole 40mg			C				Not Reported	
	Iv Lactated Ringers			C				Not Reported	
	Humalog Sliding Scale Insulin			C				Not Reported	
	Iv Covid-19 Convalescent Plasma			C				Not Reported	
	Po Acetaminophen 650mg			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2020	17868700	DIRECT	Y	LT, OT			47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Glomerular Filtration Rate Increased; Renal Disorder	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2020	17868701	DIRECT	Y	LT, OT			35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead	
	Cholecalciferol 2000 Units Daily			C				Not Reported	
	Melatonin 6 Mg Hs			C				Not Reported	
	Atorvastatin 40 Mg Daily At 6pm			C				Not Reported	
	Methylprednisolone 60 Mg Iv Q6h			C				Not Reported	
	Enoxaparin 40 Mg Sq Q12h			C				Not Reported	
	Humalog Sliding Scale			C				Not Reported	

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06-Jun-2020	17868702	DIRECT	Y	OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased	Remdesivir	Y		S				Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2020	17868703	DIRECT	Y	OT			74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; General Physical Health Deterioration; Hypoxia; Liver Function Test Abnormal	Remdesivir Famotidine Heparin Meropenem Metoprolol Sodium Chloride Tolvaptan Acetaminophen			S C C C C C C	Intravenous bolus			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2020	17869696	DIRECT	Y	OT			76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Failure	Remdesivir			S	Intravenous drip			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2020	17869704	DIRECT	Y	OT			53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2020	17869707	DIRECT	Y	OT			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead
	Vasopressin			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Miratazepine			C				Not Reported
	Buspirone			C				Not Reported
	Bisacodyl			C				Not Reported
	Citalopram			C				Not Reported
	Cholecalciferol			C				Not Reported
	Vancomycin			C				Not Reported
	Cefepime			C				Not Reported
	Diltiazem			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
Magnesium Oxide			C				Not Reported	
Oxycodone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2020	17869710	DIRECT	Y	OT			47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemodialysis; Metabolic Acidosis; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C				Not Reported
	Anakinra			C				Not Reported
	Colchicine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2020	17869716	DIRECT	Y	OT			40 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Creatinine Renal Clearance Decreased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17818529	EXPEDITED (15-DAY)		DE, LT	US-GILEAD-2020-0468184		77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Thiamine			C				Not Reported
	Doxycycline			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Sertraline A			C				Not Reported
	Tamsulosin			C				Not Reported
	Zinc			C				Not Reported
Ipratropium			C				Not Reported	
Enoxaparin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17856716	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469671		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ventricular Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fluoxetine			C		Unk		Not Reported

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Heparin	C	Unk	Not Reported
Hydroxyzine	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Trazodone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871341	DIRECT	Y				83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Piperacillin-Tazobactam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871346	DIRECT	Y	HO			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Amlodipine 5 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871365	DIRECT	Y				76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Storage Error; Wrong Technique In Product Usage Process	Remdesivir Eua			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871387	DIRECT	Y	DE, OT			81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir Tocilizumab Convalescent Plasma	Y		S C C	Intravenous bolus			Gilead Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871406	DIRECT	Y	OT			42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Ischaemic Hepatitis; Pneumonia Bacterial	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871437	DIRECT	Y				37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir Tocilizumab Azithromycin Acetaminophen Enoxaparin			S C C C C	Intravenous drip		4 DAY	Gilead Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871442	DIRECT	Y				60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error; Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead	

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08-Jun-2020	17871448	DIRECT	Y	OT			33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Creatinine Renal Clearance Decreased	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871461	DIRECT	Y	DE			90 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Disease Progression; Hypoxia; Pain; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Enoxaparin			C		Not Reported			
	Lisinopril			C		Not Reported			
	Metoprolol			C		Not Reported			
	Pantoprazole			C		Not Reported			
	Zosyn			C		Not Reported			
	Pregabalin			C		Not Reported			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17871973	DIRECT	Y	DE			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Remdesivir 100mg Iv			S	Intravenous (not otherwise specified)			Not Reported	
	Amlodipine			C		Not Reported			
	Enoxaparin			C		Not Reported			
	Levothyroxine			C		Not Reported			
	Dexmedetomidine			C		Not Reported			
	Fentanyl			C		Not Reported			
	Norepinephrine			C		Not Reported			
	Propofol			C		Not Reported			
	Vasopressin			C		Not Reported			

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08-Jun-2020	17872168	DIRECT	Y	DE			43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospice Care	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872171	DIRECT	Y				37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872244	DIRECT	Y	OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead
	Enoxaparin			C				Not Reported
	Dopamine/D5w			C				Not Reported
	Acetaminophen			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ondansetron			C				Not Reported
	Sodium Cl Flush			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Etomidate			C				Not Reported
	Furosemide			C				Not Reported
	Lactated Ringers			C				Not Reported
	Lidocaine			C				Not Reported
Midazolam			C			Not Reported		

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Pantoprazole	C	Not Reported
Potassium	C	Not Reported
Azithromycin	C	Not Reported
Hydromorphone	C	Not Reported
Fentanyl	C	Not Reported
Ceftriaxone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872250	DIRECT	Y				43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dispensing Error; Product Preparation Error; Wrong Product Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872251	DIRECT	Y	DE			83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospice Care	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872254	DIRECT	Y	OT			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872258	DIRECT	Y	DE			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S	Intravenous (not			Gilead

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872280	DIRECT	Y				42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dispensing Error; Product Preparation Error; Wrong Product Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872285	DIRECT	Y				47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dispensing Error; Product Preparation Error; Wrong Product Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872288	DIRECT	Y				65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Issue	Remdesivir	Y		S			1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872289	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration	Remdesivir	Y		S	Intravenous (not		2 DAY	Gilead

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Error; Product Preparation Issue

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872290	DIRECT	Y				56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872293	DIRECT	Y	OT			45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872296	DIRECT	Y				70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872300	DIRECT	Y				27 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration	Remdesivir	Y		S	Intravenous (not		1 DAY	Gilead

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Error; Product Preparation
Error; Product Preparation
Issue

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872303	DIRECT	Y				61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872307	DIRECT	Y				77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872312	DIRECT	Y				79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872315	DIRECT	Y				69 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17872366	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469297		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Ceftriaxone			C				Not Reported
	Dobutamine			C				Not Reported
	Doxycycline 3ddd			C				Not Reported
	Enoxaparin Becat			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Hydrocortisone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vasopressin			C				Not Reported
	Digoxin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17873015	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469646		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17873022	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-		42 YR	Female	USA

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0469641

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17873048	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469609		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Sertraline			C		Unk	Not Reported	
	Melatonin			C		Unk	Not Reported	
	Acetaminophen			C		Unk	Not Reported	
	Enoxaparin			C		Unk	Not Reported	
	Ketorolac			C		Unk	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17873100	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469628		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874653	DIRECT	Y	OT			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiomyopathy; Transaminases Decreased	Remdesivir Solution (Emergency Use Authorization) Tocilizumab	S C	Intravenous drip	Gilead Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874657	DIRECT	Y	DE			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874659	DIRECT		HO			35 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Nephropathy Toxic	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874673	DIRECT	Y				26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Drug Interaction; Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Azithromycin 500 Mg Po Daily			C				Not Reported
	Ceftriaxone 1 Gram Iv Q24h			C				Not Reported
	Dextromethorphan 60 Mg Po Q12h			C				Not Reported
	Enoxaparin 60 Mg Q12h			C				Not Reported
	Guaifenesin Er 600 Mg Po Bid			C				Not Reported
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported
	Acetaminophen/Hydrocodone			C				Not Reported

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5/235 1 Tab Q4h Prn Pain		
Alprazolam 0.5 Mg Q8h Prn	C	Not Reported
Anxiety		
Benzonatte 100 Mg Po Tid Prn	C	Not Reported
Cough		
Codeine-Guaifenesin 10-100 Mg	C	Not Reported
Po Q4h Prn Cough		
Dexmedetomidine 400 Mcg At	C	Not Reported
0.2 Mcg/Kg/Hr Iv		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874677	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Acetazolamide Extended Release			C				Not Reported
	Atorvastatin 10 Mg			C				Not Reported
	Ceftriaxone 1gm			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874681	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874686	DIRECT	Y	OT			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Inj			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874702	DIRECT	Y	DE			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bacterial Infection; Blood Creatinine Increased; Respiratory Failure; White Blood Cell Count Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Furosemide			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol			C				Not Reported
	Norepinephrine			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Morphine			C				Not Reported
	Propofol			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin			C				Not Reported
	Docusate			C				Not Reported
	Pantoprazole			C				Not Reported
	Mehtylprednisolone			C				Not Reported
	Insulin Glargine			C				Not Reported
	Venlafaxine			C				Not Reported
	Duoneb			C				Not Reported
	Guaifenesin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874708	DIRECT	Y	OT			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Allopurinol			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

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Gabapentin									Not Reported
Melatonin									Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874713	DIRECT	Y	OT			25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874717	DIRECT	Y				39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Orthostatic Hypotension	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Carvedilol			C				Not Reported
	Enoxaparin			C				Not Reported
	Levothyroxine			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874751	DIRECT	Y	OT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17874927	DIRECT	Y				63 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intercepted Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17875016	DIRECT	Y	OT			91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S				Gilead
	Amiodarone			C				Not Reported
	Apixaban			C				Not Reported
	Covalescent Plasma			C				Not Reported
	Bumex			C				Not Reported
	Plavix			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Protonix			C				Not Reported
	Metoprolol			C				Not Reported
	Nitroglycerin Patch			C				Not Reported
	Hydralazine			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Tamsulosin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17875022	DIRECT	Y				59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17875057	DIRECT	Y	OT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir	S	Not Reported
Increased; Aspartate Aminotransferase	Aspirin	C	Not Reported
Aminotransferase	Atorvastatin	C	Not Reported
Increased; Procalcitonin	Atracurium	C	Not Reported
Increased; Respiratory Distress; Troponin	Ceftriaxone	C	Not Reported
Increased; White Blood Cell Count Increased	Azithromycin	C	Not Reported
	Benzonatate	C	Not Reported
	Calcium Gluconate	C	Not Reported
	Dobutamine	C	Not Reported
	Enoxaparin	C	Not Reported
	Epoprostenol	C	Not Reported
	Etomidate	C	Not Reported
	Famotidine	C	Not Reported
	Fentanyl	C	Not Reported
	Phenylephrine	C	Not Reported
	Heparin	C	Not Reported
	Vitamin C	C	Not Reported
	Hydrocortisone	C	Not Reported
	Thiamine	C	Not Reported
	Norepinephrine	C	Not Reported
	Propofol	C	Not Reported
	Midazolam	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2020	17875136	DIRECT	Y	RI			46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Injury	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Methylprednisolone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17800831	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0467444		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Death	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17863292	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470078		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Infarction; Dysphagia; End Stage Renal Disease; Failure To Thrive; Pneumonia Viral; Respiratory Failure	Remdesivir			S		Intravenous (not otherwise specified) 100 Mg, Qd		Gilead
	Zosyn			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875072	DIRECT	Y				47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Issue	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875074	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S		Intravenous bolus		Gilead
	Ascorbic Acid 500mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 20 Mg			C				Not Reported
	Duoneb			C				Not Reported
	Lovenox			C				Not Reported
	Zosyn			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Acetaminophen 650mg Prn			C				Not Reported
	Precedex			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

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Fentanyl Iv Drip	C	Not Reported
Doxycycline	C	Not Reported
Famotidine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875122	DIRECT	Y	DE			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cardio-Respiratory Arrest; Hypoxia; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875235	DIRECT	Y	DE, OT			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Cardio-Respiratory Arrest; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Lorazepam			C				Not Reported
	D5w With 3 Amps Bicarb			C				Not Reported
	Epoprostenol			C				Not Reported
	Heparin			C				Not Reported
	Ketamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

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Rocuronium	C	Not Reported
Convalescent Serum	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875456	DIRECT	Y	OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Blood Magnesium Increased; Condition Aggravated	Remdesivir			S				Not Reported
	Resmedivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875590	DIRECT	Y	DE			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ampicillin/Sulbactam			C		Not Reported		
	Apixaban			C		Not Reported		
	Chlorpromazine			C		Not Reported		
	Diltiazem			C		Not Reported		
	Glycopyrrolate			C		Not Reported		
	Levothyroxine			C		Not Reported		
	Melatonin			C		Not Reported		
	Dulera			C		Not Reported		
	Pantoprazole			C		Not Reported		
	Prednisone			C		Not Reported		
	Sertraline			C		Not Reported		
	Hydromorphone			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875594	DIRECT	Y	HO			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead

Ascorbic Acid 500 Mg	C	Not Reported
Candesartan 16 Mg	C	Not Reported
Enoxaparin 40 Mg	C	Not Reported
Lantus 5 Units	C	Not Reported
Methylprednisolone 50 Mg	C	Not Reported
Metoprolol Succinate 25 Mg	C	Not Reported
Nifedipine 30 Mg	C	Not Reported
Pravastatin 20 Mg	C	Not Reported
Zinc Sulfate 220 Mg	C	Not Reported
Fentanyl Infusion	C	Not Reported
Dexmedetomidine Infusion	C	Not Reported
Epinephrine Infusion	C	Not Reported
Heparin Infusion	C	Not Reported
Vasopressin Infusion	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875600	DIRECT	Y				88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Transaminases Increased; Urinary Bladder Haemorrhage; Urinary Retention	Remdesivir Albuterol Atorvastatin Enoxaparin Levofloxacin Methylprednisolone Pantoprazole Senna Warfarin Acetaminophen			S C C C C C C C C C		Intravenous bolus		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875647	DIRECT	Y	OT			37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir Propofol Hydromorphone Norepinephrine			S C C C		Intravenous drip		Gilead Not Reported Not Reported Not Reported

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Docosate-Senna	C	Not Reported
Enoxaparin	C	Not Reported
Pantoprazole	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875801	DIRECT	Y	DE			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Cardiac Arrest;	Remdesivir Eua			S				Not Reported
Hypotension; Hypoxia;	Vancomycin			C				Not Reported
Lung Infiltration; Paralysis;	Tocilizumab			C				Not Reported
Procalcitonin Increased;	Pentoxifylline			C				Not Reported
Renal Failure	Rocuronium			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Metoprolol			C				Not Reported
	Kaletra			C				Not Reported
	Heparin			C				Not Reported
	Cisatricurium			C				Not Reported
	Cefepime			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875863	DIRECT	Y	LT			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest; Cardio-Respiratory Arrest; Pulse Absent	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Heparin			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Regular			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Clonazepam			C				Not Reported
	Oxycodone			C				Not Reported

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09-Jun-2020	17875891	DIRECT	Y	OT			59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead	
	Acyclovir			C					Not Reported
	Albuterol			C					Not Reported
	Aspirin			C					Not Reported
	Calcium Gluconate			C					Not Reported
	Vitamin D3			C					Not Reported
	Clonidine			C					Not Reported
	Famotidine			C					Not Reported
	Furosemide			C					Not Reported
	Guaifenesin			C					Not Reported
	Midodrine			C					Not Reported
	Multivitamin			C					Not Reported
	Potassium Chloride			C					Not Reported
	Potassium Phosphate			C					Not Reported
	Sodium Chloride Inhaled			C					Not Reported
	Sodium Phosphate			C					Not Reported
	Sulfamethoxazole/Trimethoprim			C					Not Reported
Thiamine			C				Not Reported		
Oxycodone			C				Not Reported		
Fentanyl			C				Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876085	DIRECT	Y	OT			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertensive Urgency; Renal Impairment	Remdesivir			S	Intravenous bolus			Gilead	
	Acetaminiphen			C					Not Reported
	Amlodipine			C					Not Reported
	Aspirin			C					Not Reported
	Enoxaparin			C					Not Reported
	Famotidine			C					Not Reported
	Gabapentin			C					Not Reported
	Insulin Lispro			C					Not Reported

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Labetalol Prn	C	Not Reported
Lactulose	C	Not Reported
Quetiapine	C	Not Reported
Fentanyl Drip	C	Not Reported
Ketamine Drip	C	Not Reported
Midazolam Drip	C	Not Reported
Propofol Drip	C	Not Reported
Rocuronium Drip	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876090	DIRECT	Y	DE			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Cardiac Arrest; Confusional State; Hypoxia; Obstructive Airways Disorder; Pneumothorax; Pulse Absent; Rales; Swelling	Remdesivir			S	Intravenous bolus			Gilead
	Thiamine			C				Not Reported
	Seroquel			C				Not Reported
	Haloperidol			C				Not Reported
	Pantoprazole			C				Not Reported
	Methylprednisolone			C				Not Reported
	Ketorolac			C				Not Reported
	Hydrocortisone			C				Not Reported
	Heparin			C				Not Reported
	Enoxaparin			C				Not Reported
	Cefepime			C				Not Reported
	Ascorbic Acid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876168	DIRECT	Y	OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876171	DIRECT	Y	OT			89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;	Gilead
	Atorvastatin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876176	DIRECT	Y	DE			85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Bumetanide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Escitalopram			C				Not Reported
	Famotidine			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin			C				Not Reported
	Levothyroxine			C				Not Reported
	Lorazepam			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Rocuronium			C				Not Reported
	Vancomycin			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Heparin			C				Not Reported
	Norepinephrine			C				Not Reported
	Convalenscent Serum			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876180	DIRECT	Y	HO			56 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation	Remdesivir	Y		S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876191	DIRECT	Y	OT			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuropathy Peripheral	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Hycodan			C				Not Reported	
	Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876212	DIRECT	Y	OT			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once (Loading Dose;		Gilead	
	Acetaminophen			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Fentanyl			C				Not Reported	
	Hydralazine			C				Not Reported	
	Insulin Aspart			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Lisinopril			C				Not Reported	
	Metformin			C				Not Reported	
	Midazolam			C				Not Reported	
	0.9%Ns			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Piperacillin/Tazobactam			C				Not Reported	
	Propofol			C				Not Reported	
	Rocuronium			C				Not Reported	

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09-Jun-2020	17876217	DIRECT	Y				47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip		3 DAY	Gilead
	Acetaminophen			C				Not Reported
	Albuterol Hfa Inhaler			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
Melatonin			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876300	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Monitoring Procedure Incorrectly Performed; Incorrect Dose Administered; Product Dispensing Error; Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876302	DIRECT	Y	OT			37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Empty Sella Syndrome	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin			C				Not Reported
	Metformin			C				Not Reported
	Oxycodone			C				Not Reported

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09-Jun-2020	17876309	DIRECT	Y	OT			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir		Y		S	Intravenous drip	Other Frequency:5 Day Treatment;	5 DAY	Gilead
	Atorvastatin 10mg				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17877925	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470627		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17877930	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0470607		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fluid Overload; Hypotension	Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Convalescent Plasma				C		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17879118	DIRECT	Y	OT			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Blood Magnesium Increased;	Remdesivir				S				Not Reported
	Resmedivir				C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17879136	DIRECT	Y	HO			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Creatinine Renal Clearance Decreased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)		1 HR	Gilead
	Metronidazole			C		Not Reported		
	Vancomycin			C		Not Reported		
	Cefepime			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17879147	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Bilirubin Increased; Blood Lactate Dehydrogenase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Tocilizumab			C		Not Reported		
	Doxycycline			C		Not Reported		
	Rocephin			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17879156	DIRECT	Y	OT			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Hallucination; Hallucination, Auditory; Suicidal Ideation	Remdesivir			S	Intravenous drip			Gilead
	Benzonatate (Tessalon Perles)			C		Not Reported		
	Dextromethorphan			C		Not Reported		
	Ceftriaxone			C		Not Reported		
	Doxycycline			C		Not Reported		
	Acetaminophen			C		Not Reported		
	Chlorhexidine Oral			C		Not Reported		
	Enoxaparin			C		Not Reported		
	Labetolol			C		Not Reported		
	Guaifensin Ac			C		Not Reported		

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Nifedipine	C	Not Reported
Norco 5-325	C	Not Reported
Heparin Porcine	C	Not Reported
Ondansetron	C	Not Reported

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09-Jun-2020	17879174	DIRECT	Y	DE			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity; Nephropathy Toxic	Remdesivir	Y		S	Intravenous bolus	Other Frequency:X 1;		Gilead
	Aspirin 81mg			C				Not Reported
	Atorvastatin 40mg			C				Not Reported
	Cefepime 2g			C				Not Reported
	Chlorhexidine Mouthwash			C				Not Reported
	Clopidigrel 75mg			C				Not Reported
	Dexamethasone 20mg			C				Not Reported
	Enoxiparin 40mg			C				Not Reported
	Famotidine 20mg			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular			C				Not Reported
	Levofloxacin 750mg			C				Not Reported
	Methylprednisolone 40mg			C				Not Reported
	Vancomycin			C				Not Reported
	Aceaminophen 650mg			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Phenylephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
Midazolam Drip			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17879183	DIRECT	Y	LT			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17879308	DIRECT	Y	OT			61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17818539	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468282		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Oxcarbazepine			C		Unk	Not Reported		
	Amlodipine			C		Unk	Not Reported		
	Enoxaparin			C		Unk	Not Reported		
	Famotidine			C		Unk	Not Reported		
	Insulin Lispro			C		Unk	Not Reported		
	Levetiracetam			C		Unk	Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17818552	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0468312		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypoxia; Respiratory Failure; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Convalescent Plasma			C		Unk	Not Reported		
	Ondansetron			C		Not Reported			
	Pantoprazole			C		Not Reported			
	Phenylephrine			C		Not Reported			
	Potassium Phosphate Dibasic			C		Not Reported			

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Potassium Chloride	C		Not Reported
Prismasate Bk0/3.5	C		Not Reported
Prismasol	C		Not Reported
Propofol	C		Not Reported
Scopolamine Aminoxide	C		Not Reported
Sodium Chloride	C		Not Reported
Vancomycin	C	Unk	Not Reported
Vasopressin	C		Not Reported
Vitamin B12 Aaa	C		Not Reported
Zinc Sulfate	C		Not Reported
Cefepime	C		Not Reported
Chlorhexidine	C		Not Reported
Cisatracurium	C		Not Reported
Dexmedetomidine	C		Not Reported
Normosol	C		Not Reported
Enoxaparin	C		Not Reported
Epinephrine	C		Not Reported
Fentanyl	C		Not Reported
Heparin	C		Not Reported
Hydroxychloroquine	C		Not Reported
Iopamidol	C		Not Reported
Lactated Ringers	C		Not Reported
Lorazepam	C		Not Reported
Magnesium Sulfate	C		Not Reported
Melatonin	C		Not Reported
Metoprolol Tartrate	C		Not Reported
Morphine	C		Not Reported
Norepinephrine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880273	DIRECT	Y				57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Flushing; Infusion Related Reaction	Remdesivir Injection 100 Mg/20 MI Solution	Y		S	Intravenous drip			Gilead
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Cefepim 2gm			C				Not Reported
	Cholecalciferol 1000 Iu			C				Not Reported
	Enoxaparin 40 Mg			C				Not Reported

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Famotidine 20 Mg	C	Not Reported
Ferrous Sulfate 300 Mg	C	Not Reported
Levothyroxine 75 Mcg	C	Not Reported
Midodrine 5 Mg	C	Not Reported
Prednisone 5 Mg	C	Not Reported
Vancomycin 1gm	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880274	DIRECT	Y				36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)		7 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880275	DIRECT	Y	OT			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Remdesivir	Y		S	Intravenous bolus			Gilead
	Furosemide			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880279	DIRECT	Y				68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Levofloxacin			C				Not Reported

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10-Jun-2020	17880282	DIRECT	Y				93 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Hypovolaemia; Infusion Related Reaction	Remdesivir Ancef 4.5g			S C				Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880286	DIRECT	Y	HO			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880769	DIRECT	Y	OT			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir Bumex Famotidine Insulin Heparin Midodrine Zosyn Prednisone Vancomycin			S C C C C C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880876	DIRECT	Y				64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead	

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10-Jun-2020	17880882	DIRECT	Y	OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hypoxia; Renal Impairment	Remdesivir			S	Intravenous drip			Gilead
	Vancomycin Iv			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Fluconazole			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Zinc			C				Not Reported
	Ascorbic Acid			C				Not Reported
Vit D			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881236	DIRECT	Y				73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Kink; Product Dose Omission	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Lactobacillus Rhamnosus			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Lr Infusion			C				Not Reported
	Ns Bolus			C				Not Reported
	Melatonin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881241	DIRECT	Y	OT			21 YR	Male	USA

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Desmopressin			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydrocortisone Iv			C				Not Reported
	Levothyroxine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Acetaminophen			C				Not Reported
	Ibuprofen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881248	DIRECT	Y				74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881252	DIRECT	Y					Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881257	DIRECT	Y				73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Renal Impairment; Renal Tubular Injury	Remdesivir			S			3 DAY	Gilead
	Lisinopril			C				Not Reported
	Dexmedetomidine			C				Not Reported

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Famotidine	C	Not Reported
Hydralazine	C	Not Reported
Hydrocortisone Sod Succinate	C	Not Reported
Nicardipine	C	Not Reported
Potassium Chloride	C	Not Reported
Simvastatin	C	Not Reported
Sodium Chloride Infusion	C	Not Reported
Sodium Phosphate In D5w	C	Not Reported
Potassium Phosphate	C	Not Reported
Insulin Lispro	C	Not Reported
Insulin Glargine	C	Not Reported
Fentanyl	C	Not Reported
Cefepime	C	Not Reported
Ceftriaxone	C	Not Reported
Azithromycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881264	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Ischaemic Stroke; Nervous System Disorder	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead
	Covid-19 Convalescent Plasma			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Amiodarone Drip			C				Not Reported
	Vancomycin			C				Not Reported
	Zosyn			C				Not Reported
	Azithromycin			C				Not Reported
	Prophylactic Lovenox (40 Mg Sq Bid)			C				Not Reported
	Therapeutic Lovenox (80 Mg Sq Bid)			C				Not Reported
	Prophylactic Lovenox (40 Mg Sq Bid)			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881269	DIRECT	Y				64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Liver Function Test Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Azithromycin		C		Not Reported
	Ascorbic Acid		C		Not Reported
	Docusate		C		Not Reported
	Enoxaparin		C		Not Reported
	Furosemide		C		Not Reported
	Methylprednisolone		C		Not Reported
	Zinc Sulfate		C		Not Reported

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10-Jun-2020	17881367	EXPEDITED (15-DAY)			US-GILEAD-2020-0469487		16 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Product Storage Error	Remdesivir			S	Unknown			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17881967	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470949		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Shock	Remdesivir			S	Unknown			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882192	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0471151		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Increased; Death; Oxygen Consumption Increased; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Hydralazine			C		Unk		Not Reported	

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Imdur	C	Unk	Not Reported
Ketorolac	C	Unk	Not Reported
Levemir	C	Unk	Not Reported
Linezolid	C	Unk	Not Reported
Memantine	C	Unk	Not Reported
Novolog	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Potassium Phosphate Dibasic;Sodium Phosphate	C	Unk	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unk	Not Reported
Primidone	C	Unk	Not Reported
Pyridoxine	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Vitamin D [Colecalciferol]	C	Unk	Not Reported
Convalescent Plasma	C	Unk	Not Reported
Combinent Respimat	C	Unk	Not Reported
Amlodipine	C	Unk	Not Reported
Anastrozole	C	Unk	Not Reported
Atorvastatin	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Coreg	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Clopidogrel	C	Unk	Not Reported
Cyanocobalamin	C	Unk	Not Reported
Donepezil	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Ferrous Sulfate	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported

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Insulin	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Nitroglycerin	C	Unk	Not Reported

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10-Jun-2020	17882290	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0470081		23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin-Mip [Vancomycin]			C				Not Reported
	Enoxaparin			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported
	Bumetanide			C				Not Reported
	Clonazepam			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Dobutamine			C				Not Reported
	Fentanyl			C				Not Reported
	Methylprednisolone			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882668	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470292		28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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10-Jun-2020	17882688	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469668		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882689	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469669		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatotoxicity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882771	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469821		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia Supraventricular; Atrial Fibrillation; Atrial Flutter; Ejection Fraction; Heart Rate Increased; Hypotension; Ischaemia	Remdesivir			S	Intravenous (not otherwise specified)	200mg X1, 100mg X 1		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Daily X3		Gilead	
	Levofloxacin			S	Unknown			Not Reported	
	Levothyroxine			S	Unknown			Not Reported	
	Metronidazole Amiodarone			C C				Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882790	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0469839		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebrovascular Accident; Creatinine Renal Clearance Decreased	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Topamax	C			Not Reported
	Namenda	C			Not Reported
	Imdur	C			Not Reported
	Neurontin	C			Not Reported
	Breo Ellipta	C			Not Reported
	Pepcid Ac	C			Not Reported
	Aspirin (E.C.)	C			Not Reported
	Cardizem Cd	C			Not Reported
	Levetiracetam	C			Not Reported
	Combivent	C			Not Reported
	Heparin	C			Not Reported
	Dextrose	C			Not Reported
	Morphine	C			Not Reported
	Rocephin Biochemie	C			Not Reported
	Zithromax	C			Not Reported
	Nystatin	C			Not Reported
	Cardizem Cd	C			Not Reported
	Tylenol	C			Not Reported
	Eliquis	C			Not Reported
	Sodium Chloride	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Potassium Chloride	C			Not Reported
	Decadron [Dexamethasone]	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17883629	DIRECT	Y	OT			28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Myocarditis; Respiratory Failure; Transaminases Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead	
	Remdesivir			S	Intravenous bolus			Gilead	
	Convalescent Plasma			C				Not Reported	
	Tocilizumab			C				Not Reported	

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10-Jun-2020	17883633	DIRECT	Y	OT			46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17883639	DIRECT	Y				71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

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10-Jun-2020	17883645	DIRECT	Y	HO			50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Hypotension	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead	
	Vancomycin			C				Not Reported	
	Tenofovir			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17883718	DIRECT	Y				59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Condition	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead	

Aggravated

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17837784	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468230		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Inappropriate Schedule Of Product Administration; Product Use Issue	Remdesivir			S	Unknown	Unk		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17883340	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA148347			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi	
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Ascorbic Acid			C		Unk		Not Reported	
	Fenofibrate			C		Unk		Not Reported	
	Heparin			C		Unk		Not Reported	
	Methylprednisolone			C		Unk		Not Reported	
	Nph Insulin			C		Unk		Not Reported	
	Sodium Chloride			C		Unk		Not Reported	
	Sitagliptin			C		Unk		Not Reported	
	Midazolam			C		Unk		Not Reported	
Pantoprazole			C		Unk		Not Reported		
Humuline			C		Unk		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884813	DIRECT	Y	DE			44 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased; Tachycardia; Tachypnoea	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884818	DIRECT	Y				69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884825	DIRECT	Y				57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Benzonotate			C				Not Reported
	Bisacodyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Guafenesin			C				Not Reported
	Hydrocodone Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Orphenadrine			C				Not Reported
	Prednisone			C				Not Reported
Docusate Sennosides			C				Not Reported	
Sodium Chloride 0.9%			C				Not Reported	
Temazepam			C				Not Reported	

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11-Jun-2020	17884829	DIRECT	Y	DE			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:1100 Mg Total;		Gilead
	Albumin Human 5%			C				Not Reported
	Allopurinol			C				Not Reported
	Apixaban			C				Not Reported
	Atorvastatin			C				Not Reported
	Coreg			C				Not Reported
	Enoxaparin			C				Not Reported
	Duloxetine			C				Not Reported
	Ertapenem			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Insulin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Phenylephrine			C				Not Reported
	Pregabalin			C				Not Reported
	Propofol			C				Not Reported
	Sulfasalazine			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884835	DIRECT	Y	OT			36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Zosyn			S	Intravenous (not otherwise specified)			Unknown

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Zosyn C Not Reported
Vancomycin C Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884836	DIRECT	Y				58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884843	DIRECT	Y	OT			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Dyspnoea; Nausea; Oxygen Saturation Decreased; Pain; Vision Blurred; Vomiting	Remdesivir 100 Mg Vials	Y		S	Intravenous bolus			Gilead
	Doxycycline 100 Mg Po Bid			C				Not Reported
	Methylprednisolone 40 Mg Iv Bid			C				Not Reported
	Furosemide 40mg Iv Bid			C				Not Reported
	Hydroxyzine 25 Mg Poq6h Prn			C				Not Reported
	Venlafaxine 37.5mg Po Daily			C				Not Reported
	Enoxaparin 50 Mg Sq Q12h			C				Not Reported
	Trazodone 50 Mg Po Qpm			C				Not Reported
	Melatonin 9 Mg Po Qpm			C				Not Reported
	Folic Acid 1mg Po Daily			C				Not Reported
	Pantoprazole 40mg Bid			C				Not Reported
	Thiamine 100 Mg Iv Daily			C				Not Reported
	Albuterol 2 Puffs Qid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884920	DIRECT	Y	OT			26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Vomiting	Remdesivir			S	Intravenous drip			Not Reported

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Acetaminophen	C	Not Reported
Azithromycin	C	Not Reported
Enoxaparin	C	Not Reported
Hydromorphone	C	Not Reported
Prochlorperazine	C	Not Reported
Ceftriaxone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884929	DIRECT	Y	OT			36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Symbicort			C				Not Reported
	Enoxaparin			C				Not Reported
	Lamotrigine			C				Not Reported
	Melatonin			C				Not Reported
	Tramadol			C				Not Reported
	Trazodone			C				Not Reported
	Venlafaxine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884965	DIRECT	Y	DE			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Oxygen Saturation Decreased	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884971	DIRECT	Y	OT			9 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir	Y		S	Intravenous drip		3 DAY	Gilead

Aminotransferase
Increased; Hepatic
Enzyme Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884976	DIRECT	Y				63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Presyncope; Syncope; Therapy Cessation	Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884982	DIRECT	Y				79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Haemodialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Piperacillin-Tazobactam			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884990	DIRECT	Y	HO			55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Glomerular Filtration Rate Increased	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Tocilizumab 400 Mg Iv X1			C				Not Reported	
	Hydroxychloroquine 200 Mg Po Bid			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17884998	DIRECT	Y				76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Glomerular Filtration Rate Decreased Remdesivir Y S Intravenous bolus Other Frequency:One Time; Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17885006	DIRECT	Y	OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Azotaemia; Fluid Overload; Inflammation	Remdesivir Iv Solution	Y		S	Intravenous bolus			Gilead
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Enoxaparin			C				Not Reported
	Lispro			C				Not Reported
	Hydromorphone			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17885013	DIRECT	Y	OT			36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Ascorbic Acid 150mg Oral			C				Not Reported
	Enoxaparin 100mg Sc			C				Not Reported
	Zitrhromax 500mg Iv			C				Not Reported
	Famotidine 20mg Iv Daily			C				Not Reported
	Lidocaine 5% Patch			C				Not Reported
	Methylprednisolone 125mg Iv Q8h			C				Not Reported
	Thiamine 100mg Iv Daily			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Acetaminophen 650mg Oral Q6h Prn			C				Not Reported
	Cycylcobenzaprine 10mg Oral Tid Prn			C				Not Reported
	Morphine 1mg Iv Q8h Prn			C				Not Reported

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11-Jun-2020	17885020	DIRECT	Y	OT			47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17886243	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470876		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Insulin Regular Hm			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported

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Sodium Phosphate	C	Unk	Not Reported
Succinylcholine [Suxamethonium Chloride]	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887527	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470376		77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Musculoskeletal Stiffness	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Gabapentin			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Pantoprazole			C				Not Reported
	Rivaroxaban			C				Not Reported
	Ropinirole			C				Not Reported
	Tamsulosin			C				Not Reported
	Aspirin (E.C.)			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887565	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0470402		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Benzonatate			C				Not Reported
	Amlodipine			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported

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Lactated Ringers	C	Not Reported
Sodium Chloride & Dextrose	C	Not Reported
Ceftriaxone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887576	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470407		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Dyspnoea; Hypertension; Malaise	Remdesivir			S	Intravenous (not otherwise specified)	Unk, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887628	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470406		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887630	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470688		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Unasyn [Ampicillin Sodium;Sulbactam Sodium]			C				Not Reported
	Furosemide			C				Not Reported
	Keppra			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887633	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0470433		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17887638	EXPEDITED (15-DAY)			US-GILEAD-2020-0469605		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use Issue	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Enoxaparin				C		Unk		Not Reported
	Famotidine				C		Unk		Not Reported
	Insulin Glargine				C		Unk		Not Reported
	Insulin Lispro				C		Unk		Not Reported
	Insulin Regular Beef				C		Unk		Not Reported
	Fentanyl				C		Unk		Not Reported
	Propofol				C		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888175	DIRECT	Y	DE			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bilevel Positive Airway Pressure; Dysphagia; Palliative Care; Respiratory Failure	Remdesivir				S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir				S	Intravenous bolus			Gilead
	Convalescent Plasma				C				Not Reported

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11-Jun-2020	17888194	DIRECT	Y				80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Amiodarone			C				Not Reported	
	Atorvastatin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888195	DIRECT					52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888199	DIRECT	Y	OT			66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Depression; Fear; Hypotension; Lacrimation Increased	Remdesivir			S	Intravenous drip			Gilead	
	Diltiazem			C				Not Reported	
	Metoprolol			C				Not Reported	
	Cetirizine			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Insulin Detemir			C				Not Reported	
	Metformin			C				Not Reported	
	Novolog			C				Not Reported	
	Ropinirole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888200	DIRECT	Y	OT			67 YR	Male	USA

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pneumonia; Pneumonia Pseudomonal	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Precedex			C				Not Reported
	Meropenem			C				Not Reported
	Micafungin			C				Not Reported
	Azithromycin			C				Not Reported
	Vasopressin			C				Not Reported
Metronidazole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888215	DIRECT	Y				44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Renal Function Test Abnormal	Remdesivir			S	Intravenous (not otherwise specified)		6 DAY	Gilead
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888220	DIRECT	Y	DE			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Decreased; Dyspnoea; Gastrointestinal Haemorrhage; Haematocrit Decreased; Haemoglobin Decreased; Hyperkalaemia; Oxygen Saturation Decreased; Thrombocytopenia	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S				Gilead
	Convalenscent Plasma			C				Not Reported

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11-Jun-2020	17888224	DIRECT	Y	OT			40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Renal Tubular Necrosis	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888229	DIRECT	Y				56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Pressure Systolic Increased; Chest Discomfort; Nausea	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen 650 Mg Tablet			C				Not Reported
	Lidocaine 4% Transdermal Patch			C				Not Reported
	Enoxaparin 30 Mg Subcutaneous Injection			C				Not Reported
	Docusate 100 Mg Capsule			C				Not Reported
	Polyethylene Glycol 17g Powder			C				Not Reported
	Senna Tablet			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888251	DIRECT	Y	OT			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Dialysis; Pneumonia; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen Prn			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid (Intravenous)			C				Not Reported
	Azithromycin (Intravenous)			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported

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Guaifenesin/Dextromethorphan Prn (Got 1 Dose)	C	Not Reported
Hydrocodone/Acetaminophen Tablets Prn (Got 1 Dose)	C	Not Reported
Orphenadrine Er Tablets Prn (Got 1 Dose)	C	Not Reported
Zinc Sulfate Capsules	C	Not Reported
Cisatracurium	C	Not Reported
Fentanyl Intravenous Drip	C	Not Reported
Lubricant Eye Ointment	C	Not Reported
Lorazepam Prn	C	Not Reported
Norepinephrine Intravenous Drip	C	Not Reported
Propofol Intravenous Drip	C	Not Reported
Succinylcholine (1 Dose)	C	Not Reported
Natural Tears Drops	C	Not Reported
Veruronium Prn (Got 1 Dose On 6/5)	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888256	DIRECT	Y	DS, LT			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888259	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888263	DIRECT	Y	OT			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Rash	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Enoxaparin 40 Mg	C		Not Reported
	Fluoxetine 20 Mg	C		Not Reported
	Propofol Infusion	C		Not Reported
	Fentanyl Infusion	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888265	DIRECT	Y	HO			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888269	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Amiodarone Iv			C				Not Reported
	Apixaban			C				Not Reported
	Diltiazem Iv			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Tocilizumab			C				Not Reported
	Heparin Iv			C				Not Reported
	Adenosine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888273	DIRECT	Y	OT			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Disseminated Intravascular Coagulation; Shock	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Succinylcholine	C		Not Reported
	Fentanyl	C		Not Reported
	Norepinephrine	C		Not Reported
	Cisatracurium	C		Not Reported
	Propofol	C		Not Reported
	Ketamine	C		Not Reported
	Azithromycin	C		Not Reported
	Ceftriaxone	C		Not Reported
	Epoprostenol	C		Not Reported
	Famotidine	C		Not Reported
	Heparin	C		Not Reported
	Insulin Lispro	C		Not Reported
	Pericolace	C		Not Reported
	Vancomycin	C		Not Reported
	Insulin Regular Human	C		Not Reported
	Midazolam	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888277	DIRECT	Y	DE			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration	Remdesivir Treatment Under Emergency Use Authorization (Eua)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17888314	DIRECT	Y	OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

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12-Jun-2020	17873144	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470616		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Epistaxis; Hypotension; Pulseless Electrical Activity; Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Rivaroxaban			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17889442	DIRECT	Y	DE			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17889551	DIRECT	Y	HO			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once - Loading Dos;		Gilead	
	Actemra	Y		S				Genentech	
	Zosyn			C				Not Reported	
	Vancomycin			C				Not Reported	
	Thiamine			C				Not Reported	
	Hydrocortisone			C				Not Reported	
	Synthroid			C				Not Reported	
	Versed			C				Not Reported	
	Pepcid			C				Not Reported	
	Insulin			C				Not Reported	
	Aspirin			C				Not Reported	
	Calcium Gluconate			C				Not Reported	
	Albumin			C				Not Reported	

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Heparin	C	Not Reported
Fentanyl	C	Not Reported
Amiodarone	C	Not Reported
Epinephrine	C	Not Reported
Milrinone	C	Not Reported
Norepinephrine	C	Not Reported
Vasopressin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17889554	DIRECT	Y	DE			91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; General Physical Health Deterioration	Remdesivir			S				Gilead
	Dexamethasone 20 Mg Lv Daily			C				Not Reported
	Insulin			C				Not Reported
	Lorazepam 0.5 Mg Le1			C				Not Reported
	Metoprolol 2.5 Mg Lv X1			C				Not Reported
	Metoprolol 2.5 Mg Q6h Iv			C				Not Reported
	Nitroglycerin 0.4 Mg/Hr Patch Daily			C				Not Reported
	Protonix 40 Mg Lv Q12h			C				Not Reported
	Hydromorphone			C				Not Reported
	Bicarb 8.4% Continuous Infusion			C				Not Reported
Morphine 1 Mg Lv Q4h Pn			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17889580	DIRECT	Y	OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Kidney Injury; Ischaemic Hepatitis	Remdesivir			S				Gilead
	Selinexor Vs. Placebo			C				Not Reported
	Acetaminophen			C				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17889585	DIRECT	Y	OT			33 YR	Female	USA

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Angioedema; Dyspnoea; Ear Pruritus; Eye Irritation; Eye Pruritus; Throat Irritation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Apixaban			C		Not Reported		
	Montelukast			C		Not Reported		
	Guaifenesin			C		Not Reported		
	Pantoprazole			C		Not Reported		
	Fluticasone-Vilanterol			C		Not Reported		
	Acetaminophen			C		Not Reported		
	Insulin Lispro			C		Not Reported		
	Melatonin			C		Not Reported		
	Zinc Sulfate			C		Not Reported		
	Vitamin C			C		Not Reported		
	Vitamin D			C		Not Reported		
	Albuterol-Ipratropium			C		Not Reported		
	Insulin Glargine			C		Not Reported		
Methylprednisone			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17889591	DIRECT	Y				45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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12-Jun-2020	17889595	DIRECT	Y				68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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12-Jun-2020	17889600	DIRECT	Y				61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error; Product Dose Omission	Remdesivir			S	Intravenous (not otherwise specified)		10 DAY	Gilead	

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12-Jun-2020	17889785	DIRECT	Y	OT			41 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Chills; Dyspnoea; Hypertension; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip		1 HR	Gilead	
	Acetaminophen			C				Not Reported	

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12-Jun-2020	17892601	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0471143		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Endotracheal Intubation; Liver Function Test Increased; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Bupropion			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Azithromycin			C				Not Reported	
	Benzocaine-Menthol			C				Not Reported	
	Bisacodyl			C				Not Reported	
	Calcium Carbonate			C				Not Reported	
	Diphenhydramine			C				Not Reported	

Enoxaparin [Enoxaparin Sodium]	C	Not Reported
Famotidine	C	Not Reported
Fentanyl	C	Not Reported
Guaifenesin	C	Not Reported
Hydromorphone	C	Not Reported
Melatonin	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Nystatin	C	Not Reported
Ondansetron	C	Not Reported
Polyethylene Glycol [Macrogol]	C	Not Reported
Potassium Bicarbonate/Citric Acid	C	Not Reported
Propofol	C	Not Reported
Senna [Senna Alexandrina]	C	Not Reported
Sertraline	C	Not Reported
Temazepam	C	Not Reported
Trazodone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17892603	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470917		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Endotracheal Intubation; Heart Rate Decreased; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			C	Intravenous (not otherwise specified)	50-75mcg/Kg/Min		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17892604	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470948		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Acetaminophen			C				Not Reported

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Acetylcysteine	C	Not Reported
Albuterol [Salbutamol]	C	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Not Reported
Azithromycin	C	Not Reported
Ceftriaxone	C	Not Reported
D50w	C	Not Reported
Enoxaparin	C	Not Reported
Etomidate	C	Not Reported
Hydromorphone	C	Not Reported
Insulin Lispro	C	Not Reported
Ipratropium	C	Not Reported
Methylprednisolone	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Sodium Chloride	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17892626	EXPEDITED (15-DAY)			US-GILEAD-2020-0470372		71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Povidone Iodine			C				Not Reported
	Potassium Chloride			C				Not Reported
	Simvastatin			C				Not Reported
	Insulin Lispro			C				Not Reported

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12-Jun-2020	17892627	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470082		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Creatinine Renal Clearance Decreased	Remdesivir			S	Unknown			Gilead

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12-Jun-2020	17894663	DIRECT	Y				25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Warmth	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894689	DIRECT	Y				63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894693	DIRECT	Y	OT			34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894698	DIRECT	Y	OT			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894703	DIRECT	Y	OT			83 YR	Male	USA

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Acute Kidney Injury; Rhabdomyolysis	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

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12-Jun-2020	17894725	DIRECT	Y	OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894728	DIRECT		OT			46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity; Hypotension; Platelet Count Decreased; Pneumonia; Renal Impairment; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Acetylcysteine Inhalation And Po			C				Not Reported
	Ascorbic Acid (Intravenous)			C				Not Reported
	Aspirin Suppository X 1 Dose			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levalbuterol Inhalation			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Pantoprazole (Intravenous)			C				Not Reported
	Propofol Drip			C				Not Reported
	Normal Saline Drip			C				Not Reported
Zinc Sulfate			C				Not Reported	
Zosyn			C				Not Reported	

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12-Jun-2020	17894732	DIRECT	Y	DE			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Hypoxia; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894735	DIRECT	Y				6 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Packaging Confusion; Wrong Product Administered; Wrong Technique In Product Usage Process	Remdesivir			S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894738	DIRECT	Y	DE			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Peripheral Artery Aneurysm; Retroperitoneal Haemorrhage	Remdesivir			S	Intravenous bolus			Gilead	
	Aspirin Ec 81 Mg			C		Not Reported			
	Azithromycin 250 Mg			C		Not Reported			
	Carvedilol 3.125 Mg			C		Not Reported			
	Cefepime 2 G			C		Not Reported			
	Cotrimoxazole 400-80			C		Not Reported			
	Famotidine 40 Mg			C		Not Reported			
	Heparin 5000 Units			C		Not Reported			
	Isavuconazole 372 Mg			C		Not Reported			
	Prednisone 10 Mg			C		Not Reported			
Tacrolimus 1 Mg			C	Not Reported					
Valganciclovir 450 Mg			C	Not Reported					

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12-Jun-2020	17894743	DIRECT	Y	OT			17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Lactic Acidosis	Remdesivir Convalescent Covid Plasma Tocilizumab Vancomycin Ceftazidime Epinephrine Dopamine			S C C C C C C				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894748	DIRECT	Y	OT			77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894783	DIRECT	Y				73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Tocilizumab Atorvastatin 20 Mg Heparin 7500 Units Culturelle 1 Capsule Losartan 25 Mg Cefepime 2 G Iv Vancomycin Remdesivir			S C C C C C C S	Intravenous drip		1 HR	Genentech Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894789	DIRECT	Y	OT			82 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17895655	DIRECT	Y	LT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Hypotension; Melaena	Enoxaparin (Enoxaparin 40mg/0.4ml Inj)			S	Subcutaneous			Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17895735	DIRECT	Y	RI			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Erythema Multiforme; Extravasation; Peripheral Swelling; Swelling	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Other Frequency:Am;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17895854	DIRECT	Y	DE			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17896169	DIRECT	Y	HO, RI			82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hypoxia; Respiratory Failure	Remdesivir (Eua) (Remdesivir (Eua))	S	Intravenous (not otherwise specified)	Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17896172	DIRECT	Y				71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Hepatic Enzyme Increased; Rhabdomyolysis	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17896431	DIRECT	Y	RI			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Haemodialysis; Hypotension; Nephropathy Toxic; Renal Impairment; Urate Nephropathy	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2020	17894751	DIRECT	Y	OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip	Other Frequency:Load;		Gilead
	Guaifenesin/Dxm			C				Not Reported
	Apap 650mg			C				Not Reported
	Enoxaparin 40mg Bid			C				Not Reported
	Lactobacillus			C				Not Reported
	Levofloxacin 750mg Iv			C				Not Reported

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Kbicarb/Kcitate	C	
Ns	C	
Cefepime 1g	C	

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13-Jun-2020	17894755	DIRECT	Y				34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2020	17894759	DIRECT	Y				54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash; Rash Papular	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2020	17894773	DIRECT	Y				77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:200mg Then 100mg;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2020	17894794	DIRECT	Y	OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous drip			Gilead
	Vitamin D3 5000 Units			C				Not Reported
	Ceftriaxone 1 Gm			C				Not Reported
	Thiamine 100mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported

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Enoxaparin 40mg	C	Not Reported
Acetaminophen 650 Mg	C	Not Reported
Atorvastatin 500mg	C	Not Reported
Zinc Sulfate 220	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2020	17896437	DIRECT	Y	DE			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Treatment Failure	Remdesivir Solution 100 Mg Vial Y			S		Intravenous (not otherwise specified)		Gilead
	Remdesivir Solution 100 Mg Vial Y			S		Intravenous (not otherwise specified)		Gilead
	Carboxymethylcellulose			C				Not Reported
	Chlorhexidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fluconazole			C				Not Reported
	Furosemide			C				Not Reported
	Lipid (Smolflpid)			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported
	Mupirocin			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported
	White Petrolatum-Mineral Oil Eye Ointment			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17818858	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0468531		34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Erythema; Rash Macular; Rash Vesicular	Remdesivir			S	Unknown	Unk Mg		Gilead
	Remdesivir			S	Unknown	Unk Mg		Gilead
	Acetaminophen			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported

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Vancomycin	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Tocilizumab	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Albuterol [Salbutamol]	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17848044	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469503		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Cardiac Arrest; Glomerular Filtration Rate Decreased; Liver Function Test Increased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Norco			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Cholecalciferol			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Digoxin			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Heparin			C				Not Reported
	Insulin Glargine			C				Not Reported

Insulin Lispro	C	Not Reported
Famotidine	C	Not Reported
Fentanyl	C	Not Reported
Furosemide	C	Not Reported
Losartan	C	Not Reported
Meropenem	C	Not Reported
Metformin	C	Not Reported
Methylprednisolone	C	Not Reported
Metoprolol	C	Not Reported
Midazolam	C	Not Reported
Nitroglycerin	C	Not Reported
Norepinephrine	C	Not Reported
Nortriptyline	C	Not Reported
Phenylephrine	C	Not Reported
Propofol	C	Not Reported
Tocilizumab	C	Not Reported
Warfarin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17896456	DIRECT	Y	DE			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoeic Attack; Areflexia; Cardiac Arrest;	Remdesivir Solution 100 Mg Vial Y			S	Intravenous (not otherwise specified)			Gilead
Electrocardiogram St Segment Elevation; Hypotension; Pulse Absent; Pulseless	Remdesivir Solution 100 Mg Vial Y			S	Intravenous (not otherwise specified)			Gilead
Electrical Activity; Sinus Tachycardia; Tachycardia	Acetaminophen			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Albuterol Neb Soln			C				Not Reported
	Aspirin Ec			C				Not Reported
	Chlorhexidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Fluticasone Furoate-Vilanterol			C				Not Reported
	Furosemide			C				Not Reported
	Glycopyrrolate			C				Not Reported
	Insulin Aspart			C				Not Reported
	Lidocaine			C				Not Reported

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Mupirocin	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Senna-Docusate	C	Not Reported
Tamsulosin	C	Not Reported
Tiotropium	C	Not Reported
Tocilizumab	C	Not Reported

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15-Jun-2020	17896637	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0471302		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17896769	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471271		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Body Temperature Increased; Leukocytosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Pantoprazole			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lactated Ringers			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported
	Plasma			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Acetaminophen			C		650 Mg		Not Reported
	Ibuprofen			C				Not Reported
	Diphenhydramine			C				Not Reported

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15-Jun-2020	17898685	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469453		49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		90 Mcg		Not Reported
	Ascorbic Acid			C		500 Mg		Not Reported
	Benzonatate			C		100 Mg		Not Reported
	Dexamethasone			C		20 Mg		Not Reported
	Guaifenesin And Dextromethorphan			C		Unk		Not Reported
	Docusate			C		100 Mg		Not Reported
	Senna Plus [Docusate Sodium;Sennoside A+B]			C		50/8.6 Mg		Not Reported
	Enoxaparin			C		40 Mg		Not Reported
	Famotidine			C		20 Mg		Not Reported
	Guaifenesin			C		100/5		Not Reported
	Loperamide			C		2mg/15ml		Not Reported
	Ondansetron			C		4mg/2ml		Not Reported
	Zinc Sulfate			C		220 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899305	DIRECT		OT			83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen 500mg Po Q6h Prn			C				Not Reported
	Cefepime 1g Iv Daily			C				Not Reported

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Metronidazole 500mg Iv Q12h
Tocilizumab 400mg Iv Once

C
C

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899317	DIRECT	Y	LT			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Pneumonia; Respiratory Failure	Remdesivir Covid-19 Convalescent Plasma			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899326	DIRECT	Y	OT			91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Erythema; Infusion Site Irritation; Infusion Site Reaction; Pruritus	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899334	DIRECT	Y	HO			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Creatinine Renal Clearance Increased	Remdesivir Vancomycin			S C	Intravenous drip			Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899383	DIRECT	Y	DE			82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Drug Ineffective; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899394	DIRECT	Y	OT			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Enoxaparin 40mg Subcut Q24h			C				Not Reported
	Methylprednisolone 40mg Iv Q8h			C				Not Reported
	Tocilizumab 800mg Iv Once			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Vecuronium			C				Not Reported
Famotidine 20mg Po Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899404	DIRECT	Y	OT			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Ascorbic Acid 500mg Bid			C				Not Reported
	Aspirin 325mg Po Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1g Iv Bid			C				Not Reported
	Enoxaparin 40mg Subcut Bid			C				Not Reported
	Famotidine 40mg Po Bid			C				Not Reported
	Insulin Glargine 15 Units Qbedtime			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Methylprednisolone 40mg Iv Bid			C				Not Reported
	Zinc Sulfate 220mg Bid			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899416	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Bilirubin Conjugated Decreased; Hypotension; Pyrexia; Sepsis; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Albuterol Sulfate Hfa Inhaler			C				Not Reported
	Albuterol Nebulizer			C				Not Reported
	Epoprostenol-Floan			C				Not Reported
	Midazolam			C				Not Reported
	Insulin Regular			C				Not Reported
	Insulin Lispro			C				Not Reported
	Hydromorphone			C				Not Reported
	Heparin			C				Not Reported
	Ompرازole			C				Not Reported
	Meropenam			C				Not Reported
	Linezolid			C				Not Reported
	Norepinephrine			C				Not Reported
	Lipase-Protease-Amylase			C				Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Primasol Bgk 2/3.5 Replacement Solution			C				Not Reported
	Magnesium Sulfate, Potassium Chloride In Priskasate Bgk 4/2.5 Dialysis			C				Not Reported
	Aspirin			C				Not Reported
Lisinopril			C				Not Reported	
Sodium Phosphate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899424	DIRECT	Y	OT			91 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase	Remdesivir			S				Not Reported

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Increased	Ascorbic Acid	C	Not Reported
	Azithromycin	C	Not Reported
	Cefepime	C	Not Reported
	Ceftriaxone	C	Not Reported
	Cholecalciferol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899429	DIRECT	Y	OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Respiratory Failure	Remdesivir			S	Intravenous drip			Not Reported
	Albuterol-Ipratropium Inhalation Solution			C				Not Reported
	Amiodarone			C				Not Reported
	Cefepime 2g Iv Bid			C				Not Reported
	Docusate 100mg Po Bid			C				Not Reported
	Enoxaparin 40mg Subcut Bid			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Methylprednisolone 40mg Iv Q12h			C				Not Reported
	Senna 8.6mg Po Daily			C				Not Reported
	Tocilizumab 400mg Once Scheduled			C				Not Reported
	Vancomycin 1500mg Iv Daily			C				Not Reported
	Amiodarone Drip			C				Not Reported
	Dexmedetomidine Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported
	Vasopressin Drip			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899435	DIRECT	Y	OT			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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Albuterol-Ipratropium	C	Not Reported
Amlodipine	C	Not Reported
Ascorbic Acid	C	Not Reported
Atorvastatin	C	Not Reported
Ceftriaxone	C	Not Reported
Diltiazem	C	Not Reported
Gabapentin	C	Not Reported
Glimeperide	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Isosorbide Dinitrate	C	Not Reported
Methylprednisolone	C	Not Reported
Metoclopramide	C	Not Reported
Pantoprazole	C	Not Reported
Zinc	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899442	DIRECT	Y				56 YR	Transgender	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899447	DIRECT	Y	DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Continuous Haemodiafiltration	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amiodarone Bolus And Infusion			C				Not Reported
	Aspirin Chewable 81mg Daily			C				Not Reported
	Atorvastatin 80mg Qhs			C				Not Reported
	Atracurium Infusion			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Dobutamine Infusion			C				Not Reported
	Epoprostenol Continuous Neb			C				Not Reported
	Fentanyl Infusion			C				Not Reported

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Heparin Infusion	C	Not Reported
Vitamin C 1500mg Iv Q6h,	C	Not Reported
Thiamine 200mg Iv Q12h		
Hydrocortisone 50mg Iv Q6h	C	Not Reported
Midazolam Infusion	C	Not Reported
Norepinephrine Infusion	C	Not Reported
Phenylephrine Infusion	C	Not Reported
Propofol Infusion	C	Not Reported
Sodium Bicarbonate Infusion	C	Not Reported
Vasopressin Infusion	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899460	DIRECT	Y	OT			90 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899465	DIRECT	Y	DE			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17899470	DIRECT	Y				68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Ischaemic Hepatitis; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Dextromethorphan			C				Not Reported
	Enoxaparin			C				Not Reported
	Gabapentin			C				Not Reported

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Acetaminophen	C	Not Reported
Lactulose	C	Not Reported
Magnesium Oxide	C	Not Reported
Compazine	C	Not Reported
Cisatracurium	C	Not Reported

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15-Jun-2020	17899481	DIRECT	Y				78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		4 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900464	DIRECT	Y	DE			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip			Gilead
	Eculizumab			C				Not Reported
	Methylpredisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900481	DIRECT	N	OT			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Infection; Gastric Fluid Analysis Abnormal; Gastrointestinal Obstruction; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuteral			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Ampicillin-Sulbactam			C				Not Reported

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Apixaban	C	Not Reported
Atenolol	C	Not Reported
Atorvastatin	C	Not Reported
Calcium Gluconate	C	Not Reported
Chlorhexidine Gluconate	C	Not Reported
Cholecalciferol	C	Not Reported
Dexmedetomidine	C	Not Reported
Dextrose	C	Not Reported
Digoxin	C	Not Reported
Etomidate	C	Not Reported
Famotidine	C	Not Reported
Fentanyl	C	Not Reported
Glucagon	C	Not Reported
Glycopyrrolate	C	Not Reported
Heparin	C	Not Reported
Insulin Lispro Pen	C	Not Reported

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15-Jun-2020	17900482	DIRECT	Y	OT			39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Lip Oedema; Lip Swelling; Swollen Tongue; Tongue Oedema	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 2 Gm			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900484	DIRECT	Y	OT			37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900489	DIRECT	Y	LT			30 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900494	DIRECT	Y	DE			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead
	Propofol			C				Not Reported
	Morphine			C				Not Reported
	Lovenox			C				Not Reported
	Protonix			C				Not Reported
	Metoprolol			C				Not Reported
	Zithromax			C				Not Reported
	Ceftriaxone			C				Not Reported
	Norvasc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900498	DIRECT	N	DE			7 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead
	Rocephin			C				Not Reported
	Morphine			C				Not Reported
	Dopamine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Gabapentin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900502	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:200mg/D,100mg/D;	Gilead
	Azithromycin 500mg Iv Daily	C			Not Reported
	Cefepime 1g Iv Q8h	C			Not Reported
	Enoxaparin 40mg Subq Q24h	C			Not Reported
	Epoprostenol Continuous Neb	C			Not Reported
	Fentanyl Infusion	C			Not Reported
	Heparin Infusion	C			Not Reported
	Lantus 11 Units Qhs	C			Not Reported
	Insulin Lispro Sliding Scale	C			Not Reported
	Levothyroxine 88mcg Po Daily	C			Not Reported
	Midazolam Infusion	C			Not Reported
	Norepinephrine Infusion	C			Not Reported
	Pip/Tazo 4.5g Iv Q8h (Extended Infusion)	C			Not Reported
	Propofol Infusion	C			Not Reported
	Sodium Bicarbonate Infusion	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900505	DIRECT	Y	OT			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Enoxaparin 40mg Subq Qhs			C				Not Reported
	Paroxetine 40mg Daily			C				Not Reported
	Zolpidem 10mg Po Qhs Prn			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900509	DIRECT	Y	HO, OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous drip	Other Frequency:One		Gilead

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Aminotransferase
Increased; Blood Alkaline
Phosphatase Increased

Time;

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900514	DIRECT	Y				95 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Use Issue	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead	
	Azithromycin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Metoprolol Tartrate			C				Not Reported	
	Piperacillin / Tazobactam			C				Not Reported	
	Magnesium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900528	DIRECT	Y	DE			55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead	
	Norepinephrine			C				Not Reported	
	Sodium Bicarbononate			C				Not Reported	
	Humalog			C				Not Reported	
	Lantus			C				Not Reported	
	Zosyn			C				Not Reported	
	Morphine			C				Not Reported	
	Cathflo Activase			C				Not Reported	
	Atacarium			C				Not Reported	
	Morphine			C				Not Reported	
	Actemra			C				Not Reported	
	Metoprolol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900534	DIRECT	Y	DE			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death	Remdesivir	Y	S	Intravenous drip	2 DAY	Gilead
	Norepinephrine		C			Not Reported
	Protonix		C			Not Reported
	Morphine		C			Not Reported
	Propofol		C			Not Reported
	Bicarbonate		C			Not Reported
	Atorvastatin		C			Not Reported
	Midazolam		C			Not Reported
	Furosemide		C			Not Reported
	Rocephin		C			Not Reported
	Zithromax		C			Not Reported
	Lovenox		C			Not Reported
	Kionex		C			Not Reported
	Metoprolol		C			Not Reported
	Calcium Gluconate		C			Not Reported
	Lorazepam		C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17810056	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0467380		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Death; Oliguria	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 5 Mg/MI Qd		Gilead
	Zosyn			S				Not Reported
	Vancomycin			S				Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Succinylcholine Bromide			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Naloxone			C		Unk		Not Reported
	Piperacillin/Tazobactam			C		Unk		Not Reported
	Norepinephrine			C		90 Unk		Not Reported
	Epoprostenol			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported

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Bisacodyl Sandoz	C		Unk	Not Reported
Gabapentin	C		Unk	Not Reported
Insulin Lispro	C			Not Reported
Propofol	C		Unk	Not Reported
Senna Acutifolia	C		Unk	Not Reported
Furosemide [Furosemide Sodium]	C	Intravenous (not otherwise specified)	40 Mg, Once	Not Reported
Hydroxychloroquine	C		Unk	Not Reported
Enoxaparin	C		Unk	Not Reported
Heparin	C		Unk	Not Reported
Metolazone	C		10 Mg	Not Reported
Vasopressin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17837798	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468927		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	300 Mg, Total		Gilead
	Cefepime			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Methocarbamol			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

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Vancomycin	C	Unk	Not Reported
Vasopressin	C	Unk	Not Reported
Hydrocortisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17841756	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468849		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Zosyn			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Combivent			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Precedex			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported
	Seebri			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Lopressor			C		Unk		Not Reported
	Dulera			C		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17900566	DIRECT	Y				29 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17900583	DIRECT	Y				54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Pruritus	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17900630	DIRECT	Y				72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Skin Abrasion; Urticaria	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide			C		Not Reported		
	Potassium Chloride			C		Not Reported		
	Prinivil			C		Not Reported		
	Acetaminophen Prn			C		Not Reported		
	Enoxaparin			C		Not Reported		
	Azithromycin			C		Not Reported		
Ceftriaxone			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17900640	DIRECT	Y	OT			81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17901572	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471292		51 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypermagnesaemia	Remdesivir			S	Unknown	Unk		Gilead
	Tocilizumab			C	Unknown			Not Reported
	Ccp			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17901656	DIRECT	Y	OT			48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol Infusion			C			Not Reported	
	Pantoprazole Iv			C			Not Reported	
	Midazolam Infusion			C			Not Reported	
	Norepinephrine Infusion			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17901657	DIRECT	Y	DE			93 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Atrial Fibrillation; Cardio-Respiratory Arrest; Glomerular Filtration Rate Decreased; Pulmonary Embolism	Remdesivir Under Emergency Use Authorization (Eua)			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17901658	DIRECT	Y	DE			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Myocardial Infarction; Cardio-Respiratory Arrest	Remdesivir	S	Intravenous bolus	Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17901659	DIRECT	Y	OT			29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Benzonate			C				Not Reported
	Guaifenesin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Melatonin			C				Not Reported
	Pantoprazole			C				Not Reported
	Acetamnophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17901955	EXPEDITED (15-DAY)			US-GILEAD-2020-0472521		27 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17902266	EXPEDITED (15-DAY)			US-GILEAD-2020-0472466		79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17904983	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470945		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905097	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470652		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905302	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471308		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Unknown	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905508	DIRECT	Y	OT			45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Impairment	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Not Reported	
	Atorvastatin 10mg Po Qbedtime			C				Not Reported	
	Carvedilol 12.5mg Po Bid			C				Not Reported	
	Cefepime 2g Iv Q12h			C				Not Reported	
	Daptomycin 700mg Iv Q24h			C				Not Reported	
	Insulin Glargine 35 Units Subcut Bid			C				Not Reported	

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Insulin Lispro Sliding Scale	C	Not Reported
Linezolid 600mg Iv Q12h	C	Not Reported
Nifedipine Er 60mg Daily	C	Not Reported
Heparin Drip	C	Not Reported
Hydromorphone 1mg Prn	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905511	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Meperidine			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Labetalol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Tamsulosin			C				Not Reported
	Levetiracetam			C				Not Reported
	Finasteride			C				Not Reported
	Amlodipine			C				Not Reported
	Metronidazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Rivaroxaban			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Lorazepam			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Trazodone			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Acetaminophen			C				Not Reported
	Advil Pm			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905516	DIRECT	Y	OT			73 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:One Time;		Gilead
	Azithromycin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Methylprednisone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905521	DIRECT	Y	DE			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hepatic Enzyme Increased; Refusal Of Treatment By Patient; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Clindamycin			C				Not Reported
	Methylprednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905527	DIRECT	Y	OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Hot; Flushing; Rash; Rash Erythematous; Respiratory Disorder	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905531	DIRECT	Y	OT			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir Eua			S				Not Reported

Increased; Bilirubin
Conjugated Increased;
Blood Bilirubin Increased;
Hepatic Enzyme
Increased; Surgery;
Therapy Interrupted

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905542	DIRECT	Y	DE			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Hepatic Steatosis; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S		Intravenous (not otherwise specified)		Gilead
	Ceftriaxone			C				Not Reported
	Vancomycin			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
	Propofol			C				Not Reported
	Esomeprazole			C				Not Reported
	Acorbic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Solumedrol Taper Dose			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Propranolol			C				Not Reported
	Lasix Drip			C				Not Reported
	Heparin Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Midazolam Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Rocuronium			C				Not Reported
	Metopropol			C				Not Reported
	Acetaminophine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905554	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Glomerular Filtration Rate Decreased	Remdesivir	S	Intravenous drip	Not Reported
	Ascorbic Acid 500mg Po Bid	C		Not Reported
	Aspirin 81mg Po Daily	C		Not Reported
	Enoxaparin 40mg Subcut Q24h	C		Not Reported
	Famotidine 20mg Po Bid	C		Not Reported
	Tocilizumab 800mg Iv Once	C		Not Reported
	Fentanyl Drip	C		Not Reported
	Norepinephrine Drip	C		Not Reported
	Propofol Drip	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17905569	DIRECT	Y				47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Administration Site Extravasation; Infusion Site Pain; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Sodium Chloride 0.9%			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17826572	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0467950		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		400 Mg		Not Reported
	Heparin			C				Not Reported
	Enoxaparin			C				Not Reported
	Trimethobenzamide			C		200 Mg, Once		Not Reported
	Asa			C				Not Reported
	Insulin Lispro			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported
	Levothyroxine			C				Not Reported

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Ethacrynic Acid	C		Not Reported
Metoprolol	C	Unk	Not Reported
Tradipitant	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17831684	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0468502		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Pneumonia Viral; Renal Failure	Remdesivir			S	Unknown	200 Mg		Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Aztreonam			C				Not Reported
	Calcium Chloride			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Benadryl 24 D			C				Not Reported
	Famotidine			C				Not Reported
	Breo Ellipta			C				Not Reported
	Furosemide			C				Not Reported
	Hydrocortisone			C				Not Reported
	Isosorbide			C				Not Reported
	Labetalol			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Midazolam			C				Not Reported
	Singulair			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Kcl			C				Not Reported
	Rocuronium			C				Not Reported
	Verapamil			C				Not Reported
	Fentanyl			C				Not Reported
	Flolan			C				Not Reported
	Heparin			C				Not Reported
	Amiodarone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17835874	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468237		23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C	Oral	1000 Mg Q5h		Not Reported
	Dextromethorphan			C	Oral	30 Mg		Not Reported
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Ibuprofen			C	Oral	400 Mg		Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Prednisone			C				Not Reported
Albuterol Hfa			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907183	DIRECT	Y	HO, OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Gilead
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Tocilizumab			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Pantoprazole			C				Not Reported
	Albuterol			C				Not Reported
	Potassium Chloride			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907187	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lantus Insulin			C				Not Reported
	Lispro Insulin			C				Not Reported
	Regular Insulin			C				Not Reported
	Solu-Medrol			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Hydralazine			C				Not Reported
	0.5% Normal Saline			C				Not Reported
	D5 With Sodium Bicarbonate			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907202	DIRECT	Y	OT			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; General Physical Health Deterioration	Remdesivir Eua			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907208	DIRECT	Y	DE			75 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)		9 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907210	DIRECT	Y	OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip		Gilead	
	Remdesivir 200 Mg			C			Not Reported	
	Remdesivir 100 Mg			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907216	DIRECT	Y	DE			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19 Pneumonia; Diabetic Ketoacidosis; Hypoxia	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907224	DIRECT	Y				68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation; Peripheral Swelling	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907227	DIRECT	Y	DE			88 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Gilead
	Amlodipine 2.5 Mg Po Daily			C				Not Reported
	Cholecalciferol Tablet 1000 Units Po Daily			C				Not Reported
	Cyanocobalamin 1000 Mcg Po Daily			C				Not Reported
	Dexamethasone 10 Mg Lv Daily			C				Not Reported
	Enoxapan'N 40 Mg Iv Q12h			C				Not Reported
	Levothyroxine 112 Mcg Po Daily			C				Not Reported
	Hydromorphone Pca			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907232	DIRECT	Y	OT			39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead
	Aspirin 81 Mg Po Daily			C				Not Reported
	Cettriaxone 19 Iv Daily			C				Not Reported
	Chlorhexidine 0.12% Mouthwash 15ml			C				Not Reported
	Dexamethasone 6 Mg Lv Daily			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Furosemide 20 Mg Iv Q8h			C				Not Reported
	Metoclopramide 5 Mg Iv Q8h			C				Not Reported
	Mvi			C				Not Reported
	Senna Docusate Po Bid			C				Not Reported
	Vancomycin Lv			C				Not Reported
	Artificial Tears			C				Not Reported
	Dexmedetomidine Lv Cont Infusion			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Heparin Continue Infusion			C				Not Reported
	Insulin Continuous Infusion			C				Not Reported
	Midazolam Continuous Infusion			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907303	DIRECT	Y	DE			74 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir Captopril Furosemide			S C C				Gilead Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17907768	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir 0.7 Mg/MI	Y		S	Intravenous drip			Gilead
	Remdesivir 0.7 Mg/MI	Y		S		Intravenous drip		Gilead
	Atorvastatin			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lantus Insulin			C				Not Reported
	Lispro Insulin			C				Not Reported
	Regular Insulin			C				Not Reported
	Solu-Medrol			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Hydralazine			C				Not Reported
	0.5% Normal Saline			C				Not Reported
D5 With Sodium Bicarbonate			C				Not Reported	
Fentanyl Drip			C				Not Reported	
Midazolam			C				Not Reported	
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17908452	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472502		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk, Qd		Gilead
	Propofol			C		Unk		Not Reported

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Hydromorphone	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Docusate;Senna	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17908465	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472503		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Dreams; Hallucination; Suicidal Ideation	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Benzonatate			C		Unk		Not Reported
	Dextromethorphan			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Chlorhexidine			C	Oral	Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Labetalol			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Nifedipine			C		Unk		Not Reported
	Norco			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Ondansetron			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17908535	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0472755		68 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Unknown	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17908548	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472764			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased	Remdesivir			S	Unknown			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17908571	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472816		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Replacement Therapy	Remdesivir			S	Unknown			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910859	DIRECT	Y	OT			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910866	DIRECT	Y	DS			40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous drip			Gilead	
	Doxycycline			C				Not Reported	
	Azithromycin			C				Not Reported	

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Cefepime	C	Not Reported
Enoxaparin	C	Not Reported
Furosemide	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910870	DIRECT	Y				57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S	Intravenous bolus		1 DAY	Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910874	DIRECT		OT			29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910893	DIRECT	Y	OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemodialysis; Hypotension; Renal Impairment; Septic Shock	Remdesivir 5mg/ML Injection - Eua			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir 5mg/ML Injection - Eua			S	Intravenous drip			Gilead
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Gabapentin 100mg Po Daily			C				Not Reported
	Propofol Continuous Iv			C				Not Reported

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Phenyephrine Continuous Iv	C	Not Reported
Midazolam Continuous Iv	C	Not Reported
Aspirin 81mg Oral Daily	C	Not Reported
Insulin Lispro Sq Per Protocol	C	Not Reported
Acetaminophen 1g Iv Q6h Prn	C	Not Reported
Famotidine 20mg Iv Daily	C	Not Reported
Fentanyl Continuous Iv	C	Not Reported
Furosemide 40mg Iv X 1	C	Not Reported
Albumin 25% 25g Iv X 1	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910897	DIRECT	Y	OT			29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910903	DIRECT	Y	OT			39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Tylenol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Zofran			C				Not Reported
	Fentanyl			C				Not Reported
	Protonix			C				Not Reported
	Lovenox			C				Not Reported
	Methylprednisolone			C				Not Reported
	Robutussin			C				Not Reported
	Loperamide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910907	DIRECT	Y				47 YR	Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:X 1 Dose;		Gilead
	Convalescent Plasma			C				Not Reported
	Colace 100 Mg Po Daily			C				Not Reported
	Duloxetine 60 Mg Po Daily			C				Not Reported
	Heparin 5000 Units Subq Q 8 Hours			C				Not Reported
	Culturelle 1 Po Daily			C				Not Reported
	Zosyn 2.25 G Q 6 Hours			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910919	DIRECT	Y	OT			39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Critical Illness	Remdesivir			S				Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cisatracurium			C				Not Reported
	Vancomycin			C				Not Reported
	Rocuronium			C				Not Reported
	Propofol			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Pantoprazole			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Metoprolol			C				Not Reported
	Methylprednisolone			C				Not Reported
	Lorazepam			C				Not Reported
	Levofloxacin			C				Not Reported
	Hydromorphone			C				Not Reported
	Fentanyl			C				Not Reported
	Famotidine			C				Not Reported
	Cefepime			C				Not Reported
	Azithromycin			C				Not Reported

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17-Jun-2020	17910922	DIRECT	Y	DS			61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous drip			Gilead	
	Enoxapain			C				Not Reported	
	Cefepime			C				Not Reported	
	Vancomycin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910926	DIRECT	Y				81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Impairment	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead	
	Remdesivir			S			Intravenous drip		Gilead
	Albumin 25%			C				Not Reported	
	Unasyn 3gm			C				Not Reported	
	Cefepime 2gm			C				Not Reported	
	Digoxin 125mcg			C				Not Reported	
	Etomidate 20mg			C				Not Reported	
	Furosemide			C				Not Reported	
	Linezolid 600mg			C				Not Reported	
	Meropenem			C				Not Reported	
	Metolazone			C				Not Reported	
	Metoprolol			C				Not Reported	
	Metronidazole			C				Not Reported	
	Midazolam			C				Not Reported	
	Potassium Chloride			C				Not Reported	
	Succinylcholine			C				Not Reported	
	Morphine			C				Not Reported	
	Clinimix			C				Not Reported	
	Diltiazem Drip			C				Not Reported	
	Heparin Drip			C				Not Reported	
Norepinephrine Drip			C				Not Reported		
Propofol			C				Not Reported		

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17-Jun-2020	17910931	DIRECT	Y	LT, OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Continuous Haemodiafiltration; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17910936	DIRECT	Y	DS, HO, OT			55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anuria; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Ampicillin-Sulbactam Iv			C				Not Reported	
	Azithromycin Iv			C				Not Reported	
	Dexmedetomidine Infusion			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Fentanyl Infusion			C				Not Reported	
	Midazolam Infusion			C				Not Reported	
	Norepinephrine Infusion			C				Not Reported	
	Propofol Infusion			C				Not Reported	
	Rocuronium Injection			C				Not Reported	
	Tocilizumab Injection			C				Not Reported	
	Vancomycin Injection			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17911462	DIRECT	Y	DE			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Pulse Absent; Ventricular Tachycardia	Remdesivir Eua			S	Intravenous (not otherwise specified)		2 HR	Gilead	

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17-Jun-2020	17911526	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased	Remdesivir, 0.7mg/ML	Y		S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lantus Insulin			C				Not Reported
	Lispro Insulin			C				Not Reported
	Regular Insulin			C				Not Reported
	Solu-Medrol			C				Not Reported
	Pantoprazole			C				Not Reported
	Rocuronium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Hydralazine			C				Not Reported
	0.5% Normal Saline			C				Not Reported
	D5 With Sodium Bicarbonate			C				Not Reported
	Fentanyl Drip			C				Not Reported
Midazolam			C				Not Reported	
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17805184	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	US-GILEAD-2020- 0466961		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Hepatic Function Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Metformin			C				Not Reported
	Atorvastatin			C				Not Reported
	Atropine			C				Not Reported
	Ceftazidime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dextrose			C				Not Reported
	Midazolam			C				Not Reported
Morphine			C				Not Reported	

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Naloxone	C			Not Reported
Neostigmine	C			Not Reported
Norepinephrine	C			Not Reported
Pantoprazole	C			Not Reported
Rocuronium	C			Not Reported
Vancomycin	C			Not Reported
Vasopressin	C			Not Reported
Hydrocortisone	C	Intravenous (not otherwise specified)	100 Mg	Not Reported
Epinephrine	C			Not Reported
Fentanyl Abz	C			Not Reported
Lorazepam	C			Not Reported
Propofol	C			Not Reported
Flumazenil	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17835872	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468272		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Potassium			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

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18-Jun-2020	17842534	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468511		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Hypromellose			C				Not Reported
	Benzocaine			C				Not Reported
	Benzonatate			C				Not Reported
	Bisacodyl			C				Not Reported
	Ceterezol			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydrocodone Bitartrate And Acetaminophen			C				Not Reported
	Albuterol;Ipratropium			C				Not Reported
	Melatonin			C				Not Reported
	Morphine			C				Not Reported
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Simethicone			C				Not Reported
	Sodium Chloride			C				Not Reported
	Tramadol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17844495	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468824		26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

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Remdesivir	S	otherwise specified) Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Covalescent Plasma	C		Unk	Not Reported
Tocilizumab	C		Unk	Not Reported
Chlorhexidine	C			Not Reported
Olanzapine	C			Not Reported
Pantoprazole	C			Not Reported
Potassium Chloride	C			Not Reported
Acetaminophen	C			Not Reported
Hyaluronidase	C			Not Reported
Sodium Phosphate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17848043	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469167		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Escitalopram			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Polycarbophil			C		Unk		Not Reported

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Acetaminophen	C	Unk	Not Reported
Acetaminophen	C		Not Reported
Alprazolam	C	Unk	Not Reported

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18-Jun-2020	17868205	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469507		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pyrexia; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzotropine [Benzatropine]			C				Not Reported
	Carvedilol			C				Not Reported
	Divalproex			C				Not Reported
	Donepezil			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular Hm			C				Not Reported
	Ipratropium Bromide And Albuterol Sulfate			C				Not Reported
	Loratadine			C				Not Reported
	Methylprednisolone Sodium Succinate			C				Not Reported
	Montelukast			C				Not Reported
	Ibrutinib			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported
	Tamsulosin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Zosyn			C				Not Reported

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18-Jun-2020	17873038	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469296		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir				S	Intravenous (not otherwise specified)	Unk		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17910335	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472813		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Piperacillin & Tazobactam				C		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17910451	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473164		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Creatinine Renal Clearance Increased	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17910487	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473079		90 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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18-Jun-2020	17912038	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17912045	DIRECT	Y				62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Incorrect Dose Administered	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17912177	DIRECT	Y	OT			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Humulin N			C				Not Reported
	Humulin R			C				Not Reported
	Metoprolol Tartrate			C				Not Reported

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Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Ondansetron	C	Not Reported
Propofol	C	Not Reported
Vancomycin	C	Not Reported

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18-Jun-2020	17912699	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473172		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Enoxaparin			C				Not Reported
	Paroxetine			C				Not Reported
	Zolpidem			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17913269	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473152		40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Dyspnoea; Hypotension; Hypoxia	Remdesivir			S	Unknown	Unk		Gilead
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17913808	EXPEDITED (15-DAY)			US-GILEAD-2020-0471183		29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Malfunction	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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18-Jun-2020	17914120	EXPEDITED (15-DAY)			US-GILEAD-2020-0468293		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead	
	Acetaminophen			C		650 Mg, Prn		Not Reported	
	Aquaphor Healing			C	Topical	Unk		Not Reported	
	Cholecalciferol			C	Oral	1000 U		Not Reported	
	Citalopram			C		15 Mg, Qhs		Not Reported	
	Citalopram			C				Not Reported	
	Albuterol Hfa			C	Respiratory (inhalation)	2 Puffs		Not Reported	
	Trazodone			C	Oral	25 Mg		Not Reported	
	Dextrose & Sodium Chloride			C	Intravenous (not otherwise specified)	1000 MI		Not Reported	

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18-Jun-2020	17914752	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0472809		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Death; Electrocardiogram St Segment Elevation; Hypotension; Pulseless Electrical Activity; Shock; Sinus Tachycardia; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Acetaminophen			C		Unk		Not Reported	
	Albuterol [Salbutamol]			C		Unk		Not Reported	
	Aspirin Ec			C		Unk		Not Reported	
	Chlorhexidine			C		Unk		Not Reported	
	Chlorhexidine			C		Unk		Not Reported	
	Enoxaparin			C		40 Mg, Qd		Not Reported	

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Enoxaparin	C	50 Unk	Not Reported
Enoxaparin	C	100 Unk	Not Reported
Etomidate	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Fluticasone Furoate	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Glycopyrrolate [Glycopyrronium]	C	Unk	Not Reported
Insulin Aspart	C	Unk	Not Reported
Lidocaine	C	Unk	Not Reported
Mupirocin	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Senna [Senna Alexandrina]	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported
Tiotropium	C	Unk	Not Reported
Tocilizumab	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914772	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473016		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Eye Irritation; Pruritus	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Apixaban			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Guaifenesin			C				Not Reported
	Pantoprazole			C		Unk		Not Reported
	Fluticasone; Vilanterol			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported

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Melatonin	C	Unk	Not Reported
Zinc Sulfate	C	Unk	Not Reported
Vitamin C [Ascorbic Acid]	C	Unk	Not Reported
Vitamin D [Colecalciferol]	C	Unk	Not Reported
Albuterol;Ipratropium	C	Unk	Not Reported
Insulin Glargine	C	Unk	Not Reported
Methylprednisolone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914891	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473119		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914932	EXPEDITED (15-DAY)			US-GILEAD-2020-0472409		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914935	EXPEDITED (15-DAY)			US-GILEAD-2020-0472420		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914942	EXPEDITED (15-DAY)			US-GILEAD-2020-0472425		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914944	EXPEDITED (15-DAY)			US-GILEAD-2020-0472430		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914946	EXPEDITED (15-DAY)			US-GILEAD-2020-0472433		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914950	EXPEDITED (15-DAY)			US-GILEAD-2020-0472462		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914962	EXPEDITED (15-DAY)			US-GILEAD-2020-0472474		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914964	EXPEDITED (15-DAY)			US-GILEAD-2020-0472486		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914965	EXPEDITED (15-DAY)			US-GILEAD-2020-0472480		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914967	EXPEDITED (15-DAY)			US-GILEAD-2020-0472504		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914972	EXPEDITED (15-DAY)			US-GILEAD-2020-0472507		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915858	DIRECT	Y				69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Crestor			C				Not Reported
	Azithromycin			C				Not Reported
	Cisatracurium			C				Not Reported
	Propofol			C				Not Reported
	Terazosin			C				Not Reported
	Cefepime			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915865	DIRECT	Y	OT			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Dyspnoea; Hypersensitivity; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Acetaminophen			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915873	DIRECT	Y				42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir Under Emergency Use Authorization (Eua)	Y		S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915881	DIRECT	Y				41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Throat Tightness	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C			Not Reported	
	Enoxaparin			C			Not Reported	
	Amitryptiline			C			Not Reported	
	Amphetamine-Dextroamphetamine			C			Not Reported	
	Citalopram			C			Not Reported	
	Clonazepam			C			Not Reported	
	Montelukast			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915886	DIRECT	Y				36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915949	DIRECT	Y				66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Blood Creatine Increased; Dialysis	Remdesivir	Y	S	Intravenous drip	Gilead
	Coreg		C		Not Reported
	Lisinopril		C		Not Reported
	Propofol		C		Not Reported
	Fentanyl		C		Not Reported
	Enoxaparin		C		Not Reported
	Furosemide		C		Not Reported
	Zinc		C		Not Reported
	Azithromycin		C		Not Reported
	Ns		C		Not Reported
	Albumin 25%		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915955	DIRECT	Y	DE			84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Azotaemia; Hypotension; Lung Consolidation; Paralysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Heparin Drip			C				Not Reported
	Percedex Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Midazolam Drip			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
	Esomeprazole			C				Not Reported
	Ascobic Acid			C				Not Reported
	Seleniun			C				Not Reported
	Zinc			C				Not Reported
	Tpn			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915963	DIRECT	Y	DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Acute Respiratory Failure; Condition Aggravated;	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
Dialysis; Hypoxia; Lung Consolidation; Multiple Organ Dysfunction Syndrome; Pseudomonas Test Positive; Respiratory Acidosis	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Apixabn		C		Not Reported
	Heparin		C		Not Reported
	Docusate		C		Not Reported
	Humalog Sliding Scale		C		Not Reported
	Meropenem		C		Not Reported
	Seroquel		C		Not Reported
	Vancomycin		C		Not Reported
	Zinc Sulfate		C		Not Reported
	Ascobic Acid		C		Not Reported
	Fentanyl		C		Not Reported
	Propofol		C		Not Reported
	Ativan		C		Not Reported
	Selenium		C		Not Reported
	Versed		C		Not Reported
	Norepineohrine		C		Not Reported
	Rocuronium		C		Not Reported
	Cefepime		C		Not Reported
	Vitamin D3		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915988	DIRECT	Y				43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Macular	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17915997	DIRECT	Y				65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Remdesivir	Y		S	Intravenous drip			Gilead

Glomerular Filtration Rate
Decreased; Renal
Impairment; Respiratory
Failure; Septic Shock

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17916329	DIRECT	Y	OT			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir Injection 100 Mg/Vial Y			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Injection 100 Mg/Vial Y			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Brimonidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Lantus Insulin			C				Not Reported
	Humalog Insulin			C				Not Reported
	Latanoprost			C				Not Reported
	Solu-Medrol			C				Not Reported
	Oseltamivir			C				Not Reported
	Zosyn			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Tamsulosin			C				Not Reported
	Ziprasidone			C				Not Reported
	Hydralazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17847986	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469172		92 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Ativan			C				Not Reported

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Morphine	C	Not Reported
Glycopyrrolate [Glycopyrronium Bromide]	C	Not Reported
Hydromorphone	C	Not Reported
Unasyn Im/Iv	C	Not Reported
Haldol Decan	C	Not Reported
Heparin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17868197	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469457		49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Dehydration; Hypotension; Syncope	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Tussionex [Hydrocodone;Phenyltoloxamine]			C				Not Reported
	Solu-Medrol			C		Unk		Not Reported
	Sodium Chloride 0.9%			C				Not Reported
	Thiamine			C		Unk		Not Reported
	Zinc Sulfate [Zinc Sulfate Monohydrate]			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Mupirocin			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17901688	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0471284		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypermagnesaemia	Remdesivir			S	Unknown	Unk		Gilead	
	Remdesivir			S				Gilead	
	Lasix [Furosemide Sodium]			C				Not Reported	
	Ccp			C				Not Reported	
	Tocilizumab Recombinant			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17916163	DIRECT	Y	HO			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:lv		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17916168	DIRECT	Y	HO			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Urea Increased; Hepatic Enzyme Increased; Respiratory Disorder	Remdesivir (Eua) (Remdesivir (Eua))			S		Other Route:lv		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17916319	DIRECT	Y				46 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia; Nausea	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17916363	DIRECT	Y				59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Renal Disorder	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17916633	DIRECT	Y				54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
	Acetaminophen			C				Not Reported	
	Albuterol Hfa			C				Not Reported	
	Ascorbic Acid 500 Mg			C				Not Reported	
	Benzonatate 100 Mg			C				Not Reported	
	Dextromethorphan-Guaifenesin 10-100			C				Not Reported	
	Enoxaparin 40 Mg			C				Not Reported	
	Metformin 1000 Mg			C				Not Reported	
	Tocilizumab 400 Mg			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Levothyroxine 75 Mcg			C				Not Reported	
	Oxymetazoline Nasal Spray			C				Not Reported	
	Zinc Sulfate 220 Mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17917085	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473734		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Kidney Injury; Bilirubin Conjugated Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Sodium Phosphate	C			Not Reported
	Lisinopril	C			Not Reported
	Aspirin (E.C.)	C			Not Reported
	Magnesium Sulfate;Potassium Chloride	C			Not Reported
	Primasol	C			Not Reported
	Rocuronium	C			Not Reported
	Propofol	C			Not Reported
	Lipase	C			Not Reported
	Norepinephrine	C			Not Reported
	Linezolid	C			Not Reported
	Meropenem	C			Not Reported
	Ompرازole	C			Not Reported
	Heparin	C			Not Reported
	Hydromorphone	C			Not Reported
	Insulin Lispro	C			Not Reported
	Insulin Regular Beef	C			Not Reported
	Midazolam	C			Not Reported
	Epoprostenol [Epoprostenol Sodium]	C			Not Reported
	Albuterol Sulfate Hfa	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17918257	EXPEDITED (15-DAY)			US-GILEAD-2020- 0472481		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17918557	EXPEDITED (15-DAY)		OT	US-GILEAD-2020- 0468535		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Aspartate Aminotransferase Increased; Gastrointestinal Haemorrhage; Haematochezia	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Hydromorphone	C			Not Reported
	Acetaminophen	C			Not Reported
	Zofran [Ondansetron]	C			Not Reported
	Vitamin D3	C			Not Reported
	Titalac [Calcium Carbonate]	C			Not Reported
	Seroquel	C			Not Reported
	Calcium Gluconate	C			Not Reported
	Lasix [Furosemide]	C			Not Reported
	Lovenox [Enoxaparin Sodium]	C			Not Reported
	Miralax	C			Not Reported
	Benadryl	C			Not Reported
	Levophed	C			Not Reported
	Magnesium Sulfate	C			Not Reported
	Potassium Chloride	C			Not Reported
	Clozaril	C			Not Reported
	Propofol	C			Not Reported
	Amidate [Etomidate]	C			Not Reported
	Quelicin	C			Not Reported
	Fentanyl	C			Not Reported
	Versed	C			Not Reported
	Humulin	C			Not Reported
	Humalog	C			Not Reported
	Ancef [Ceftriaxone Sodium]	C			Not Reported
	Protonix [Omeprazole]	C			Not Reported
	Flagyl [Metronidazole]	C			Not Reported
	Rocephin [Ceftriaxone]	C			Not Reported
	Vancomycin	C			Not Reported
	Zenpep	C			Not Reported
	Prilosec [Omeprazole]	C			Not Reported
	Potassium Bicarbonate	C			Not Reported
	Zemuron	C			Not Reported
	Convalescent Plasma	C		Unk	Not Reported
	Levaquin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919219	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473354		76 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Creatinine Renal Clearance Decreased; Death; Renal Failure	Remdesivir			S	Unknown			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919225	EXPEDITED (15-DAY)			US-GILEAD-2020-0473117		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919515	EXPEDITED (15-DAY)			US-GILEAD-2020-0473064		5 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Product Dosage Form Administered; Off Label Use	Remdesivir			S	Intravenous (not otherwise specified)	2.5 Mg/Kg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919730	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473961		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919777	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473916		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919795	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473915		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921943	DIRECT	Y	HO			27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Liver Function Test Increased; Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir Via Eua			S	Intravenous bolus			Gilead
	Piperacillin-Tazobactam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921949	DIRECT	Y	DE			53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Vancomycon			C				Not Reported
	Omnipaque 350 Mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921951	DIRECT	Y	OT			35 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Cessation; Transaminases Increased	Remdesivir Dexamethasone			S C				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921956	DIRECT	Y	DE			81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palliative Care	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921960	DIRECT	Y	DE			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; General Physical Health Deterioration; Rhabdomyolysis	Remdesivir Remdesivir			S S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Other Frequency:1 Time Dose;		Gilead Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921964	DIRECT	Y	OT			67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatotoxicity; Liver Function Test Increased	Remdesivir Atorvastatin Cholecalciferol Enoxaparin Famotidine Hydrocortisone Piperacillin/Tazobactam Valproic Acid			S C C C C C C C	Intravenous bolus			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921966	DIRECT	Y	OT			37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations; Ventricular Tachycardia	Remdesivir For Emergency Use Authorization			S	Intravenous drip		2 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921972	DIRECT	Y	DE			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921986	DIRECT	Y	DE			95 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17921992	DIRECT	Y	OT			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Related Reaction; Pruritus; Rash	Remdesivir Guaifenesin Enoxaparin Convalescent Plasma			S C C C	Intravenous drip	Other Frequency:Once;	5 DAY	Gilead Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922004	DIRECT	Y	OT			38 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S				Gilead
	Clonazepam			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Midazolam			C				Not Reported
	Tocilizumab			C				Not Reported
Vecuronium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922013	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Faeces Discoloured	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922039	DIRECT	Y	DE			94 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922045	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Enoxaparin 110mg Sc Q12h			C				Not Reported
	Famotidine 20mg Iv Bid			C				Not Reported

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Creatinine Increased	Fentanyl Infusion	C	Not Reported
	Hydroxychloroquine	C	Not Reported
	Norepinephrine Infusion	C	Not Reported
	Piperacillin-Tazobactam	C	Not Reported
	Propofol Infusion	C	Not Reported
	Vancomycin Iv	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922077	DIRECT	Y	OT			37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Ceftriaxone 1g Ivpb			C				Not Reported
	Colchicine 0.6mg			C				Not Reported
	Probenacid 500mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Hydrocortisone 50mg			C				Not Reported
	Duoneb			C				Not Reported
	Ondansetron 4mg			C				Not Reported
	Promethazine 12.5mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922091	DIRECT	Y				21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Not Reported
	Enoxaparin			C				Not Reported
	Flovent Hfa			C				Not Reported
	Ondansetron			C				Not Reported
	Guiafenesin			C				Not Reported
	Senna-Docusate			C				Not Reported
	Albuterol Hfa			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922096	DIRECT					68 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir Remdesivir			S C				Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922100	DIRECT	Y	OT			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir Methylprednisolone Enoxparin Ceftriaxone Losartan Doxycycline Azithromycin			S C C C C C C				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17922121	DIRECT		OT				Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir Vancomycin Cefepime	Y		S C C			7 DAY	Gilead Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2020	17922104	DIRECT		OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

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20-Jun-2020	17922192	DIRECT	Y	OT			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2020	17922080	DIRECT	Y				37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia	Remdesivir Eua Solution			S	Intravenous drip			Gilead
	Enoxaparin 40 Mg Sq Daily			C				Not Reported
	Filgastim 480 Mcg Once			C				Not Reported
	Topiramate 50 Mg Qday			C				Not Reported
	Zinc Sulfate 220 Mg Qday			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2020	17922087	DIRECT	Y				92 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir Eua Solution			S	Intravenous drip			Gilead
	Aspirin 81 Mg Daily			C				Not Reported
	Atorvastatin 80 Mg			C				Not Reported
	Carvedilol 6.25 Mg			C				Not Reported
	Enoxaparin 40 Mg Sq			C				Not Reported
	Furosemide 40 Mg X 1			C				Not Reported
	Pantoprazole 40 Mg Daily			C				Not Reported
	Piperacillin/Tazobactam 2.25g Q6h			C				Not Reported
	Potassium Chloride 40 Meq Q4h			C				Not Reported
	Vancomycin 1 Gm X 1			C				Not Reported

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21-Jun-2020	17922109	DIRECT	Y	HO			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Condition Aggravated	Remdesivir Eua Solution			S	Intravenous drip			Gilead
	Baclofen 5 Mg Tid			C				Not Reported
	Gabapentin 300 Mg Qpm			C				Not Reported
	Heparin Sq Tid			C				Not Reported
	Midodrine 10 Mg Tid			C				Not Reported
	Piperacillin/Tazobactam 3.375g Q8h			C				Not Reported
	Vancomycin 1.25g Bid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2020	17922134	DIRECT	Y	OT			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Condition Aggravated	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2020	17922135	DIRECT	Y	DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once, Then 100mg;		Gilead
	Albuterol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Aspirin			C				Not Reported
	Lovenox			C				Not Reported
	Finasteride			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lopressor			C				Not Reported
	Oxycodone			C				Not Reported
Tamsulosin			C				Not Reported	

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21-Jun-2020	17922138	DIRECT	Y				42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Exposure During Pregnancy; Foetal Heart Rate Abnormal; Gestational Diabetes; High Risk Pregnancy; Premature Labour	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Zithmax			C				Not Reported
	Rocephin			C				Not Reported
	Lovenox			C				Not Reported
	Insuin Sliding Scale			C				Not Reported
	Labetadol			C				Not Reported
Prenatal Vitamin			C				Not Reported	
Ursodiol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2020	17922140	DIRECT	Y	OT			36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombocytopenia	Remdesivir			S	Intravenous bolus	Other Frequency:One Time;		Not Reported
	Lovenox			C				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17892600	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470905		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Generalised Oedema	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Simethicone			C				Not Reported
	Heparin			C				Not Reported

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22-Jun-2020	17922259	DIRECT	Y				71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Injection Site Extravasation	Remdesivir			S	Intravenous drip	Other Frequency:Once;	5 DAY	Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17923114	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473800		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Docusate			C		Unk	Not Reported		
	Enoxaparin			C		Unk	Not Reported		
	Famotidine			C		Unk	Not Reported		
	Lantus			C		Unk	Not Reported		
	Lispro Insulin			C		Unk	Not Reported		
	Insulin Regular Hm			C		Unk	Not Reported		
	Solu-Medrol			C		Unk	Not Reported		
	Pantoprazole			C		Unk	Not Reported		
	Rocuronium			C		Unk	Not Reported		
	Sodium Bicarbonate			C		Unk	Not Reported		
	Hydralazine			C		Unk	Not Reported		
	Normal Saline			C		Unk	Not Reported		
	D5 With Sodium Bicarbonate			C		Unk	Not Reported		
	Fentanyl			C		Unk	Not Reported		
Midazolam			C	Unk	Not Reported				
Norepinephrine			C	Unk	Not Reported				

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Propofol			C			Unk			Not Reported
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22-Jun-2020	17923759	DIRECT	Y	DE			67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir	Y		S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17923785	DIRECT	Y				53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Albuterol Hfa			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Robitussin Ac			C				Not Reported	
	Lovenox			C				Not Reported	
	Solumedrol			C				Not Reported	
	Lasix			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17923803	DIRECT	Y	OT			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead	
	Doxycycline			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17923809	DIRECT	Y	OT			71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Remdesivir	Y		S				Not Reported	

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22-Jun-2020	17923814	DIRECT	Y	OT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Haemodialysis; Urine Output Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Initial Dose;		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Atorvastatin Oral			C				Not Reported
	Fenobirarte Oral			C				Not Reported
	Dexamethasone Iv			C				Not Reported
	Norepinephrine Iv Infusion			C				Not Reported
	Midazolam Iv Infusion			C				Not Reported
	Hydromorphone Iv Infusion			C				Not Reported
	Rocuronium Iv Infusion			C				Not Reported
	Fentanyl Iv			C				Not Reported
	Propofol Infusion			C				Not Reported
	Famotidine Iv			C				Not Reported
	Acetaminophen Tablet			C				Not Reported
	Phenobarbital Inj Iv			C				Not Reported
	Potassium Bicarb-Citric Acid Tablet			C				Not Reported
	Insulin Regular Infusion			C				Not Reported
	Etomidate Iv			C				Not Reported
	Aspirin Tablet			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17923823	DIRECT	Y	DE			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Disease Progression	Remdesivir	Y		S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Bupropion			C				Not Reported
	Buspirone			C				Not Reported

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Ceftriaxone	C	Not Reported
Fentanyl	C	Not Reported
Hydrocortisone	C	Not Reported
Pantoprazole	C	Not Reported
Propofol	C	Not Reported
Norepinephrine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17923855	DIRECT	Y	OT			34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17924892	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0474386		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Benzonatate			C				Not Reported
	Dextromethorphan Hbr & Guaifenesin			C				Not Reported
	Enoxaparin			C				Not Reported
	Metformin			C				Not Reported
	Tocilizumab			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levothyroxine			C				Not Reported
	Oxymetazoline			C				Not Reported
	Zinc Sulfate			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17925092	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0473804		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Metronidazole			C				Not Reported
	Vancomycin			C		Unk		Not Reported
	Meperidine [Pethidine Hydrochloride]			C		Unk		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Labetalol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported
	Levetiracetam			C		Unk		Not Reported
	Finasteride			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Rivaroxaban			C		Unk		Not Reported
	Albuterol [Salbutamol Sulfate]			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Cyclobenzaprine			C		Unk		Not Reported
	Trazodone			C		Unk		Not Reported
Multivitamin [Vitamins Nos]			C		Unk		Not Reported	
Acetaminophen			C		Unk		Not Reported	
Advil Pm [Diphenhydramine Citrate;Ibuprofen]			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17925342	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0474408		38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Clonazepam			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Epoprostenol			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
Vecuronium			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928219	DIRECT	Y	OT			40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928222	DIRECT		DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Kidney Injury; Remdesivir S Intravenous drip Gilead
Cardiogenic Shock

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928224	DIRECT	Y	OT			53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928230	DIRECT	Y	HO, LT			86 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Furosemide 80mg Po Qam			C				Not Reported
	Lisinopril 40mg Po Qam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928233	DIRECT	Y	HO			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S				Gilead
	Dexamethasone 6mg Once			C				Not Reported
	Daily Po							
	Cefepime 1gm Every 24 Hours			C				Not Reported
	Iv							

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928237	DIRECT	Y				48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous bolus			Not Reported
	Rosuvastatin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Tocilizumab			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
Metoprolol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928253	DIRECT	Y	HO			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Culture Positive; Candida Test Positive	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			S	Intravenous (not otherwise specified)			Genentech
	Tocilizumab Dexamethasone 10mg			C C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928265	DIRECT					67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928273	DIRECT	Y	OT			47 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Ascorbic Acid 1000 Mg Po Bid			C				Not Reported
	Azithromycin 500 Mg Daily			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin 40 Mg Daily			C				Not Reported
	Iohexol			C				Not Reported
	Acetaminophen 650 Mg X1 Dose			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928290	DIRECT	Y	OT			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Pulmonary Function Test Decreased; Shock	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Amiodarone			C				Not Reported
	Apixiban			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Fuorsemide			C				Not Reported
	Propofol			C				Not Reported
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Phenylephrine			C				Not Reported
	Dexamethasone			C				Not Reported
	Vasopressin			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928301	DIRECT	Y				70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Albuterol Nebulizer			C				Not Reported
	Azithromycin			C				Not Reported

Cefepime	C	Not Reported
Ceftriaxone	C	Not Reported
Dexamethasone	C	Not Reported
Plasma-Lyte-A	C	Not Reported
Enoxaparin	C	Not Reported
Finasteride	C	Not Reported
Insulin (Long Acting, Short Acting, And Infusion)	C	Not Reported
Linezolid	C	Not Reported
Lorazepam	C	Not Reported
Olanzapine	C	Not Reported
Pantoprazole	C	Not Reported
Senna/Docusate	C	Not Reported
Tamsulosin	C	Not Reported
Potassium Chloride	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17928545	DIRECT	Y	RI			44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir 100 Mg			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17842544	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468274		34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Pressure Increased; Erythema; Heart Rate Increased; Hyperhidrosis; Nausea; Oxygen Saturation Decreased; Respiratory Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

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23-Jun-2020	17857266	EXPEDITED (15-DAY)			US-GILEAD-2020-0468544		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Issue	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17872272	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0469302		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	100 Mg		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Dopamine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
Propofol			C		Unk		Not Reported	
Hydromorphone			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17896650	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0472197		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Myocardial Infarction; Acute Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

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Syndrome; Acute Respiratory Failure; Arrhythmia; Cardiomyopathy; Death; Ischaemic Hepatitis; Respiratory Distress	Aspirin [Acetylsalicylic Acid;Ascorbic Acid]	C	Unknown	81 Mg	Not Reported
	Penicillin [Benzylpenicillin Potassium]	C			Not Reported
	Amiodarone	C	Intravenous bolus	Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Atracurium	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Dobutamine	C		Unk	Not Reported
	Epoprostenol	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
	Hydrocortisone	C		Unk	Not Reported
	Midazolam	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Phenylephrine	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Sodium Bicarbonate	C		Unk	Not Reported
	Vasopressin	C		Unk	Not Reported
	Famotidine	C		Unk	Not Reported
	Thiamine	C		Unk	Not Reported
	Insulin Lispro	C		Unk	Not Reported
	Metoprolol Tartrate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17930765	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474819		76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

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				otherwise specified)					
	Ceftriaxone		C			Unk			Not Reported
	Aspirin [Acetylsalicylic Acid]		C			Unk			Not Reported
	Lovenox [Enoxaparin Sodium]		C			Unk			Not Reported
	Finasteride		C			Unk			Not Reported
	Insulin Lispro		C			Unk			Not Reported
	Lopressor		C			Unk			Not Reported
	Oxycodone		C			Unk			Not Reported
	Tamsulosin		C			Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17930918	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474713		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Covid-19; Hepatic Enzyme Increased; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			C		Unk	Not Reported	
	Clindamycin			C		Unk	Not Reported	
	Methylprednisolone			C		Unk	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17930929	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472715		40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Lasix [Furosemide]			C		Not Reported		
	Tocilizumab			C		Not Reported		
	Solu-Medrol			C		Not Reported		
	Cefepime			C		Not Reported		
	Vancomycin			C		Not Reported		
	Montelukast			C		Not Reported		

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Atorvastatin	C	Not Reported
Azithromycin	C	Not Reported
Zinc Sulfate	C	Not Reported
Enoxaparin	C	Not Reported
Humalog	C	Not Reported
Pantoprazole	C	Not Reported
Meropenem	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17931108	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0474396		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk, Qd		Gilead
	Piperacillin & Tazobactam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17933002	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474849		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17933440	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0474844		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Oxygen Therapy	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Bupropion			C		Unk		Not Reported

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Buspirone	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Hydrocortisone	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Warfarin	C		Not Reported
Prednisone	C		Not Reported
Albuterol [Salbutamol]	C		Not Reported
Levaquin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934300	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934303	DIRECT	Y	OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Renal Impairment	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934307	DIRECT	Y				46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Gilead

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23-Jun-2020	17934311	DIRECT	Y	OT			69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Cessation; Transaminases Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934317	DIRECT	Y	HO			24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea; Liver Function Test Increased	Remdesivir, 100 Mg			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934320	DIRECT	Y	DE			81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Respiratory Acidosis	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Amlodipine			C				Not Reported	
	Omeprazole			C				Not Reported	
	Epoetin Alfa-Epbx			C				Not Reported	
	Cinacalcet			C				Not Reported	
	Sodium Bicarbonate			C				Not Reported	
	Ventolin			C				Not Reported	
	Allopurinol			C				Not Reported	
	Azithromycin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Actemra			C				Not Reported	
	Normal Saline Ivf			C				Not Reported	
	Convalescent Plasma			C				Not Reported	
	Apresoline			C				Not Reported	
	Atrovent			C				Not Reported	
	Bumetanide			C				Not Reported	
	Losartan			C				Not Reported	

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Apixaban	C	Not Reported
Lipitor	C	Not Reported
Lopressor	C	Not Reported
Enoxaparin	C	Not Reported
Potassium Chloride	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934326	DIRECT	Y				54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dialysis; Respiratory Failure	Remdesivir			S				Not Reported
	Chlorhexidine Topical			C				Not Reported
	Omeprazole			C				Not Reported
	Acetaminophen			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Heparin			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
Rocronium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934330	DIRECT	Y	DE			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospice Care	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Cefepime			C				Not Reported
	Chlorhexidine Topical			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Metronidzole			C				Not Reported
	Mupirocin (Nasal)			C				Not Reported
	Potassium Phosphate			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Norephrinepine			C				Not Reported
Potassium Chloride			C				Not Reported	

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23-Jun-2020	17934335	DIRECT	Y				52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted; Transaminases Increased	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934340	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Device Occlusion; Face Oedema; Haemodialysis; International Normalised Ratio Increased; Oxygen Saturation Abnormal; Renal Impairment; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg X 1, 100mg/D;		Gilead
	Acetaminophen 650mg Po Q6h Prn			C				Not Reported
	Albumin 5% 12.5g Iv Once			C				Not Reported
	Amlodipine 10mg Po Daily			C				Not Reported
	Aspirin Chew 81mg Po Daily			C				Not Reported
	Atorvastatin 20mg Po Qhs			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Cefepime 1g Iv Q24h			C				Not Reported
	Dexamethasone 6mg Iv Q24h			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Enoxaparin 40mg Subq Q24h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide 40mg And 80mg Iv			C				Not Reported
	Heparin 7500 Units Q8h			C				Not Reported
	Hydrochlorothiazide 12.5mg Po Daily			C				Not Reported
Lantus Subq Qhs			C				Not Reported	
Insulin Lispro Sliding Scale 5x/Day			C				Not Reported	
Levothyroxine 88mcg Po Daily			C				Not Reported	

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Propofol Infusion	C	Not Reported
Midazolam Infusion	C	Not Reported
Norepinephrine Infusion	C	Not Reported
Pip/Tazo	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934369	DIRECT	Y	OT			29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 2 Grams Q24			C				Not Reported
	Doxycycline 100 Mg Bid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934375	DIRECT	Y				26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934391	DIRECT	Y				56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Creatinine Increased; Dyspnoea; Glomerular Filtration Rate Decreased; Sars-Cov-2 Test Positive; Septic Shock	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Atracurium			C				Not Reported
	Senna/Colace			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lispro Insulin			C				Not Reported
	Oxycodone			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Vancomycin			C				Not Reported

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Heparin	C	Not Reported
Hydromorphone	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Vasopressin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934397	DIRECT	Y	DE			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Disease Progression; Pneumonia; Respiratory Failure; Respiratory Failure; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934404	DIRECT	Y	OT			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Sedation; Wheezing	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine			C				Not Reported
	Propofol			C				Not Reported
	Midazolam			C				Not Reported
	Insulin			C				Not Reported

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23-Jun-2020	17934408	DIRECT	Y	OT			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead	
	Ampicillin-Sulbactam			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Preparation H Cream			C				Not Reported	
	Tocilizumab			C				Not Reported	
	Vancomycin			C				Not Reported	
	Potassium Chloride			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934411	DIRECT	Y	DE			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Refusal Of Treatment By Patient; Refusal Of Treatment By Relative	Remdesivir			S				Not Reported	
	Ceftriaxone			C				Not Reported	
	Doxycycli Ne			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934416	DIRECT	Y	DE			78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934422	DIRECT	Y	OT			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934450	DIRECT	Y	OT			83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934468	DIRECT	Y	DE			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Sars-Cov-2 Test Positive	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934475	DIRECT	Y	DE			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardio- Respiratory Arrest; Haemodynamic Instability; Pulseless Electrical Activity	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Conalescent Plasma			C				Not Reported
	Hydroxychloroquine 400 Mg Po			C				Not Reported
	Azithromycin 500 Mg Iv X 1			C				Not Reported
	Azithromycin 250 Mg Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Methyprednisolone 40 Mg Iv Q12hr			C				Not Reported
	Thiamine 100 Mg Po Bid			C				Not Reported
	Zinc Sulfate 220 Mg Po Once Daily			C				Not Reported
	Vasopressin Iv 20 Units/MI			C				Not Reported
	Enoxaparin 70 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 70 Mg Sq Once Daily			C				Not Reported

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Cefepime 1 Gm Iv	C	Not Reported
Ascorbic Acid 1500 Mg Iv Q6hr	C	Not Reported
Ascorbic Acid 1500 Po Once Daily	C	Not Reported
Atorvastatin 80 Mg Po Once Daily	C	Not Reported
Amiodarone 450 Mg Iv Infusion	C	Not Reported
Amiodarone 200 Mg Po Once Daily	C	Not Reported
Aspirin 81 Mg Po Once Daily	C	Not Reported
B-12 1000 Mcg Sq Once Daily	C	Not Reported
Diltiazem 100 Mg Iv Infusion	C	Not Reported
Diltiazem 30 Mg Po Q8hr	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17848032	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468530		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bilirubin Conjugated Increased; Transaminases Increased	Remdesivir			S	Unknown	Unk		Gilead
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Hydromorphone			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Regular Hm			C				Not Reported
	Ketamine			C				Not Reported
	Lorazepam			C				Not Reported
	Norepinephrine			C				Not Reported
	Oxycodone			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol 3350			C				Not Reported
	Propofol			C				Not Reported
	Quetiapine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17873054	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470425		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Creatinine Increased; Cardiac Arrest; Hypoxia; Respiratory Failure; Vomiting	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17881349	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470063		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Product Preparation Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Bisacodyl			C		Unk		Not Reported
	Chlorhexidine			C	Oral	Unk, Bid		Not Reported
	Robitussin Dm			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Menthol [Levomenthol]			C		Unk		Not Reported
	Methocarbamol			C		Unk		Not Reported
	Bengay [Menthol;Methyl Salicylate]			C		Unk		Not Reported
	Solu-Medrol			C		Unk		Not Reported
	Bactroban [Mupirocin]			C		Unk		Not Reported
	Zofran [Ondansetron]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Miralax			C		Unk		Not Reported
	Ns			C		Unk		Not Reported
	Gabapentin			C				Not Reported
	Doxycycline			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

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Potassium Chloride	C	Unk	Not Reported
Convalescent Plasma	C	Unk	Not Reported
Cymbalta	C		Not Reported
Neurontin	C		Not Reported
Robaxin	C		Not Reported
Lasix [Furosemide]	C		Not Reported
Eliquis	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17890267	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470430		50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Connection Issue; Drug Monitoring Procedure Incorrectly Performed	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17892602	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470906		74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Mouth Haemorrhage; Respiratory Failure; Urine Output Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir Plasma			S				Gilead
				C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Heparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17914726	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473031		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Aspartate	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Aminotransferase Increased; Blood Bilirubin Increased; Disseminated Intravascular Coagulation; Shock	Remdesivir	S			Gilead
	Succinylcholine Bromide	C			Not Reported
	Fentanyl	C			Not Reported
	Norepinephrine	C			Not Reported
	Cisatracurium	C			Not Reported
	Propofol	C			Not Reported
	Ketamine	C			Not Reported
	Azithromycin	C			Not Reported
	Ceftriaxone	C			Not Reported
	Epoprostenol	C			Not Reported
	Famotidine	C			Not Reported
	Heparin	C			Not Reported
	Insulin Lispro	C			Not Reported
	Vancomycin	C			Not Reported
	Insulin Regular Hm	C			Not Reported
	Midazolam	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17932085	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472177			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Chills; Dyspnoea; Hypertension; Oxygen Saturation Decreased; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17935081	DIRECT	Y	HO			21 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Guaifenesin			C				Not Reported
	Heparin			C				Not Reported

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Hydrocodone-Chlorpheniramine			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17935114	DIRECT	Y				52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extra Dose Administered	Remdesivir Injection			S	Intravenous drip		30 MIN	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17935120	DIRECT	Y	OT			55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Das181			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17936231	DIRECT	Y	DE			72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoxia; Respiratory Failure	Remdesivir			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17936237	DIRECT	Y	OT			53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)		9 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17936244	DIRECT	Y				48 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Calcium Gluconate			C				Not Reported
	Chlorhexidine Topical			C				Not Reported
	Dextrose D50w			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Metoprolol			C				Not Reported
	Ocular Lubricant (Artificial Tears)			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Veletri			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17936250	DIRECT	Y	HO			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir 100 Mg/20ml	Y		S	Intravenous drip			Gilead
	Cefepime 1000 Mg			C				Not Reported
	Linezolid 600 Mg			C				Not Reported
	Dexamethasone 20 Mg			C				Not Reported
	Tocilizumab 600 Mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17936256	DIRECT	Y				88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

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Aminotransferase Increased	Vancomycin	C	Not Reported
	Piperacillin/Tazobactam	C	Not Reported
	Fentanyl	C	Not Reported
	Dexamethasone	C	Not Reported

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24-Jun-2020	17936262	DIRECT	Y				64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Increased; Haemodialysis; Respiratory Failure	Remdesivir	Y		S	Intravenous bolus		8 DAY	Gilead
	Atracurium			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Lispro			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Senna-Docusate			C				Not Reported
	Hydromorphone			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
Acetaminophen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17938926	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472220		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Hypotension; Supraventricular Extrasystoles; Ventricular Tachycardia	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17940295	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0474225		29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased Remdesivir S Unknown Unk Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17940954	DIRECT	Y	OT			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Solution For Injection	Y		S	Intravenous bolus			Gilead
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported
	Heparin			C				Not Reported
	Insulin Isophane			C				Not Reported
	Insulin Lispro			C				Not Reported
	Latanoprost			C				Not Reported
	Metronidazole			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Polyethylene Glycol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17940981	DIRECT	Y	DE			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17940998	DIRECT	Y	DE			36 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Hypoxia; Respiratory Acidosis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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Ascorbic Acid	C	Not Reported
Dexamethasone	C	Not Reported
Atorvastatin	C	Not Reported
Propofol	C	Not Reported
Cholecalciferol	C	Not Reported
Cisatracurium	C	Not Reported
Etomidate	C	Not Reported
Fentanyl	C	Not Reported
Ferrous Gluconate	C	Not Reported
Heparin	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Insulin Regular	C	Not Reported
Magnesium Sulfate	C	Not Reported
Midazolam	C	Not Reported
Zinc Sulfate	C	Not Reported
Pantoprazole	C	Not Reported
Pregabalin	C	Not Reported
Rocuronium	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Vitamin A	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941007	DIRECT	Y				25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use In Unapproved Therapeutic Environment	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Vancomycin			C				Not Reported
	Cafazolin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Methadone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941017	DIRECT	Y	OT			36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Dyspnoea; Platelet Count Increased	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;	Gilead
	Acetaminophen 325mg Po Q6h	C			Not Reported
	Pain 1-3, Fever				
	Benzonatate 100-200mg Po Q8h	C			Not Reported
	Enoxaparin 30mg Subq Q12h	C			Not Reported
	Ketorolac 15mg Iv Q6h Prn Pain 4-6	C			Not Reported
	Melatonin 6mg Po Qhs Prn	C			Not Reported
	Methylprednisolone 30mg Iv Q8h	C			Not Reported
	Methylprednisolone 30mg Iv Q12h	C			Not Reported
	Promethazine-Codeine 6.25/10/5ml Po Q4h Prn	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941055	DIRECT		OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941061	DIRECT	Y	OT			24 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941070	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Doxycycline	C		Not Reported
	Amlopine	C		Not Reported
	Carvedilol	C		Not Reported
	Tamsulosin	C		Not Reported
	Aspirin	C		Not Reported
	Enoxaparin	C		Not Reported
	Methylprednisolone	C		Not Reported
	Prednisone	C		Not Reported
	Atorvastatin	C		Not Reported
	Quetiapine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941080	DIRECT	Y	LT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Oxygen Saturation Decreased	Remdesivir			S	Intravenous bolus			Gilead
	Buspirone			C				Not Reported
	Midazolam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941088	DIRECT	Y	DE, LT			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Glomerular Filtration Rate Increased; Hypotension; Hypoxia; Right Ventricular Failure	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 325mg Pr Q4h			C				Not Reported
	Albumin 25g Iv Q6h			C				Not Reported
	Azithromycin 500mg Iv Q24h			C				Not Reported
	Senokot-S 8.6/50mg 2 Tabs Qhs			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Cisatracurium 10mg Iv Q1h Prn			C				Not Reported
	Vent Synchrony							
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Epinephrine Infusion			C				Not Reported
	Epoprostenol Continuous Neb			C				Not Reported

Fentanyl Infusion	C	Not Reported
Folic Acid 1mg Ng Daily	C	Not Reported
Heparin 5000 Units Subq Q8h	C	Not Reported
Duoneb Q4h	C	Not Reported
Linezolid 600mg Iv Q12h	C	Not Reported
Midazolam Infusion	C	Not Reported
Mvi With Minerals	C	Not Reported
Norepinephrine Infusion	C	Not Reported
Pantoprazole 40mg Iv Q24h	C	Not Reported
Phenylephrine Infusion	C	Not Reported
Pip/Tazo	C	Not Reported
Propofol Infusion	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941097	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Covid-19;	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
Fibrin D Dimer Increased;	Albumin 12.5-25 Grams Iv			C				Not Reported
Hypercalcaemia; Hypoxia;	Aspirin Ec 81mg Daily			C				Not Reported
Leukocytosis; Pneumonia;	Atorvastatin 40mg Qhs			C				Not Reported
Renal Failure;	Azithromycin 500mg Iv Q24h			C				Not Reported
Tachycardia; Tachypnoea	Ceftriaxone 1g Iv Daily			C				Not Reported
	Carvedilol 6.25mg Po Bid			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Precedex Infusion			C				Not Reported
	Enoxaparin 40mg Daily			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Insulin Lispro Sliding Scale 4x/Day			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Nicardipine Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Amiodarone Infusion			C				Not Reported
	Amiodarone 200mg Po Bid			C				Not Reported

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24-Jun-2020	17941108	DIRECT	Y	OT			54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead	
	Acetaminophen 650mg Po Q6h Pain 1-3, Fever			C				Not Reported	
	Azithromycin 500mg Iv Daily			C				Not Reported	
	Ceftriaxone 1g Iv Daily			C				Not Reported	
	Dexamethasone 6mg Po Daily			C				Not Reported	
	Enoxaparin 40mg Qhs And 30mg Bid			C				Not Reported	
	Robitussin Dm 5ml Po Q4h Prn			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941115	DIRECT	Y	HO			30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Nephropathy Toxic; Renal Impairment	Remdesivir Injection 100mg/20ml (5mg/MI)	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	Unknown	
	Tocilizumab Injections	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Not Reported	
	Mucomyst 20%			C				Not Reported	
	Maalox Plus			C				Not Reported	
	Ascorbic Acid 500mg Tablet			C				Not Reported	
	Aspirin 81mg			C				Not Reported	
	Atorvastatin 40mg Tablet			C				Not Reported	
	Chlorhexidine Oral Rinse			C				Not Reported	
	Dexamethasone 5mg Iv			C				Not Reported	
	Enoxaparin 35mg Sq			C				Not Reported	
	Etomidate 16mg Iv			C				Not Reported	
	Famotidine 20mg Iv			C				Not Reported	
	Melatonin 10mg Po			C				Not Reported	
	Zosyn 3.75mg Iv			C				Not Reported	
	Rocuronium 70mg Iv			C				Not Reported	
	Vancomycin 1250mg Iv			C				Not Reported	

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Zinc 220mg C Not Reported
Tocilizumab Injections S Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941156	DIRECT	Y	OT			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Alanine Aminotransferase Increased; Hypoxia; Oxygen Saturation Decreased; Pneumonia; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;		Gilead
	Acetaminophen 325mg Po Q6h Prn Pain 1-3			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv/Po Daily			C				Not Reported
	Precedex Infusion			C				Not Reported
	Diltiazem Infusion			C				Not Reported
	Enoxaparin 30mg Q12h Or 40mg Q24h			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine 20mg Iv Q4h Prn			C				Not Reported
	Lantus Qhs			C				Not Reported
	Insulin Lispro Sliding Scale 4x/D			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Pip/Tazo			C				Not Reported
	Propofol Infusion			C				Not Reported
	Tocilizumab 400mg Iv Once			C				Not Reported
	Vecuronium 10mg Iv Q1h Prn			C				Not Reported
	Vent Dyssynchrony							
Vit C 1500mg Q6h, B1 200mg Iv Q12h				C				Not Reported
Zinc Sulfate 220mg Po Daily				C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941256	DIRECT	Y	DE			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hypotension; Oxygen Saturation Decreased; Pulse Absent	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;	Gilead
	Acetaminophen 650mg Po Q4h	C			Not Reported
	Prn Pain 1-3, Fever				
	Aspirin Ec 81mg Daily	C			Not Reported
	Atorvastatin 20mg Qhs	C			Not Reported
	Azithromycin 500mg Iv Q24h	C			Not Reported
	Cefepime 1g Iv Q6h	C			Not Reported
	Ceftriaxone 1g Iv Q24h	C			Not Reported
	Dexamethasone 6mg Po Daily	C			Not Reported
	Precedex Infusion	C			Not Reported
	Enoxaparin 40mg Subq Daily	C			Not Reported
	Epinephrine Infusion	C			Not Reported
	Epoprostenol Continuous Neb	C			Not Reported
	Famotidine 20mg Iv Q12h	C			Not Reported
	Lantus 25-30 Units Qhs	C			Not Reported
	Insulin Lispro Sliding Scale 4x/D	C			Not Reported
	Metoclopramide 10mg +	C			Not Reported
	Diphenhydramine 25mg Iv Q6h				
	Metoprolol 5mg Iv Q4h Prn Sbp > 160 Or Hr>100	C			Not Reported
	Tocilizumab 400mg Iv Once	C			Not Reported
	Vitamin C 1g Q12h, Zinc 2250mg Po Q12h	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941265	DIRECT	Y	OT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Decreased; Hypotension	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941275	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir	Y		S	Intravenous drip			Gilead

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24-Jun-2020	17941286	DIRECT	Y	OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:200 Once,100x4days;		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17941803	DIRECT	Y	OT			50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir 100mg			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17818496	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0468321		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Acute Kidney Injury; Acute Respiratory Distress Syndrome; Covid-19 Pneumonia; Hypernatraemia; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Enoxaparin [Enoxaparin Sodium]			C		100 Mg		Not Reported	
	Insulin			C		Unk		Not Reported	
	Methylprednisolone			C		Unk		Not Reported	
	Lorazepam			C		Unk		Not Reported	
	Levophed			C		Unk		Not Reported	
	Dopamine			C		Unk		Not Reported	
Epinephrine Hydrochloride			C		Unk		Not Reported		

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Phenylephrine	C	Unk	Not Reported
Epoprostenol	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Piperacillin/Tazobactam	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Amiodarone	C	Unk	Not Reported
Ketamine [Ketamine Hydrochloride]	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Rocuronium	C	Unk	Not Reported
Tocilizumab	C	Intravenous (not otherwise specified) 800 Mg	Not Reported
Sodium Bicarbonate	C	Unk	Not Reported
Vasopressin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17881950	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470915		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Alprazolam			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Vitamin E [Tocopherol]			C		Unk		Not Reported
	Ondansetron			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Proscar			C		Unk		Not Reported
	Zestril			C		Unk		Not Reported
	Tamsulosin			C		Unk		Not Reported

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25-Jun-2020	17882692	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469672		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17892599	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470904		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased;	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
Cerebrovascular Accident;	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
Depressed Level Of Consciousness;	Remdesivir			S				Gilead	
Hemiparesis	Remdesivir Plasma			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17923215	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473789		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Aspirin (E.C.)			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Dextromethorphan			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Gabapentin			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Lactulose			C				Not Reported	
	Magnesium Oxide			C				Not Reported	
	Compazine [Prochlorperazine Maleate]			C				Not Reported	

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Cisatracurium			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17925226	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473427		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Death; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Azithromycin			C				Not Reported	
	Cefepime			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Epoprostenol			C				Not Reported	
	Fentanyl			C				Not Reported	
	Heparin			C				Not Reported	
	Lantus			C				Not Reported	
	Insulin Lispro			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Piperacillin/Tazobactam			C				Not Reported	
	Propofol			C				Not Reported	
	Sodium Bicarbonate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17940248	EXPEDITED (15-DAY)		LT, OT	US-SA-2020SA158391			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Bradycardia; Cytokine Storm; Disseminated Intravascular Coagulation; Haemoglobin Decreased; Hyperglycaemia; Hypertension; Iron Deficiency; Lactic	Lovenox			S	Subcutaneous	80 Mg		Sanofi	
	Remdesivir			S	Unknown	Unk		Not Reported	
	Fentanyl			C		Unk		Not Reported	
	Duloxetine			C		Unk		Not Reported	
	Gabapentin			C		Unk		Not Reported	
	Metoprolol			C		Unk		Not Reported	

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Acidosis; Liver Injury;	Midazolam	C	Unk	Not Reported
Pneumonia;	Levetiracetam	C	Unk	Not Reported
Retroperitoneal	Pantoprazole	C	Unk	Not Reported
Haematoma; Septic	Propofol	C	Unk	Not Reported
Shock; Shock	Otezla	C	Unk	Not Reported
Haemorrhagic; Swelling	Tocilizumab	C	Unk	Not Reported
	Vancomycin	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Ceftriaxone	C	Unk	Not Reported
	Ferrous Sulfate	C	Unk	Not Reported
	Methylprednisolone	C	Unk	Not Reported
	Polyethylene Glycol [Macrogol]	C	Unk	Not Reported
	Cefepime	C	Unk	Not Reported
	Ativan	C	Unk	Not Reported
	Docusate;Senna	C	Unk	Not Reported
	Lactulose	C	Unk	Not Reported
	Nicotine	C	Unk	Not Reported
	Duoneb	C	Unk	Not Reported
	Suboxone	C	Unk	Not Reported
	Chlorhexidine	C	Unk	Not Reported
	Azithromycin	C	Unk	Not Reported
	Acetaminophen	C	Unk	Not Reported
	Dextromethorphan	C	Unk	Not Reported
	Meropenem	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942646	DIRECT	Y	OT			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase	Remdesivir			S	Intravenous (not			Not Reported

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Increased; Aspartate
Aminotransferase
Increased; Blood Alkaline
Phosphatase Increased;
Blood Bilirubin Increased;
Therapy Cessation

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942947	DIRECT	Y	OT			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942953	DIRECT	Y	OT			81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Dyspnoea; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942965	DIRECT	Y				64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir Injection	Y		S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942969	DIRECT	Y	LT, OT			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Disease Progression; Hepatic Function Abnormal; Hypotension; Multiple Organ Dysfunction Syndrome; Renal Impairment; Tachycardia	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Acetaminophen	C		Not Reported
	Albuterol	C		Not Reported
	Amiodarone	C		Not Reported
	Aspirin	C		Not Reported
	Atorvastatin	C		Not Reported
	Azithromycin	C		Not Reported
	Docusate Sodium	C		Not Reported
	Ephinephrine	C		Not Reported
	Famotidine	C		Not Reported
	Fentanyl	C		Not Reported
	Furosemide	C		Not Reported
	Guaifenesin	C		Not Reported
	Heparin	C		Not Reported
	Humulin N	C		Not Reported
	Humulin R	C		Not Reported
	Atrovent Hfa	C		Not Reported
	Lactulose	C		Not Reported
	Melatonin	C		Not Reported
	Meropenem	C		Not Reported
	Methylprednisolone	C		Not Reported
	Midazolam	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942976	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertension; Rash Erythematous; Rash Papular; Tachycardia	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Not Reported
	Azithromycin 250 Mg			C				Not Reported
	Effexor 150 Mg			C				Not Reported
	Mirtazapine 45 Mg			C				Not Reported
	Ceftriaxone 2g			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17943053	DIRECT	Y	HO			47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Intestinal Perforation	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Tocilizumab	S	Intravenous (not otherwise specified) Other Frequency:Once;	Genentech
	Ceftriaxone	C		Not Reported
	Azithromycin	C		Not Reported
	Methylprednisolone	C		Not Reported
	Enoxaparin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17946669	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475647		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17946844	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475654		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17946943	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475655		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947072	DIRECT	Y	DE			85 YR	Female	USA

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Hypotension; Respiratory Rate Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947079	DIRECT	Y	OT			89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin 40 Mg			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Cholecalciferol 4000 Iu			C				Not Reported
	Dexamethasone 5 Mg Iv			C				Not Reported
	Folic Acid 1 Mg			C				Not Reported
	Furosemide 40 Mg Iv Once			C				Not Reported
	Pantoprazole 40 Mg Iv			C				Not Reported
	Piperacillin-Tazobactam 2.25 G Iv			C				Not Reported
	Selenium 200 Mcg			C				Not Reported
	Thiamine 250 Mg			C				Not Reported
	Vitamin E 1000 Iu			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Dexmedetomidine Infusion 400 Mc/ 100 MI			C				Not Reported
	Heparin Infusion 25000 Units/ 500 MI			C				Not Reported
	Norepinephrine Infusion 16 Mg/ 250 MI			C				Not Reported
	Ascorbic Acid 1000 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947091	DIRECT	Y	OT			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;	Gilead
	Ceftriaxone	C			Not Reported
	Amiodarone	C			Not Reported
	Apixaban	C			Not Reported
	Dexamethasone	C			Not Reported
	Azithromycin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947136	DIRECT	Y	OT			85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutrophil Count Decreased; Platelet Count Decreased; White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Carvedilol			C				Not Reported
	Citalopram			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Diltiazem			C				Not Reported
	Doxycycline			C				Not Reported
	Insulin Glargine			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Pantoprazole			C				Not Reported
	Warfarin			C				Not Reported
	Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947147	DIRECT	Y	DE			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947154	DIRECT	Y	DE			51 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus			Gilead
	Amiodarone 150 Mg Iv			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 80 Mg			C				Not Reported
	Cefepime 2 Gm Iv			C				Not Reported
	Dexamethasone 10 Mg Iv			C				Not Reported
	Famotidine 20 Mg Iv			C				Not Reported
	Fluconazole 200 Mg Iv			C				Not Reported
	Metronidazole 500 Mg Iv			C				Not Reported
	Valproic Acid 500 Mg Iv			C				Not Reported
	Vancomycin 1000 Mg Iv			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947164	DIRECT	Y				49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dialysis; Renal Failure	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17948215	DIRECT	Y	OT			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17835873	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468468		75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported

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Amlodipine	C	Oral	10 Mg	Not Reported
Apixaban	C	Oral	2.5 Mg	Not Reported
Doxazosin	C	Oral	4 Mg	Not Reported
Hydralazine	C		Unk	Not Reported
Lorazepam	C		Unk	Not Reported
Combivent Respimat	C		Unk	Not Reported
Ascorbic Acid	C	Oral	500 Mg	Not Reported
Cholecalciferol	C	Oral	2000 Iu	Not Reported
Levothyroxine	C		Unk	Not Reported
Zinc Sulfate	C		Unk	Not Reported
Tylenol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17835882	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468290		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Swelling; Throat Irritation	Remdesivir			S	Unknown	200 Mg		Gilead
	Albuterol Hfa			C		Unk		Not Reported
	Nystatin			C		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Dipridamole			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Letrozole			C		Unk		Not Reported

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Amlodipine	C	Unk	Not Reported
Lisinopril	C	Unk	Not Reported
Sitagliptin	C	Unk	Not Reported
Metformin	C	Unk	Not Reported
Empagliflozin	C	Unk	Not Reported
Diphenhydramine	C	Intravenous (not otherwise specified) Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17877950	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0470603		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Docusate;Senna			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17892305	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469665		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C	Oral	20 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Etomidate			C	Intravenous (not otherwise specified)	20 Mg		Not Reported

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Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Tocilizumab	C	Intravenous (not otherwise specified)	400 Mg	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	2500 Mg	Not Reported
Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17948303	DIRECT	Y	LT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S				Gilead
	Albuterol Mdi Q6hr Prn			C				Not Reported
	Guaifenesin 600 Mg Q12h			C				Not Reported
	Allopurinol 300 Mg Bid			C				Not Reported
	Aspirin 81 Mg Qd			C				Not Reported
	Enoxaparin 40 Mg Qhs			C				Not Reported
	Humalog Ssi			C				Not Reported
	Levothyroxine 137mcg Qd			C				Not Reported
	Omeprazole 20 Qd			C				Not Reported
	Melatonin 5mg Qhs			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17948310	DIRECT	Y	OT			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Rash; Rash	Remdesivir	S	Intravenous bolus	Other Frequency:Once;	Gilead
Erythematous; Red Man Syndrome	0.9% Sodium Chloride 1l	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17948403	DIRECT	Y	HO			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Melatonin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949179	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475738		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Albumin (Human)			C				Not Reported
	Azithromycin			C				Not Reported
	Senokot-S			C				Not Reported
	Ceftriaxone Sodium			C				Not Reported
	Cisatracurium			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine			C				Not Reported
	Epoprostenol [Epoprostenol Sodium]			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin			C				Not Reported
	Duoneb			C				Not Reported
	Linezolid			C				Not Reported
	Midazolam			C				Not Reported

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Multivitamins;Minerals	C	Not Reported
Norepinephrine	C	Not Reported
Pantoprazole	C	Not Reported
Phenylephrine	C	Not Reported
Piperacillin & Tazobactam	C	Not Reported
Propofol	C	Not Reported
	Unk	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949182	DIRECT	Y				37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extra Dose Administered	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Labetalol			C				Not Reported
	Furosemide			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Famotidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949291	DIRECT	Y	HO, OT			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bundle Branch Block Right; Heart Rate Decreased; Nodal Rhythm; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin 500mg Po Qam			C				Not Reported
	Ondansetron 4mg Iv X1 At 2052 On 6/20			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949624	DIRECT	Y				70 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported
	Amlodipine			C				Not Reported
	Fioricet			C				Not Reported
	Enoxaparin			C				Not Reported
	Zetia			C				Not Reported
	Robitussin			C				Not Reported
	Mag-Ox 400			C				Not Reported
	Niacin Cr			C				Not Reported
Zinc			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949632	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agonal Rhythm; Gastrointestinal Haemorrhage; Hypotension; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949709	DIRECT	Y	DS			53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Hemiparesis	Remdesivir			S	Intravenous bolus			Gilead
	Heparin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17950233	DIRECT	Y	DE			87 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip			Gilead

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Tocilizumab	C	Not Reported
Hydrocortisone	C	Not Reported
Dexamethasone	C	Not Reported

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26-Jun-2020	17950264	DIRECT	Y	DE			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Hypotension; Respiratory Distress	Remdesivir Tocilizumab Levofloxacin Ceftriaxone Azithromycin			S C C C C	Intravenous bolus			Gilead Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17950269	DIRECT	Y	LT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17950326	DIRECT	Y	OT			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17950382	DIRECT	Y				49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Pyrexia	Remdesivir			S				Not Reported

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26-Jun-2020	17951103	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0475616		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C			Not Reported	
	Benzonatate			C			Not Reported	
	Bisacodyl			C			Not Reported	
	Ceftriaxone			C			Not Reported	
	Cyclobenzaprine			C			Not Reported	
	Enoxaparin			C			Not Reported	
	Famotidine			C			Not Reported	
	Gabapentin			C			Not Reported	
	Guaifenesin			C			Not Reported	
	Hydrocodone Bitartrate And Acetaminophen			C			Not Reported	
	Morphine			C			Not Reported	
	Orphenadrine			C			Not Reported	
	Prednisone			C			Not Reported	
	Docusate			C			Not Reported	
Sodium Chloride			C	Not Reported				
Temazepam			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17951358	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0475730		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Ceftriaxone			C			Unk	Not Reported
	Azithromycin			C			Unk	Not Reported
	Atorvastatin			C			Unk	Not Reported
	Asa			C			Unk	Not Reported
	Vitamin D3			C			Unk	Not Reported

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Enoxaparin	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Guaifenesin	C	Unk	Not Reported
Methylprednisolone	C	Unk	Not Reported
Pantoprazole	C	Unk	Not Reported
Dexmedetomidine	C	Unk	Not Reported
Propofol	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952105	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475740		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Aspirin Ec			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Precedex			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Lantus			C				Not Reported
	Insulin Lispro			C				Not Reported
	Metoclopramide			C				Not Reported
	Metoprolol			C				Not Reported
	Tocilizumab			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Normal Saline			C				Not Reported
	Clopidogrel			C				Not Reported

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Dicyclomine [Dicycloverine Hydrochloride]	C		Not Reported
Insulin	C		Not Reported
Metformin	C		Not Reported
Metoprolol Tartrate	C		Not Reported
Ranitidine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952320	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476715		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952476	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476711		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952547	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0476372		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Platelet Count Increased; Product Dose Omission	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Benzonatate			C				Not Reported
	Enoxaparin			C				Not Reported
	Ketorolac			C				Not Reported
	Melatonin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Promethazine - Codeine [Codeine Phosphate;Promethazine			C				Not Reported

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Hydrochloride]
Acetaminophen

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952601	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475755		83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma Hydroxychloroquine			C		Unk		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Once		Not Reported
	Azithromycin			C	Oral	250 Mg, Qd		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Thiamine			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Vasopressin			C		Unk		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Bid		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Qd		Not Reported
	Cefepime			C		Unk		Not Reported
	Ascorbic Acid			C	Intravenous (not otherwise specified)	1500 Mg, Q6h		Not Reported
	Ascorbic Acid			C	Oral	1500 Mg, Qd		Not Reported
	Atorvastatin			C	Oral	80 Mg, Qd		Not Reported
	Amiodarone			C	Intravenous (not otherwise specified)	450 Mg		Not Reported
	Amiodarone			C	Oral	200 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952608	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476714		61 YR	Male	USA

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Death	Remdesivir			S	Unknown			Gilead
	Remdesivir			S		Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952610	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0476284		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin Fumarate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Precedex			C				Not Reported
	Diltiazem			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Hydralazine			C				Not Reported
	Lantus			C				Not Reported
	Insulin Lispro Dci			C				Not Reported
	Norepinephrine Bitartrate			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Vecuronium			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952624	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0476289		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Bilirubin Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Aspirin (E.C.)	C			Not Reported
	Atorvastatin	C			Not Reported
	Azithromycin	C			Not Reported
	Ceftriaxone	C			Not Reported
	Carvedilol	C			Not Reported
	Dexamethasone	C			Not Reported
	Precedex	C			Not Reported
	Enoxaparin	C			Not Reported
	Famotidine	C			Not Reported
	Fentanyl	C			Not Reported
	Insulin Lispro	C			Not Reported
	Midazolam	C			Not Reported
	Nicardipine	C			Not Reported
	Norepinephrine	C			Not Reported
	Propofol	C			Not Reported
	Amiodarone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952666	EXPEDITED (15-DAY)			US-GILEAD-2020-0476262		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use Issue	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952676	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476716		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955105	DIRECT	Y				74 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Therapy Interrupted	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955109	DIRECT	Y	DE			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cardiac Arrest; Pancytopenia; Pulseless Electrical Activity; Sepsis	Remdesivir			S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955112	DIRECT	Y	DE			91 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Levofloxacin			C				Not Reported	
	Azithromycin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955114	DIRECT	Y				45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Heart Rate Decreased; Sinus Bradycardia	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955116	DIRECT	Y	DE			66 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Bradycardia; Cardiac Arrest; Condition Aggravated; Pulseless Electrical Activity; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma Tocilizumab			C C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955124	DIRECT	Y				33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Transcription Medication Error	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Ketorolac			C				Not Reported
	Albuterol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955127	DIRECT	Y				59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extra Dose Administered	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Daily;	1 DAY	Gilead
	Remdesivir	Y		S				Intravenous (not otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955136	DIRECT	Y				67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oxygen Saturation Decreased	Remdesivir	Y		S	Intravenous drip			Gilead
	Odefsey			C				Not Reported
	Lisinopril			C				Not Reported
	Ceftriaxone			C				Not Reported

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Azithromycin	C	Not Reported
Atorvastatin	C	Not Reported
Asa	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17955138	DIRECT	Y	DS			17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Appendicitis; Pneumatosis Intestinalis; Respiratory Failure	Remdesivir	Y		S	Intravenous bolus		4 DAY	Gilead
	Famotidine 20 Mg Iv Qd			C				Not Reported
	Morphine 2mg Iv Prn Q2h			C				Not Reported
	Dexamethasone 6mg Iv Qd			C				Not Reported
	Ondansetron 4mg Iv Prn Q8hr			C				Not Reported
	Morphine Drip 0.025mg/Hour			C				Not Reported
	Dexmedetomidine Iv Drip			C				Not Reported
	Insulin Drip			C				Not Reported
	Metronidazole 500mg Iv Q 8 Hrs			C				Not Reported
	Cefepime 2g Iv Q 12h			C				Not Reported
	Lorazepam 2mg Q4hprn			C				Not Reported
	Enoxaparin 40mg Sq			C				Not Reported
	Melatonin 3mg Hs			C				Not Reported
	Azithromycin Oral			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2020	17955143	DIRECT	Y	LT			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hypotension; Ischaemic Hepatitis; Transaminases Increased	Remdesivir			S	Intravenous drip			Gilead
	Centrum Multivitamin Oral Solution			C				Not Reported
	Enoxaparin 40 Mg Injection			C				Not Reported
	Phytonadione 5 Mg Tablet			C				Not Reported
	Potassium Phosphate 30 Mmol Injection			C				Not Reported
	Acetaminophen 650 Mg Oral Liquid			C				Not Reported
	Cefepime 2g Injection			C				Not Reported
	Dexmedetomidine Continuous			C				Not Reported

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Infusion			
Famotidine 20 Mg Injection	C		Not Reported
Fentanyl Continuous Infusion	C		Not Reported
Hydrocortisone 50 Mg Injection	C		Not Reported
Insulin Aspart	C		Not Reported
Peptamen Continuous Enteral Nutrition	C		Not Reported
Polyethylene Glycol 17g Packet	C		Not Reported
Senna Oral Solution	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2020	17955146	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955074	DIRECT		OT			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased; Therapy Change	Warfarin			S				Not Reported
	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955085	DIRECT	Y	OT			85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Dyspnoea; Infusion Related Reaction; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955147	DIRECT	Y				76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; General Physical Health Deterioration	Remdesivir	Y		S	Intravenous bolus		2 DAY	Gilead
	Amiodarone			C				Not Reported
	Atracurium			C				Not Reported
	Buspirone			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Memantine			C				Not Reported
	Metoprolol			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Pregabalin			C				Not Reported
	Senna			C				Not Reported
	Venlafaxine			C				Not Reported
	Epoprostenol			C				Not Reported
	Hydromorphone			C				Not Reported
Midazolam			C				Not Reported	
Norepinephrine			C				Not Reported	
Propofol			C				Not Reported	
Sodium Bicarbonate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955173	DIRECT	Y				53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955174	DIRECT	Y	DE			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Organ	Remdesivir			S	Intravenous bolus			Gilead

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Dysfunction Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955178	DIRECT	Y	LT			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Ammonia Increased; Aspartate Aminotransferase Increased; International Normalised Ratio Increased; Prothrombin Time Prolonged; Sars-Cov-2 Test Positive	Remdesivir Lyophilized Powder			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir Lyophilized Powder			S	Intravenous bolus		Gilead	
	Amiodarone Continuous Infusion			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955182	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17955186	DIRECT	Y	OT			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Sinus Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Quetiapine			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17818878	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GILEAD-2020-0468569		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Cerebrovascular Accident	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Remdesivir	S			Gilead
	Acetaminophen	C		Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported
	Magnesium Sulfate	C		Unk	Not Reported
	Potassium Bicarbonate	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17835865	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468246		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Abnormal; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Atorvastatin			C	Oral	20 Mg		Not Reported
	Propofol			C		Unk		Not Reported
	Chlorhexidine			C	Oral	15 MI, Bid		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	10 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Bid		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Insulin Aspart			C	Subcutaneous	Unk		Not Reported
	Insulin Detemir			C	Subcutaneous	10 Units		Not Reported
	Piperacillin/Tazobactam			C	Intravenous (not otherwise specified)	3.375 G, Tid		Not Reported

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Acetaminophen			C			Unk			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
29-Jun-2020	17848037	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468536		55 YR	Male	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Hypotension; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead			
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd		Gilead			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
29-Jun-2020	17882776	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469674		77 YR	Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead			
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead			
	Enoxaparin			C		Unk		Not Reported			
	Famotidine			C		Unk		Not Reported			
	Lorazepam			C		Unk		Not Reported			
	Hydromorphone			C		Unk		Not Reported			
	Metoclopramide			C		Unk		Not Reported			
	Ceftriaxone			C		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
29-Jun-2020	17955177	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1059286		64 YR	Male	ITA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Erythema; Hypersensitivity; Off Label	Piperacillin/Tazobactam			S	Intravenous drip	13 Gram, Qd		Not Reported			

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Use; Rash Maculo-Papular	Remdesivir	S	Intravenous drip	100 Milligram, Qd	Mylan
	Hydroxychloroquine Sulfate	C	Oral	400 Milligram	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956863	DIRECT	Y	OT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Covid-19 Pneumonia; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone 2 Gm Ivpb Daily			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Doxycycline 100 Mg Po Twice Daily			C				Not Reported
	Enoxaparin 70 Mg Sq Twice Daily			C				Not Reported
	Iohexol (Omnipaque) 90 MI Iv X 1			C				Not Reported
	Multivitamin With Minerals Po Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956864	DIRECT	Y	OT			44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956865	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Intravenous drip			Gilead
	Cefepime			C				Not Reported
	Amiodarone			C				Not Reported
	Doxycycline			C				Not Reported

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Fentanyl	C	Not Reported
Vecuronium	C	Not Reported
Propofol	C	Not Reported
Levophed	C	Not Reported
Levothyroxine	C	Not Reported
Decadron	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956866	DIRECT	Y	OT			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Disease Progression; Liver Function Test Increased; Therapy Interrupted	Remdesivir			S				Not Reported
	Fenofibrate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956881	DIRECT	Y	OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		4 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956925	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR- APL-2020-031011			Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Furosemide			S	Unknown	Unk		Aurobindo
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported

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Remifentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Ceftriaxon	C	Intravenous (not otherwise specified)	Unk	Not Reported
Movicolon	C	Oral	Unk	Not Reported
Nadroparin	C	Subcutaneous	Unk	Not Reported
Cisatracurium	C	Intravenous (not otherwise specified)	Unk	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Supradyn	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956968	DIRECT	Y	DE			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Wrong Technique In Product Usage Process	Remdesivir	Y		S	Intravenous drip			Gilead
	Ofirmev Iv			C				Not Reported
	Acetaminophen Sol 325mg/10ml			C				Not Reported
	Acetylcysteine Sol 20%			C				Not Reported
	Albuterol Inh			C				Not Reported
	Amiodarone Iv			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Benzonatate 100mg			C				Not Reported
	Calcium Gluconate Iv			C				Not Reported
	Ceftriaxone 1g			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin			C				Not Reported
	Epinephrine Drip			C				Not Reported
	Famotidine 20mg Iv			C				Not Reported
	Insulin Glargine			C				Not Reported
Norepinephrine Drip			C				Not Reported	
Zosyn			C				Not Reported	
Propofol			C				Not Reported	
Vancomycin			C				Not Reported	

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Vasopressin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956974	DIRECT	Y	OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Feeling Abnormal	Remdesivir			S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956980	DIRECT	Y	OT			58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Liver Function Test Increased	Remdesivir Propofol Norepinephrine Fentanyl			S C C C	Intravenous bolus			Gilead Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956985	DIRECT	Y	OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir Ascorbic Acid Dexamethasone Tramadol Zinc Sulfate Acetaminophen Enoxaparin Guaifenesin			S C C C C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956992	DIRECT	Y				46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Therapy Interrupted	Remdesivir		S		Intravenous (not otherwise specified)				Gilead
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29-Jun-2020	17956994	DIRECT	Y				32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Product Use Issue	Remdesivir				S	Intravenous (not otherwise specified)		5 DAY	Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17956998	DIRECT	Y				33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Product Use Issue	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17957001	DIRECT	Y				34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir		Y		S	Intravenous drip		1 DAY	Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17957034	DIRECT	Y	OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Covid-19; Glomerular Filtration Rate Decreased	Remdesivir				S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir				S	Intravenous (not		2 DAY	Gilead

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otherwise specified)

Tocilizumab 600mg Iv X1	C	Not Reported
Diprivan 1000 Mg/100 MI Infusion	C	Not Reported
Norepinephrine 16mg/250 MI Infusion	C	Not Reported
Sodium Bicarbonate 150 Meq/ 1000 MI Swi	C	Not Reported
Vasopressin 40 Unit/100 MI Ns	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17957040	DIRECT	Y				27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17957735	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476718		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Glomerular Filtration Rate Decreased	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17957740	EXPEDITED (15-DAY)			US-GILEAD-2020-0476394		25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use Issue	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			C		Unk		Not Reported
	Cefazolin			C		Unk		Not Reported
	Cefepime			C		Unk		Not Reported

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Dexamethasone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Methadone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17957773	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0476697		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown			Gilead
	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17958217	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0476315		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin [Enoxaparin Sodium]			C				Not Reported
	Robitussin Dm			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960773	DIRECT	Y	OT			28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S				Not Reported
	Benzocain-Menthol Lozenge			C				Not Reported

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Increased; Therapy
Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960783	DIRECT	Y	DE			52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Condition Aggravated; Metabolic Acidosis	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960861	DIRECT	Y				43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intercepted Product Dispensing Error; Product Preparation Error	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960869	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Inadequately Controlled; Blood Pressure Systolic Increased; Hypertension	Remdesivir			S	Intravenous bolus		5 DAY	Gilead
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefuroxime			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Humalog			C				Not Reported
	Ultimate Flora Probiotic			C				Not Reported
Lisinopril			C				Not Reported	
Potassium Chloride			C				Not Reported	

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Pravastatin	C	Not Reported
Acetaminophen	C	Not Reported
Haldol	C	Not Reported
Hydralazine	C	Not Reported
Effer-K (Potassium Bicarb - Citric Acid)	C	Not Reported
Magnesium Iv	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960883	DIRECT	Y	HO			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dose Omission; Transcription Medication Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960897	DIRECT	Y				24 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17960951	DIRECT	Y	HO			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Nausea; Peripheral Swelling; Swelling Face	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Azithromycin			C				Not Reported
	Cefdinir			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

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	Famotidine								Not Reported
	Zinc Sulfate								Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961055	DIRECT	Y				50 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Convalescent Plasma Tocilizumab			C				Not Reported	Not Reported
				C				Not Reported	Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961069	DIRECT	Y	HO			54 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Kidney Injury; Cardio-Respiratory Arrest; Heart Rate Decreased; Hepatic Enzyme Increased; Ischaemic Hepatitis; Pulseless Electrical Activity; Renal Tubular Necrosis	Remdesivir	Y		S	Intravenous bolus			Gilead	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2020	17961119	DIRECT	Y	OT			72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Glomerular Filtration Rate Decreased; Hepatic Enzyme Increased; Renal Impairment; Therapy Cessation	Remdesivir			S	Intravenous bolus			Not Reported	
	Albuterol/Ipratropium Nebulizer Q6h			C				Not Reported	
	Ascorbic Acid 500mg Po Daily			C				Not Reported	
	Azithromycin 500mg Iv Daily			C				Not Reported	
	Ceftriaxone 2g Iv Daily			C				Not Reported	
	Cholecalciferol 1000 Unit Po			C				Not Reported	

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Daily			
Dexamethasone 6mg Iv Daily	C		Not Reported
Docusate/Senna 50-8.6mg 2 Tab Po Qhs	C		Not Reported
Heparin 5000 Unit Q8h	C		Not Reported
Insulin Glargine 30 Unit Subq Qhs	C		Not Reported
Insulin Lispro Sliding Scale Subq Q4h	C		Not Reported
Pantoprazole 40mg Iv Daily	C		Not Reported
Zinc 220mg Po Q12h	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17961135	DIRECT	Y	OT			31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Maternal Exposure During Pregnancy; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17961246	DIRECT	Y				36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dose Omission	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17961537	DIRECT	Y	DE			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Remdesivir 100mg Vial			S	Intravenous (not			Gilead

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Bacteraemia; General Physical Health Deterioration; Hepatic Failure; Hypernatraemia; Multiple Organ Dysfunction Syndrome; Septic Shock; Toxic Encephalopathy; Unresponsive To Stimuli	Remdesivir 100mg Vial Doxycycline Enoxaparin Piperacillin-Tazobactam Pantoprazole Vancomycin Furosemide Insulin Fentanyl Norepinephrine Propofol	S C C C C C C C C C	otherwise specified) Intravenous (not otherwise specified)	Other Frequency:9 Doses;	Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17835876	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0468482		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Blood Alkaline Phosphatase Increased; Hypotension	Remdesivir Atorvastatin Ceftriaxone Desvenlafaxine Epoetin Alfa Famotidine Heparin Hydrocortisone Sodium Succinate Hydrocortisone Sodium Succinate Insulin Glargine Insulin Lispro Methadone Methadone			S C C C C C C C C C C C C	Intravenous (not otherwise specified)	200 Mg, Once Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Metoprolol	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Pregabalin	C	Unk	Not Reported
Azithromycin	C	Unk	Not Reported
Hydroxychloroquine	C	Unk	Not Reported
Acetaminophen	C	Oral	650 Mg, Q4hr
Nystatin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17886471	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0471777		35 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Pleuritic Pain	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Cholecalciferol			C		2000 Iu, Qd		Not Reported
	Melatonin			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Humalog			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17910399	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472995		17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Lactic Acid Increased	Remdesivir			S	Unknown	Unk		Gilead
	Epinephrine			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17914699	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0473311		85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Bile Output Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Ampicillin And Sulbactam			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Atenolol			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Calcium Gluconate			C		Unk		Not Reported
	Chlorhexidine Gluconate			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported
	Dextrose			C		Unk		Not Reported
	Digoxin			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Glucagon			C		Unk		Not Reported
	Glycopyrrolate [Glycopyrronium Bromide]			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17914716	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0472817		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Pneumonia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Norepinephrine Bitartrate Convalescent Plasma			C C	Intravenous (not otherwise specified)	2 Units		Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17962822	DIRECT	Y	DE			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemodynamic Instability; Heart Rate Decreased; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen Iv			C				Not Reported
	Albumin 25%			C				Not Reported
	Albuterol 0.5% Hhn Prn			C				Not Reported
	Carbidopa-Levodopa 25/100			C				Not Reported
	Dopamine Infusion			C				Not Reported
	Enoxaparin 95 Mg			C				Not Reported
	Haloperidol 2.5 Mg Prn			C				Not Reported
	Insulin Aspart Prn			C				Not Reported
	Ipratropium/Albuterol Hhn			C				Not Reported
	Lorazepam 2 Mg X 1			C				Not Reported
	Morphine 2 Mg Prn			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Pantoprazole 40 Mg Iv			C				Not Reported
	Pimavanserin 17 Mg			C				Not Reported
Sennosides-Docusate 1 Tab			C				Not Reported	
Vasopressin Infusion			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17962874	DIRECT	Y	HO			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 1000 Mg			C				Not Reported
	Aspirin 81 Mg			C				Not Reported
	Atorvastatin 40 Mg			C				Not Reported
	Clopidogrel 75 Mg			C				Not Reported
	Dextromethorphan-Guaifenesin 30-600 Mg			C				Not Reported
	Dexmedetomidine Infusion			C				Not Reported
	Dopamine Infusion			C				Not Reported
	Enoxaprin 40 Mg			C				Not Reported
	Tocilizumab 400 Mg X 1			C				Not Reported
	Furosemide 20-40 Mg			C				Not Reported
	Haloperidol 1-2.5 Mg Prn			C				Not Reported
	Levothyroxine 50 Mcg			C				Not Reported
	Linezolid 600 Mg Iv			C				Not Reported
	Melatonin 3-9 Mg			C				Not Reported
	Methylprednisolone/Prednisone			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Olanzapine 2.5 Mg			C				Not Reported
	Pantoprazole 40 Mg			C				Not Reported
	Piperacillin-Tazobactam 4.5 G			C				Not Reported
Quetiapine 12.5 Mg			C				Not Reported	
Rivastigmine 9.5 Mg Td			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17962879	DIRECT	Y	OT			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Jaundice	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg			C				Not Reported
	Ceftriaxone 2 G			C				Not Reported

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Heparin Infusion	C	Not Reported
Methylprednisolone 40 Mg	C	Not Reported
Chlorthalidone 25 Mg	C	Not Reported
Mometasone-Formoterol Inh	C	Not Reported
Guaifenesin-Codeine Prn	C	Not Reported
Acetaminophen Prn	C	Not Reported
Labetalol Iv Prn	C	Not Reported
Dexmedetomidine Infusion	C	Not Reported
Verapamil 360 Mg	C	Not Reported
B Complex W/ Zinc	C	Not Reported
Hydroxychloroquine	C	Not Reported
Propofol Infusion	C	Not Reported
Fentanyl Ivp Prn	C	Not Reported
Cisatracurium Infusion	C	Not Reported
Nicardipine Infusion	C	Not Reported
Chlordiazepoxide 100 Mg	C	Not Reported
Dexamethasone	C	Not Reported
Sennosides	C	Not Reported
Pantoprazole/Famotidine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17962885	DIRECT	Y				84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash	Remdesivir			S		Other Frequency:Once;		Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17962891	DIRECT	Y	OT			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash	Remdesivir	Y		S	Intravenous drip			Gilead
	Fosphenytoin			C				Not Reported
	Levetiracetam			C				Not Reported

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30-Jun-2020	17962898	DIRECT	Y	OT			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir 100 Mg Iv Daily In Ns 250 MI	Y		S	Intravenous drip			Gilead
	Albuterol Hfa 180 Mcg Q6 Hrs			C				Not Reported
	Ascorbate 500 Mg Po Q6 Hrs			C				Not Reported
	Cholecalciferol 2000 Iu Oral Daily			C				Not Reported
	Enoxaparin 60 Mg Sq Daily			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Flonase 50 Mcg Inhaled Daily			C				Not Reported
	Insulin Sq			C				Not Reported
	Loratidine 10 Mg Po Daily			C				Not Reported
	Melatonin 6 Mg Po Qhs			C				Not Reported
	Oxymetolazone Q Spary Nasal Qid			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported
	Promethazine With Codeine 5 MI Po Q6 Hrs Prn Cough			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17963068	DIRECT	Y	OT			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17963540	DIRECT	Y	OT			31 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17963546	DIRECT	Y	OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip	Other Frequency:X1, 100 Mg Q24h;		Gilead	
	Remdesivir			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17963622	DIRECT	Y	OT			27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Steatosis; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Ascorbic Acid 500 Mg Po Bid With Food			C				Not Reported	
	Benonate 200 Mg 2 Caps Po Q8h Prn For Cough			C				Not Reported	
	Cholecalciferol 2,000 Iu Po Daily With Food			C				Not Reported	
	Enoxaparin 80 Mg Sq Q12h			C				Not Reported	
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported	
	Pantoprazole 40 Mg Po Daily			C				Not Reported	
	Zinc Sulfate 200 Mg Po Daily			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17963628	DIRECT	Y				33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Kidney Injury; Blood Creatine Phosphokinase Increased	Remdesivir Lyophilized Powder	S	Intravenous bolus	Gilead
	Dexamethasone	C		Not Reported
	Tocilizumab	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17963633	DIRECT	Y				72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17964680	EXPEDITED (15-DAY)			US-GILEAD-2020-0477205			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose	Remdesivir			S	Unknown	Unk		Gilead
	Remdesivir			S	Unknown	200 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967202	DIRECT	Y	OT			70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967203	DIRECT	Y	OT			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Pulmonary Hypertension; Right Ventricular Enlargement; Therapy	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Four Times Daily			C				Not Reported

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Cessation	Cholcecalciferol 4,000 Iu Po Daily	C	Not Reported
	Digoxin 0.25 Mg Iv Q8h X3 Doses	C	Not Reported
	Enoxaparin 40 Mg Sq Q12h	C	Not Reported
	Ferrous Sulfate 325 Mg Po Daily	C	Not Reported
	Gabapentin 600 Mg Po Qhs	C	Not Reported
	Hydrochlorothiazide 12.5 Mg Po Daily	C	Not Reported
	Furosemide 20 Mg Iv Bid	C	Not Reported
	Levothyroxine 75 Mcg Po Daily	C	Not Reported
	Lisinopril 20 Mg Po Daily	C	Not Reported
	Methylprednisolone 20 Mg Iv Q6h	C	Not Reported
	Multivitamin 1 Tab Po Daily	C	Not Reported
	Omata-3 Fatty Acids 1 Gram Po Daily	C	Not Reported
	Pantoprazole 40 Mg Po Daily	C	Not Reported
	Ramelteon 8 Mg Po Qhs	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967229	DIRECT	Y				51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Bid			C				Not Reported
	Azithromycin 500 Mg Iv Q24h			C				Not Reported
	Ceftriaxone 1 Gm Iv Q24h			C				Not Reported
	Enoxaparin 50 Mg Sq Q12h			C				Not Reported
	Famotidine 20 Mg Po Q12h			C				Not Reported
	Guaifenesin 200 Mg Po Q8h			C				Not Reported
	Methylprednisolone 40 Mg Iv Q12h			C				Not Reported
	Ramelteon 8 Mg Po Qhs			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967232	DIRECT	Y				87 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time Only;		Gilead
	Ascorbic Acid 1,000 Mg Po Daily With Food			C				Not Reported
	Calcium/Vitamin D 500mg/200 Iu Po Bid			C				Not Reported
	Cholecalciferol 2,000 Iu Po Daily			C				Not Reported
	Docusate 200 Mg Po Bid			C				Not Reported
	Enoxaparin 30 Mg Sq Q12h			C				Not Reported
	Famotidine 20 Mg Iv Q24h			C				Not Reported
	Guaifenesin 600 Mg Er Po Bid			C				Not Reported
	Methylprednisolone 40 Mg Iv Q12h			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967235	DIRECT	Y	OT			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967239	DIRECT	Y				80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Increased; Renal Impairment; Sinus Bradycardia	Remdesivir	Y		S	Intravenous bolus			Gilead
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17967243	DIRECT	Y	HO			31 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Decreased	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17862152	EXPEDITED (15-DAY)			US-GILEAD-2020-0468845		334 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Administered To Patient Of Inappropriate Age	Remdesivir			S	Intravenous (not otherwise specified)	37.5 Mg, Once		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17902698	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0472649		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Allopurinol			C				Not Reported	
	Apixaban			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Coreg			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Duloxetine			C				Not Reported	
	Ertapenem			C				Not Reported	
	Fentanyl			C				Not Reported	
	Folic Acid			C				Not Reported	
	Furosemide			C				Not Reported	
	Hydroxychloroquine			C				Not Reported	
	Insulin			C				Not Reported	
	Methylprednisolone			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Phenylephrine			C				Not Reported	
	Pregabalin			C				Not Reported	

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01-Jul-2020	17908558	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0472776		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			C				Not Reported
	Famotidine			C				Not Reported
	Insulin Regular [Insulin Bovine]			C				Not Reported
	Normal Saline			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Detemir			C				Not Reported
	Methylprednisolone			C				Not Reported
Thiamine			C				Not Reported	
Zinc Sulfate			C				Not Reported	
Duoneb			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17909732	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0472780		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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Colchicine	S	Oral	0.6 Mg	Not Reported
Ascorbic Acid	C			Not Reported
Cisatracurium	C			Not Reported
Fentanyl	C			Not Reported
Heparin	C			Not Reported
Midazolam	C			Not Reported
Norepinephrine	C			Not Reported
Piperacillin/Tazobactam	C			Not Reported
Potassium Chloride	C			Not Reported
Propofol	C			Not Reported
Tocilizumab	C			Not Reported
Albuterol [Salbutamol]	C			Not Reported
Atorvastatin	C			Not Reported
Chlorhexidine	C			Not Reported
Cholecalciferol	C			Not Reported
Famotidine	C			Not Reported
Insulin Aspart	C			Not Reported
Levemir	C			Not Reported
Methylprednisolone	C			Not Reported
Sitagliptin	C			Not Reported
Zinc Sulfate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17967464	DIRECT	Y	OT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Selinexor Study Drug			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968112	DIRECT	Y	OT			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

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Bio-K Plus	C	Not Reported
Insulin Lispro	C	Not Reported
Famotidine	C	Not Reported
Propofol	C	Not Reported
Norepinephrine	C	Not Reported
Lorazepam	C	Not Reported
Hydromorphone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968116	DIRECT	Y	OT			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip			Gilead
	Normal Saline			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968121	DIRECT	Y	OT			83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous drip		5 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968349	DIRECT	Y	OT			31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pruritus	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968402	DIRECT	Y	OT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase	Remdesivir			S	Intravenous drip			Gilead
	Pravastatin 40 Mg-Home			C				Not Reported

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Increased		Medication							
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968586	DIRECT	Y				52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Interrupted	Remdesivir			S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968698	DIRECT	Y				66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Glomerular Filtration Rate Decreased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Amlodipine 5mg(Home Med)			C				Not Reported	
	Azithromycin 500mg Iv Daily			C				Not Reported	
	Rocephin 1g Iv Daily			C				Not Reported	
	Dexamethasone 6mg Iv Daily			C				Not Reported	
	Lovenox 100mg Every 12 Hours			C				Not Reported	
	Lantus 5-10 Units			C				Not Reported	
	Protonix 40mg Iv Daily			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17969275	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0476702		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17969652	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477741		87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Tocilizumab	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17969833	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477758		85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17970016	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0475372		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Liver Function Test Increased; Multiple Organ Dysfunction Syndrome; Renal Impairment; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Alprazolam			C		Unk, Prn		Not Reported
	Guaifenesin			C		Unk, Prn		Not Reported
	Acetaminophen;Hydrocodone			C		Prn		Not Reported
	Vecuronium			C		Unk, Prn		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Azithromycin			C		Intravenous (not otherwise specified)	Unk	Not Reported
	Azithromycin			C		Oral	Unk	Not Reported
	Calcium Gluconate			C			Unk	Not Reported
Ceftriaxone			C			Unk	Not Reported	
Cefepime			C		Intravenous (not otherwise specified)	Unk	Not Reported	

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Dopamine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Etomidate	C		Unk	Not Reported
Fentanyl	C		Unk	Not Reported
Finasteride	C		Unk	Not Reported
Enoxaparin	C		Unk	Not Reported
Fondaparinux	C		Unk	Not Reported
Normal Saline	C	Intravenous (not otherwise specified)	Unk	Not Reported
Furosemide	C		Unk	Not Reported
Hydrocortisone Sodium Succinate	C		Unk	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Phenylephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Phentolamine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17970047	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477761		80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17970432	EXPEDITED (15-DAY)			US-GILEAD-2020-0477650		36 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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01-Jul-2020	17970835	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477744		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Tocilizumab			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17971155	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477738		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Ascorbic Acid			C		Unk		Not Reported	
	Dexamethasone			C		Unk		Not Reported	
	Tramadol			C		Unk		Not Reported	
	Zinc Sulfate			C		Unk		Not Reported	
	Acetaminophen			C		Unk		Not Reported	
	Enoxaparin			C		Unk		Not Reported	
	Guaifenesin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17971172	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477689		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	Unk		Gilead	

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01-Jul-2020	17971828	EXPEDITED (15-DAY)			US-GILEAD-2020-0477767		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Overdose	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17971883	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477750			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17972596	DIRECT	Y					Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17972654	DIRECT	Y	HO			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Increased; Hyperhidrosis; Infusion Related Reaction; Tachycardia; Tachypnoea	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;	60 MIN	Gilead

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01-Jul-2020	17972661	DIRECT	Y					Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Bilirubin Increased; International Normalised Ratio Increased; Prothrombin Time Prolonged	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17972667	DIRECT	Y					Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17878097	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470902		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Pantoprazole			C		Unk		Not Reported	
	Piperacillin / Tazobactam			C		Unk		Not Reported	
	Vancomycin			C		Unk		Not Reported	
	Midazolam			C		Unk		Not Reported	
	Angiotensin li			C		Unk		Not Reported	
	Diltiazem			C		Unk		Not Reported	
	Ketamine			C		Unk		Not Reported	
	Coumadin			C				Not Reported	
	Levophed			C				Not Reported	

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02-Jul-2020	17882667	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470043		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Oxybutin			C		Unk		Not Reported
	Losartan			C				Not Reported
	Enoxaparin			C				Not Reported
	Potassium			C				Not Reported
	Gabapentin			C				Not Reported
	Duloxetine			C				Not Reported
	Lorazepam			C				Not Reported
	Rocuronium			C				Not Reported
	Melatonin			C				Not Reported
	Levothyroxine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Buspirone			C				Not Reported
	Amlodipine			C				Not Reported
Prednisone			C				Not Reported	
Propofol			C				Not Reported	
Pencillin			C				Not Reported	
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17887632	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470690		50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Ischaemic Hepatitis; Liver Function Test Increased; Shock; Supraventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Amiodarone			S	Unknown			Not Reported

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Aripiprazole	C	Unk	Not Reported
Aripiprazole	C		Not Reported
Famotidine	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported
Insulin Lispro	C	Unk	Not Reported
Insulin Regular Hm	C	Unk	Not Reported
Ceftriaxone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Potassium	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Bupropion	C	Unk	Not Reported
Bupropion	C		Not Reported
Cetirizine	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Prednisone	C	Unk	Not Reported
Sertraline	C	Unk	Not Reported
Sertraline	C		Not Reported
Trazodone	C	Unk	Not Reported
Ocrelizumab	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17892597	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470641		75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Propofol			C		Unk		Not Reported

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Norepinephrine	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Insulin Regular Hm	C	Unk	Not Reported
Insulin Lispro	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Levothyroxine	C	Unk	Not Reported
Atorvastatin	C	Unk	Not Reported
Linezolid	C	Unk	Not Reported
Insulin Glargine	C	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Metolazone	C	Unk	Not Reported
Insulin Isophane	C	Unk	Not Reported
Bumetanide	C	Unk	Not Reported
Losartan	C	Unk	Not Reported
Metformin	C	Unk	Not Reported
Plasma	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17918275	EXPEDITED (15-DAY)			US-GILEAD-2020-0472228		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Lactobacillus Rhamnosus			C				Not Reported

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Methylprednisolone Sodium Succinate

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17940380	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0474255		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Throat Tightness	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			S	Unknown	Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Dextroamphetamine Sulfate			C		Unk		Not Reported
	Citalopram			C		Unk		Not Reported
	Clonazepam			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973626	DIRECT	Y	HO, RI			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dialysis; Renal Impairment; Respiratory Distress; Therapy Interrupted	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973938	DIRECT	Y	OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Abdominal Tenderness; Oedematous Pancreatitis	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Dexamethasone	C		Not Reported
	Fenofibrate	C		Not Reported
	Acetaminophen	C		Not Reported
	Atorvastatin	C		Not Reported
	Ceftriaxone	C		Not Reported
	Cyclobenzaprine	C		Not Reported
	Diltiazem	C		Not Reported
	Doxycycline	C		Not Reported
	Enoxaparin	C		Not Reported
	Ketorolac	C		Not Reported
	Hydromorphone	C		Not Reported
	Levothyroxine	C		Not Reported
	Metoprolol	C		Not Reported
	Ondansetron	C		Not Reported
	Oxycodone Immediate Release	C		Not Reported
	Oxycodone 12 Hour	C		Not Reported
	Pantoprazole	C		Not Reported
	Simethicone	C		Not Reported
	Prochlorperazine	C		Not Reported
	Ropinirole	C		Not Reported
	Ramelteon	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973951	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Levetiracetam			C				Not Reported
	Pantoprazole			C				Not Reported
	Piperacelli/Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Valproic Acid			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973957	DIRECT	Y				37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973971	DIRECT		OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Acetaminophen 500mg Po Q6h Prn			C				Not Reported	
	Dexamethasone 6mg Ivp Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973976	DIRECT		OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Aspirin 81mg Daily			C				Not Reported	
	Dexamethasone 6mg Ivp Daily			C				Not Reported	
	Norepinephrine Iv Drip			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17973979	DIRECT		HO			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate	Remdesivir			S				Not Reported	

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Aminotransferase
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974146	DIRECT	Y				80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974168	DIRECT	Y	HO, OT			47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Neo-Syneprine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974184	DIRECT	Y				77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Lipitor			C				Not Reported
	Rocephin			C				Not Reported
	Zithromax			C				Not Reported
	Aspirin			C				Not Reported
	Allopurinol			C				Not Reported
	Tylenol			C				Not Reported
	Lovenox			C				Not Reported

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Solumedrol	C	Not Reported
Mucinex	C	Not Reported
Prilosec	C	Not Reported
Verapamil	C	Not Reported
Lantus	C	Not Reported
Humalog	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974353	DIRECT	Y	OT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Dexamethasone 6 Mg Daily			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Enoxaparin 40 Mg Daily			C				Not Reported
	Acetaminophen 650 Mg Every 4 Hours As Needed			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974358	DIRECT	Y	LT, OT			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported
	Humulin R			C				Not Reported
	Reglan			C				Not Reported
	Versed			C				Not Reported
	Norepinephrine			C				Not Reported
	Protonix			C				Not Reported
	Propofol			C				Not Reported

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Senna	C	Not Reported
Robitussin Dm	C	Not Reported
Vancomycin	C	Not Reported
Ceftazidime	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974408	EXPEDITED (15-DAY)			US-GILEAD-2020-0478162		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Error	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974504	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardiac Arrest; Glomerular Filtration Rate Decreased; International Normalised Ratio Increased; Liver Function Test Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17974863	EXPEDITED (15-DAY)			US-GILEAD-2020-0478240			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error	Remdesivir			S	Unknown			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17976027	EXPEDITED (15-DAY)			US-GILEAD-2020-0478186			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Storage Error	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17976305	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478153			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir				S	Unknown	Unk		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982134	DIRECT	Y				52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dispensing Error; Therapy Interrupted	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982135	DIRECT	Y	HO			43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Kidney Disease	Remdesivir		Y		S	Intravenous bolus			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982136	DIRECT	Y	DE			85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Renal Failure	Remdesivir	Y	S	Gilead
	Cefepime		C	Not Reported
	Dexmedetomidine		C	Not Reported
	Docusate		C	Not Reported
	Epinephrine		C	Not Reported
	Hydromorphone		C	Not Reported
	Methylprednisolone		C	Not Reported
	Midazolam		C	Not Reported
	Norepinephrine		C	Not Reported
	Sennoside		C	Not Reported
	Sucralfate		C	Not Reported
	Vancomycin		C	Not Reported
	Vasopressin		C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982137	DIRECT		HO			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir	Y		S				Gilead
	Alprazolam			C				Not Reported
	Anakinra			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Chloride			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982138	DIRECT	Y				81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Feeling Hot; Flushing	Remdesivir			S				Not Reported
	Morphine Inj			C				Not Reported
	Lantus			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Norepinephrine			C				Not Reported

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Dexamethasone	C	Not Reported
Enoxaparin	C	Not Reported
Atorvastatin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982146	DIRECT	Y				48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982150	DIRECT	Y	OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest; Hypoxia; Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982155	DIRECT	Y	DE			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Cardiac Arrest; Hypercapnia; Hypoxia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Enoxaparin 60 Mg Sq Q12hrs			C				Not Reported
	Methylprednisolone 60 Mg Ivp Q6hr			C				Not Reported
	Remdesivir 200 Mg Iv X 1			C				Not Reported
	Remdesivir 100 Mg Iv Once Daily			C				Not Reported
	Zinc 220 Mg Po Bid			C				Not Reported

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Ascorbic Acid 1,000 Mg

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2020	17982267	DIRECT	Y	DS, LT, OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Cardiac Arrest; Hepatitis; Pulseless Electrical Activity	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17877919	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470907		91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported
	Diltiazem			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17878098	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470903		74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Covid-19; Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Morphine			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17887631	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470900		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Arformoterol			C				Not Reported
	Budesonide			C				Not Reported
	Docusate;Senna			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Insulin			C				Not Reported
	Potassium Chloride			C				Not Reported
	Rocuronium			C				Not Reported
	Ropinirole			C				Not Reported
	Lorazepam			C				Not Reported
Fentanyl			C				Not Reported	
Ketamine			C				Not Reported	
Midazolam			C				Not Reported	
Dexmedetomidine			C				Not Reported	
Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17898305	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0471872		91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Death	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Amiodarone			C		Unk		Not Reported

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Apixaban	C	Unk	Not Reported
Plasma	C	Unk	Not Reported
Bumex	C	Unk	Not Reported
Plavix	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Heparin	C	Unk	Not Reported
Insulin	C	Unk	Not Reported
Protonix [Omeprazole]	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported
Nitroglycerin	C	Unk	Not Reported
Hydralazine	C	Unk	Not Reported
Isosorbide Mononitrate	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Hydromorphone	C	Unk	Not Reported
Bicarbonate	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17898779	EXPEDITED (15-DAY)		DE, DS, LT, OT	US-GILEAD-2020-0472460		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Cerebrovascular Accident; Death; Pulmonary Function Test Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Zosyn			C		Unk		Not Reported

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Azithromycin	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	40 Mg Sq Bid	Not Reported
Lovenox [Enoxaparin Sodium]	C	80 Mg Sq Bid	Not Reported
Lovenox [Enoxaparin Sodium]	C	40 Mg Sq Bid	Not Reported
Acetaminophen	C		Not Reported
Albuterol [Salbutamol]	C		Not Reported
Aspirin [Acetylsalicylic Acid]	C		Not Reported
Enoxaparin	C		Not Reported
Normal Saline	C		Not Reported
Piperacillin/Tazobactam	C		Not Reported
Potassium Chloride	C		Not Reported
Albuterol;Ipratropium	C		Not Reported
Famotidine	C		Not Reported
Fentanyl	C		Not Reported
Furosemide	C		Not Reported
Propofol	C		Not Reported
Succinylcholine	C		Not Reported
[Suxamethonium Chloride]			
Folic Acid	C		Not Reported
Lactated Ringers	C		Not Reported
Thiamine	C		Not Reported
Vecuronium	C		Not Reported
Formoterol	C		Not Reported
Iohexol	C		Not Reported
Potassium Phosphate	C		Not Reported
[Potassium Phosphate Dibasic]			
Sodium Bicarbonate	C		Not Reported
Lorazepam	C		Not Reported
Morphine	C		Not Reported
Scopolamine [Hyoscine]	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17918232	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473912		88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amlodipine			C				Not Reported

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Cholecalciferol	C	Not Reported
Cyanocobalamin	C	Not Reported
Dexamethasone	C	Not Reported
Enoxaparin	C	Not Reported
Levothyroxine	C	Not Reported
Hydromorphone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982159	DIRECT	Y				16 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982172	DIRECT	Y				24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982173	DIRECT	Y	OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S				Not Reported
	Norepinephrine			C				Not Reported
	Atorvastatin			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982174	DIRECT	Y				35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982175	DIRECT	Y	DE			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Convalescent Plasma			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982177	DIRECT	Y	HO			69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Amiodarone Drip			C				Not Reported	
	Ascorbic Acid Tablet			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Zinc Sulfate Capsule			C				Not Reported	
	Azithromycin Iv			C				Not Reported	
	Ceftriaxone Iv			C				Not Reported	
	Fentanyl Drip			C				Not Reported	
	Midazolam Drip			C				Not Reported	
	Dexamethasone Iv			C				Not Reported	
	Enoxaparin Inj			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982178	DIRECT	Y	OT			72 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Extravasation	Remdesivir			S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982179	DIRECT	Y				34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Product Dose Omission; Transcription Medication Error	Remdesivir	Y		S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982180	DIRECT	Y	DE			37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Condition Aggravated; Hepatic Failure; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			C				Not Reported	
	Convalescent Plasma			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982188	DIRECT	Y	DS, OT			76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Atorvastatin			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Metoprolol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Ticagrelor			C				Not Reported	

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Eptifibatide	C	Not Reported
Fentanyl	C	Not Reported
Heparin	C	Not Reported
Phenylephrine	C	Not Reported
Propofol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982194	DIRECT	Y	DE			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead
	Enoxaparin 90mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Levofloxacin 750mg			C				Not Reported
	Lorazepam 0.5mg			C				Not Reported
	Acetaminophen 650mg			C				Not Reported
	Dopamine Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982200	DIRECT	Y	LT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead
	Albuterol 4mg			C				Not Reported
	Cefepime 1g			C				Not Reported
	Chlorhexidine Mouthwash			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Enoxaparin 90mg			C				Not Reported
	Furosemide 20mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Linezolid 600mg			C				Not Reported
	Meropenem 1g			C				Not Reported
	Multivitamin			C				Not Reported
	Cisatracurium Drip			C				Not Reported
	Fentanyl Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported
	Propofol Drip			C				Not Reported

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Midazolam Drip		C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982201	DIRECT	Y	LT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Dialysis; General Physical Health Deterioration; Klebsiella Infection; Liver Function Test Increased; Pneumonia Bacterial; Sepsis	Remdesivir	Y		S	Intravenous (not otherwise specified)		2 DAY	Gilead	
	Amiodarone			C				Not Reported	
	Docusate Senna			C				Not Reported	
	Famotidine			C				Not Reported	
	Insulin			C				Not Reported	
	Piperacillin/Tazobactam			C				Not Reported	
	Vancomycin			C				Not Reported	
	Senna			C				Not Reported	
	Fentanyl			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Phenylephrine			C				Not Reported	
	Propofol			C				Not Reported	
	Rocuronium			C				Not Reported	
	Vasopressin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982207	DIRECT	Y	LT			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Urea Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead	
	Remdesivir	Y		S	Intravenous bolus			Gilead	
	Albuterol 4mg			C				Not Reported	
	Amlodipine 10mg			C				Not Reported	
	Ceftriaxone 1g			C				Not Reported	
	Cholhexidine Mouthwash			C				Not Reported	
	Dexamethasone 6mg			C				Not Reported	
	Enoxaparin 100mg			C				Not Reported	
	Furosemide 40mg			C				Not Reported	
	Guaifenesin 400mg			C				Not Reported	

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Pantoprazole 40mg	C	Not Reported
Miralax 17g	C	Not Reported
Sertraline 100mg	C	Not Reported
Vancomycin 1500mg	C	Not Reported
Potassium Chloride 20meq	C	Not Reported
Precedex Drip	C	Not Reported
Fentanyl Drip	C	Not Reported
Norepinephrine Drip	C	Not Reported
Propofol Drip	C	Not Reported
Versed Drip	C	Not Reported
Azithromycin 500mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982210	DIRECT	Y				16 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Famotidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2020	17982208	DIRECT	Y	OT			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2020	17982259	DIRECT	Y	OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Remdesivir			S				Not Reported

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Therapy Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2020	17982241	DIRECT	Y	DE			59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Concomitant Disease Aggravated; Covid-19	Remdesivir			S				Gilead
	Calcium Gluconate			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Pantoprazole			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2020	17982246	DIRECT	Y	DS, HO, OT			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Haemodialysis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17892593	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020- 0470929		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Zinc			C				Not Reported
	Pantoprazole			C				Not Reported
	Meropenem			C				Not Reported
	Levothyroxine			C				Not Reported
	Levetiracetam			C				Not Reported
	Hydrocortisone			C				Not Reported
	Famotidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Cipro [Ciprofloxacin]			C				Not Reported
Azithromycin			C				Not Reported	

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Ascorbic Acid	C	Not Reported
Dopamine	C	Not Reported
Norepinephrine	C	Not Reported
Vasopressin	C	Not Reported
Plasma	C	Not Reported
Nacl	C	Not Reported
Alprazolam	C	Not Reported
Calcium Gluconate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983088	DIRECT	Y	HO			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Creatinine Increased	Remdesivir Ceftriaxone Azithromycin	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983112	DIRECT	Y	OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy; Inflammation; Liver Injury	Remdesivir For Injection 100mg/Vial Azithromycin Ceftriaxone Dexamethasone			S	Intravenous bolus			Gilead Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983193	DIRECT		OT				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Pain; Infusion Site	Remdesivir (Emergency Use) 5mg/MI Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;		Gilead

Swelling; Lip Swelling;
Swollen Tongue

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983340	DIRECT		DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (Emergency Use) 5mg/MI Solution	Y		S	Intravenous (not otherwise specified)	Frequency: Q24h		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983444	DIRECT		DE				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (Emergency Use) 5mg/MI Solution	Y		S		Other Route:lv		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983447	DIRECT		DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (Emergency Use) 5mg/MI Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;Other Route:lv		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983700	DIRECT		DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir (Emergency Use) 5mg/MI Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;		Gilead

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06-Jul-2020	17983885	EXPEDITED (15-DAY)			US-GILEAD-2020-0478621			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error	Remdesivir			S	Unknown			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983929	DIRECT	Y				81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Remdesivir	Y		S	Intravenous bolus		5 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983955	DIRECT		HO, OT			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased; Oxygen Saturation Decreased; Renal Impairment	Remdesivir			S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983959	DIRECT	Y	OT			44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
	Famotidine			C				Not Reported	
	Docusate			C				Not Reported	
	Morphine			C				Not Reported	
	Furosemide			C				Not Reported	

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06-Jul-2020	17984057	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17984090	DIRECT	Y				40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Sars-Cov-1 Test Positive	Remdesivir			S	Intravenous drip			Gilead
	Budesonide 0.5 Mg Nebulizer			C				Not Reported
	Caboxymethylcellulose			C				Not Reported
	Ophthalmic Drops							
	Cisatracurium			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Aspart & Detemir			C				Not Reported
	Lpratropium-Albuterol Nebulizer			C				Not Reported
	Ketamine			C				Not Reported
	Midazolam			C				Not Reported
Norepinephrine			C				Not Reported	
Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17984415	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Prerenal Failure; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

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06-Jul-2020	17984440	DIRECT	Y	OT			57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
	Acetaminophen			C				Not Reported	
	Cefepime			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Lisinopril			C				Not Reported	
	Montelukast			C				Not Reported	
	Tamsulosin			C				Not Reported	
	Vancomycin			C				Not Reported	
	Sodium Chloride 0.9%			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17984443	DIRECT	Y				70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Dyspnoea; Pyrexia	Remdesivir			S	Intravenous drip			Gilead	
	Remdesivir			S	Intravenous drip			Gilead	
	Carboxymethylcellulose Ophthalmic Drops			C				Not Reported	
	Cisatracurium			C				Not Reported	
	Dexmedetomidine			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Fentanyl			C				Not Reported	
	Hydralazine			C				Not Reported	
	Insulin			C				Not Reported	
	Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17984445	DIRECT	Y	OT			76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous drip	Other Frequency:One Time Dose;	Gilead
	Acetaminophen	C			Not Reported
	Atorvastatin	C			Not Reported
	Dexamethasone	C			Not Reported
	Enoxaparin	C			Not Reported
	Ondansetron	C			Not Reported
	Ergocalciferol	C			Not Reported
	Zinc Sulfate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17985429	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479043		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C				Not Reported
	Ascorbate De Sodium			C				Not Reported
	Cholecalciferol			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Flonase [Fluticasone Propionate]			C				Not Reported
	Insulin			C				Not Reported
	Loratadine			C				Not Reported
	Melatonin			C				Not Reported
	Oxymetazoline			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Promethazine With Codeine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987868	DIRECT	Y				47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling; Thrombotic Thrombocytopenic Purpura	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987887	DIRECT	Y	OT			14 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Anakinra			C				Not Reported
	Clindamycin			C				Not Reported
	Cefepime			C				Not Reported
	Convalescent Plasma			C				Not Reported
	Bactrim			C				Not Reported
	Advair			C				Not Reported
	Montelukast			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987893	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Brain Death; Brain Herniation; Cerebral Infarction; Cerebrovascular Accident; Pupil Fixed; Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S				Gilead
	Atovastatin			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Clopidogrel			C				Not Reported
	Aspirin			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Amlodipine			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Heparin			C				Not Reported
	Humalog			C				Not Reported
	Lantus			C				Not Reported
	Vancomycin			C				Not Reported

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Zinc	C	Not Reported
Fentanyl Drip	C	Not Reported
Versed Drip	C	Not Reported
Nicardipine Drip	C	Not Reported
Norepinephrine Drip	C	Not Reported
Rucuronium Drip	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987900	DIRECT	Y	OT			88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip			Gilead
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ampicillin			C				Not Reported
	Dexamethasone			C				Not Reported
	Furosemide			C				Not Reported
	Sertraline			C				Not Reported
	Heparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987905	DIRECT	Y	DE			31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemodynamic Instability; Haemoglobin Decreased; Klebsiella Infection; Multiple Organ Dysfunction Syndrome;	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
Pneumonia Pseudomonal; Respiratory Failure; Thrombocytopenia	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Fentanyl			C				Not Reported
	Humalog			C				Not Reported
	Meropenem			C				Not Reported
	Methylperdnisolone Tapper Dose			C				Not Reported
	Micafungin			C				Not Reported

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Tocilizumab	C	Not Reported
Protonix	C	Not Reported
Selenium	C	Not Reported
Zinc	C	Not Reported
Vancomycin	C	Not Reported
Tpn	C	Not Reported
Heparin Drip	C	Not Reported
Levoped Drip	C	Not Reported
Versed Drip	C	Not Reported
Rocuronium Drip	C	Not Reported
Vasopressin	C	Not Reported
Fondaparinux	C	Not Reported
Heparin Subcut	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987929	DIRECT	Y	DE			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen 650mg Supp			C				Not Reported
	Azithromycin 500mg Iv			C				Not Reported
	Dexmedetomidine Drip			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	D5 Ns @ 125ml/Hr			C				Not Reported
	Docusate 100mg			C				Not Reported
	Enoxaparin 60mg Every 24 Hours			C				Not Reported
	Fentanyl 0.35-05mcg/Kg			C				Not Reported
	Guaifenesin 400mg			C				Not Reported
	Lactobacillus			C				Not Reported
	Levofloxacin 750mg			C				Not Reported
	Lorazepam			C				Not Reported
	Norepinephrine 0.05-3mcg/Kg/Min			C				Not Reported
	Pantoprazole 40mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17987937	DIRECT	Y	HO			43 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip		5 DAY	Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17988013	DIRECT	Y	HO			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Blood Urea Increased; C-Reactive Protein Increased; Chest X-Ray Abnormal; Covid-19; Dyspnoea; Interleukin Level Increased; Parosmia; Platelet Count Decreased; Respiratory Failure; Sars-Cov-2 Test Positive; Taste Disorder	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17988060	DIRECT	Y	DE			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Blood Calcium Decreased; Blood	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Every 24		Not Reported
	Remdesivir			S				Not Reported

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Creatinine Increased; Blood Sodium Decreased; Blood Urea Increased; Cardiac Arrest; Covid-19 Pneumonia; Oxygen Saturation Decreased; Renal Tubular Necrosis; Respiratory Failure; Sars- Cov-2 Test Positive; Sepsis	Albuterol Aspirin Ceftriaxone Azithromycin Enoxaparin Guaifenesin Insulin Aspart	C C C C C C C	otherwise specified) Hour;		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17988148	DIRECT	Y	OT			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sars-Cov-2 Test Positive; Vaginal Haemorrhage	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17988186	DIRECT	Y	HO			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ammonia Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Chills; Cough; Dyspnoea; Hypotension; Myalgia; Nausea; Oxygen Saturation Decreased; Platelet Count Decreased; Pneumonia Viral; Pyrexia; Renal Failure; Urine Output Decreased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17988189	DIRECT	Y	HO			16 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir 100 Mg/20 MI Iv Solution (Eua Suppl)	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab (Actemra) 800mg			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17988409	DIRECT	Y					Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17910125	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0473143		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Death; Hepatotoxicity; Hypotension; Infection; Ischaemic Hepatitis; Ischaemic Hepatitis; Liver Function Test Increased; Platelet Count Decreased; Pneumonia; Renal Impairment; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetylcysteine			C	Oral	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Levalbuterol [Levosalbutamol]			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Normal Saline			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported

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Zosyn			C			Unk			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
07-Jul-2020	17988860	DIRECT	Y				73 YR	Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		10 DAY	Gilead			
	Aspirin			C				Not Reported			
	Azithromycin			C				Not Reported			
	Ceftriaxone			C				Not Reported			
	Cisatracurium			C				Not Reported			
	Decadron			C				Not Reported			
	Digoxin			C				Not Reported			
	Fentanyl			C				Not Reported			
	Lasix			C				Not Reported			
	Heparin			C				Not Reported			
	Norepinephrine			C				Not Reported			
	Diprivan			C				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
07-Jul-2020	17988990	DIRECT	Y	OT			29 YR	Male	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Calculus Bladder; Flank Pain; Haematuria	Remdesivir			S				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
07-Jul-2020	17988996	DIRECT	Y				84 YR	Male	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Dyspnoea; Respiratory Symptom	Remdesivir			S	Intravenous (not otherwise specified)			Gilead			
	Enoxaparin 40 Mg			C				Not Reported			
	Atorvastatin 40 Mg			C				Not Reported			

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Aspirin Ec 81 Mg		C			Not Reported				
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07-Jul-2020	17989008	DIRECT	Y	OT			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; White Blood Cell Count Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
	Ammonium Lactate Topical 1 App Bid			C				Not Reported	
	Clonazepam 0.5 Mg Po Bid			C				Not Reported	
	Dexamethasone 6 Mg Po Daily			C				Not Reported	
	Divalproex Sodium 125 Mg Ec Tablet Po Tid			C				Not Reported	
	Levetiracetam 1000 Mg Po Hs			C				Not Reported	
	Mirtazapine 15 Mg Dis Tablet Po Hs			C				Not Reported	
	Lactulose 40 G Po Bid Prn			C				Not Reported	
	Melatonin 15 Mg Po Hs			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989012	DIRECT	Y				53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead	
	Hydrocodone-Homatropine 5- 1.5mg			C				Not Reported	
	Bactrim Ds			C				Not Reported	
	Cephalexin 500mg			C				Not Reported	
	Insulin Lispro 4 Units			C				Not Reported	
	Insulin Glargine 6 Units			C				Not Reported	
	Benzonatate 200mg			C				Not Reported	
	Acetaminophen 650mg			C				Not Reported	
	Enoxaparin 40mg			C				Not Reported	
	Dexamethasone 6mg Iv			C				Not Reported	
Albuterol 2.5mg Inh			C				Not Reported		

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989536	DIRECT	Y	OT			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Tenderness; Anorectal Discomfort; Hypophagia; Nausea; Oral Candidiasis; Oral Discomfort; Oral Discomfort; Therapy Cessation; Tongue Discomfort	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin 10mg			C				Not Reported
	Diltiazem 240mg Cd			C				Not Reported
	Famotidine 20mg			C				Not Reported
	Flecainide 150mg			C				Not Reported
	Hydrochlorothiazide 12.5 Mg			C				Not Reported
	Metoprolol 25mg			C				Not Reported
	Nystatin 5ml Oral Suspension			C				Not Reported
	Omeprazole 40mg			C				Not Reported
	Potassium			C				Not Reported
	Prednisone 40mg			C				Not Reported
Rivaroxaban 20mg			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989541	DIRECT	Y	DE			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Acute Respiratory Failure; Bradycardia; Cardiac Arrest; Chest Pain; Confusional State; Electrocardiogram Abnormal; Hypoxia; Metabolic Encephalopathy; Pneumonia Viral; Pulse Absent; Pulseless Electrical Activity;	Remdesivir			S	Intravenous bolus			Gilead

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Troponin Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989579	DIRECT		OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Amiodarone 200mg Po Daily			C				Not Reported
	Aspirin 162mg Po Daily			C				Not Reported
	Dexamethasone 8mg Ivp Daily			C				Not Reported
	Dexmedetomidine Iv Drip			C				Not Reported
	Dexamethasone 6mg Ivp Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989582	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479372		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Rosuvastatin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Tocilizumab			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989584	DIRECT		OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin 40mg Sq Daily			C				Not Reported
	Aspirin 162mg Po Daily			C				Not Reported

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Dexamethasone 8mg Ivp Daily	C	Not Reported
Dexmedetomidine Iv Drip	C	Not Reported
Furosemide 40mg Ivp Bid	C	Not Reported
Dexamethasone 6mg Ivp Daily	C	Not Reported
Norepinephrine Iv Drip	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989596	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479362		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Bio K Plus			C				Not Reported
	Insulin Lispro			C				Not Reported
	Famotidine			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Lorazepam			C				Not Reported
	Hydromorphone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989615	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0479459		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Unknown	Unk		Gilead
	Alprazolam			C				Not Reported
	Anakinra			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Metoprolol			C				Not Reported
	Potassium Chloride			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17989632	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0479491		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Cholecalciferol			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Dexamethasone			C				Not Reported
Enoxaparin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17990947	EXPEDITED (15-DAY)			US-GILEAD-2020-0479511		34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Dose Omission; Product Dispensing Error	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	200 Mg		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993587	DIRECT	Y	DE			45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inflammatory Marker Increased; Pulseless Electrical Activity; Suspected Covid-19	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remedesivir			C				Not Reported
	Nimbex			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported

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Dexamethasone	C	Not Reported
Cefepime	C	Not Reported
Azithromycin	C	Not Reported
Ceftriaxone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993623	DIRECT	Y	DE			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous bolus			Gilead
	Ceftriaxone 1 Gm Iv			C				Not Reported
	Albuterol-Ipratropium 3 MI			C				Not Reported
	Apixaban 2.5 Mg			C				Not Reported
	Azithromycin 500 Mg Tab			C				Not Reported
	Dexamethasone 6 Mg Tab			C				Not Reported
	Famotidine 20 Mg Iv			C				Not Reported
	Metoprolol 50 Mg Tab			C				Not Reported
	Fentanyl Iv			C				Not Reported
	Norepinephrine Iv			C				Not Reported
Propofol Iv			C				Not Reported	
Vasopressin Iv			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993627	DIRECT	Y	HO			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir	Y		S				Gilead
	Sulfasalazine			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxazosin			C				Not Reported
	Benazepril			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993645	DIRECT	Y	HO, LT, OT			59 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Dialysis; Hyperkalaemia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993651	DIRECT	Y				74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993658	DIRECT	Y				70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir (Eua)			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amlodipine (Norvasc) Tablet 2.5 Mg			C				Not Reported
	Ascorbic Acid (Vitamin C) (Vitamin C) Tablet 500 Mg			C				Not Reported
	Aspirin Tablet 325 Mg			C				Not Reported
	Atorvastatin (Lipitor) Tablet 80 Mg			C				Not Reported
	Ceftriaxone (Rocephin) 2 Gm In Dextrose 5 % 100 MI Ivpb			C				Not Reported
	Azithromycin (Zithromax) 500 Mg In Dextrose 5 % In Water (D5w) 250 MI			C				Not Reported
	Dexamethasone (Decadron) Tablet 6 Mg			C				Not Reported
	Enoxaparin (Lovenox) 40 Mg/0.4 MI Injection 40 Mg			C				Not Reported
	Famotidine (Pepcid) 20 Mg In Sodium Chloride (Pf) 0.9 % Iv			C				Not Reported
	Guaifenesin (Mucinex) 12 Hr Tablet 600 Mg			C				Not Reported

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Mirtazapine (Remeron) Tablet 45 Mg	C	Not Reported
Pramipexole (Mirapex) Tablet 0.375 Mg	C	Not Reported
Tamsulosin (Flomax) 24 Hr Capsule 0.8 Mg	C	Not Reported
Thiamine Mononitrate (Vit B1) Tablet 100 Mg	C	Not Reported
Zinc Sulfate (Zincate) Capsule 220 Mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993663	DIRECT	Y				51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993705	DIRECT	Y	RI, OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S				Gilead
	Ceftazidime 2 G (Fortaz/Tazicef)			C				Not Reported
	Albuterol 90 Meg/Actuation Hfa Mdi 4 Puff (Proair/Proventilnentolin)			C				Not Reported
	Pecid 20mg			C				Not Reported
	Fentanyl (Pf) In Ns 10 Mcg/MI Iv Soln			C				Not Reported
	Haloperidol Lactate In] 2 Mg (Haldol) :			C				Not Reported
	Lorazepam In] 2 Mg (Ativan)			C				Not Reported
	Midazolam (Pf) In] 2 Mg (Versed)			C				Not Reported

Norepinephrine In Ns 8 Mg/250 MI (32 Mcg/MI) Lv Premix	C	Not Reported
Phenylephrine 200 Mg In Sodium Chloride 0.9% 250 MI Iv Soln	C	Not Reported
Quetiapine Tab 25 Mg (Seroquel) :	C	Not Reported
Vancomycin Per Protocol	C	Not Reported
Venlafaxine Tab 75 Mg (Effexor)	C	Not Reported
Azithromycin 500mg (Zithromax)	C	Not Reported
Ceftriaxone Add Vial 2 G (Rocephin)	C	Not Reported
Lasix 40mg	C	Not Reported
Vecuronium Inj 7.5 Mg (Norcuron)	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993808	DIRECT	Y	OT			46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Enoxaparin 150 Mg			C				Not Reported
	Hydralazine			C				Not Reported
	Ceftriaxone 1 Gm			C				Not Reported
	Insulin Glargine			C				Not Reported
	Dexamethasone 10 Mg			C				Not Reported
	Heparin 5000			C				Not Reported
	Acetaminophen 650			C				Not Reported
	Insulin Lispro			C				Not Reported
	Albuterol			C				Not Reported
	Mometasone			C				Not Reported
	Ondansetron			C				Not Reported
	Aromatic Inhaler			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993885	DIRECT	Y				75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Nausea; Vomiting	Remdesivir	S	Intravenous bolus	Other Frequency:Once;	Gilead
	Doxycycline	C			Not Reported
	Convalescent Plasma	C			Not Reported

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08-Jul-2020	17877952	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470593		74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumothorax; Pseudomonal Bacteraemia	Blinded Placebo			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Blinded Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Blinded Tocilizumab			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ceftriaxone			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Ketamine			C		Unk		Not Reported
	Ativan			C				Not Reported
	Morphine			C				Not Reported
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17882304	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0470944		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactic Acid Increased; Bronchiectasis; Death;	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported

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Emphysema; Fibrin D Dimer Increased; Inflammatory Marker Increased; Oxygen Consumption Increased; Pulmonary Embolism; Shock Symptom	Doxycycline	C	Unk	Not Reported
	Ceftriaxone	C	Unk	Not Reported
	Docusate Sodium	C	Unk	Not Reported
	Donepezil	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Fluoxetine	C	Unk	Not Reported
	Melatonin	C	Unk	Not Reported
	Omeprazole	C	Unk	Not Reported
	Potassium Chloride	C	Unk	Not Reported
	Propofol	C	Unk	Not Reported
	Risperidone	C	Unk	Not Reported
	Senna [Senna Alexandrina]	C	Unk	Not Reported
	Quetiapine	C	Unk	Not Reported
	Polyethylene Glycol [Macrogol]	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Heparin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17917676	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473055		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Enoxaparin			C				Not Reported
	Miralax			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Solu-Medrol			C				Not Reported
	Synthroid			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17993892	DIRECT	Y	OT			37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994296	DIRECT	Y	LT			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported
	Methylprednisilone			C				Not Reported
	Lisinopril/Hctz 20/25mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994533	DIRECT	Y	HO, OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Condition Aggravated; Sepsis; Therapy Interrupted	Remdesivir			S				Not Reported
	Methylprednisolone			C				Not Reported
	Furosemide			C				Not Reported
	Dexmedatomidine			C				Not Reported
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994568	DIRECT		DE			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir	Y		S				Gilead
	Allopurinol			C				Not Reported
	Methotrxate			C				Not Reported

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Pravastatin	C	Not Reported
Valsartan	C	Not Reported
Nebumetone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994788	DIRECT	Y	LT			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Disorientation; Dyspnoea; Tachycardia; Tachypnoea	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994791	DIRECT	Y	DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Hypotension; Hypoxia; Respiratory Disorder; Septic Shock; Tachycardia; Tachypnoea	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994796	DIRECT	Y	DE			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Aspartate	Remdesivir			S	Intravenous drip			Gilead
Aminotransferase Increased; Atrial Fibrillation; Body Temperature Increased; Cardiac Arrest; Death; Hypercapnia; Hypoxia;	Diamox			C				Not Reported
Otorrhoea; Oxygen Saturation Decreased; Streptococcus Test	Human Albumin			C				Not Reported
	Cefepime			C				Not Reported
	Rocephine			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994799	DIRECT	Y	HO, OT			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir	Y		S	Intravenous bolus			Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Dutasteride			C				Not Reported
	Enoxaparin			C				Not Reported
	Ezetimibe			C				Not Reported
	Pantoprazole			C				Not Reported
	Fentanyl			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17994804	DIRECT	Y	HO, OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin Aspart/ Ssi			C				Not Reported
	Midodrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Fentanyl			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17995004	DIRECT	Y	DE, HO			66 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17995169	DIRECT	Y	OT			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
Insulin Nph			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17995173	DIRECT	Y	DE			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous drip		1 DAY	Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17995201	DIRECT	Y	OT			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Benzonatate 100mg Q8h			C				Not Reported
	Zyrtex 10mg Q24h			C				Not Reported
	Dexamethasone 6mg Qday			C				Not Reported
	Enoxaparin 40mg Q12h			C				Not Reported
	Famotidine 20mg Q12h			C				Not Reported
	Guaifenisin 600mg Q12h			C				Not Reported

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Insulin	C	Not Reported
Levothyroxine	C	Not Reported
Miralax	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17995224	DIRECT	Y	OT			40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Sars-Cov-2 Test Positive	Remdesivir For Eua			S				Not Reported
	Acetaminophen			C				Not Reported
	Trental			C				Not Reported
	Thiamine			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Nicoderm Cq			C				Not Reported
	Theradex-M			C				Not Reported
	Novolog			C				Not Reported
	Robitussin			C				Not Reported
	Folic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Aspirin			C				Not Reported
	Vitamin C			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17996062	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480084		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17996089	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479988			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not	200 Mg, Qd		Gilead

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Remdesivir	S	otherwise specified) Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Enoxaparin	C	Subcutaneous	30 Mg, Bid	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
Azithromycin	C	Oral	500 Mg, Qd	Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17996184	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0479551		43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead
	Blood Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Oxygen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17996766	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480078		32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Hypercapnia; Hypoxia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Zinc			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported

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08-Jul-2020	17997341	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0480039		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Bilirubin Increased; Coagulopathy; Fibrin D Dimer Increased; Inflammation; Liver Injury; Prothrombin Time Prolonged; Serum Ferritin Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk Unk, Qd		Gilead	
	Azithromycin			C		Unk		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Dexamethasone			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17997547	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480700		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Thrombocytopenia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17997766	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479946		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead	
	Atorvastatin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Ampicillin			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Furosemide			C				Not Reported	
	Sertraline			C				Not Reported	
	Heparin			C				Not Reported	

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08-Jul-2020	17998717	DIRECT	Y	OT			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flushing; Lacrimation Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998751	DIRECT	Y				16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir Dexamethasone Famotadine Azithromycin Ondansetron Acetaminophen			S C C C C C	Intravenous (not otherwise specified)			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998765	DIRECT	Y	DE			52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypoxia; Pulseless Electrical Activity	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998772	DIRECT	Y				32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Therapy	Remdesivir			S	Intravenous drip			Gilead	

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Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998777	DIRECT	Y				76 YR	Female	PRI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Phlebitis	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998781	DIRECT	Y	DE			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lactic Acidosis; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Heparin Sodium			C				Not Reported
	Cefuroxime Axetil			C				Not Reported
	Vancomycin			C				Not Reported
	Furosemide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998787	DIRECT	Y	DE			87 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Enoxaparin 40 Mg Daily			C				Not Reported
	Enoxaparin 40 Mg Bid			C				Not Reported
	Furosemide 20 Or 40 Mg			C				Not Reported

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Carvediol 25mg Bid	C	Not Reported
Ceftriaxone 2 Gm Daily	C	Not Reported
Azithromycin 500mg Daily	C	Not Reported
Levothyroxine 88mcg Daily	C	Not Reported
Escitalopram 20 Mg Daily	C	Not Reported
Aspirin 325 Mg Daily	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	17877683	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469518		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin 2			C		Unk		Not Reported
	Linezolid			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Lorazepam			C				Not Reported
	Phenylephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	17910384	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0472974		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acidosis; Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Decreased; Death; Encephalopathy; Pneumonia Bacterial; Renal Failure; Renal Tubular Necrosis; Respiratory Failure; Sepsis; Shock	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Unk	Gilead
	Acetaminophen	C		Unk	Not Reported
	Albuterol [Salbutamol]	C		Unk	Not Reported
	Ascorbic Acid	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Guaifenesin And Dextromethorphan	C		Unk	Not Reported
	Hydrocodone/Acetaminophen	C		Unk	Not Reported
	Orphenadrine	C		Unk	Not Reported
	Zinc Sulfate	C		Unk	Not Reported
	Cisatracurium	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Lubricant Eye Ointment	C		Unk	Not Reported
	Lorazepam	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Propofol	C		Unk	Not Reported
	Succinylcholine [Suxamethonium]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	17960463	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLABS-2020M1059896			Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Furosemide			S		Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Mylan

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Paracetamol	C	Oral	Unk	Mylan
Noradrenaline /00127502/	C	Intravenous (not otherwise specified)	Unk	Mylan
Remifentanyl	C	Intravenous (not otherwise specified)	Unk	Mylan
Ceftriaxon	C	Intravenous (not otherwise specified)	Unk	Mylan
Movicolon	C	Oral	Unk	Mylan
Nadroparin	C	Subcutaneous	Unk	Mylan
Cisatracurium	C	Intravenous (not otherwise specified)	Unk	Mylan
Propofol	C	Intravenous (not otherwise specified)	Unk	Mylan
Supradyn /07499601/	C	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	17999429	DIRECT	Y	OT			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Choking Sensation; Dyspnoea; Lip Swelling	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin 500mg Daily			S				Not Reported
	Rocephin 1g Twice Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Zyrtec 10mg Daily			C				Not Reported
	Duo Nebs			C				Not Reported
	Amlodipine 5mg Daily			C				Not Reported
	Ascorbic Acid 500mg Q12			C				Not Reported
	Colace			C				Not Reported
	Lovenox 40mg Daily			C				Not Reported
	Flonase Daily			C				Not Reported
	Singulair 10mg Daily			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	17999519	DIRECT	Y				57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Product Dispensing Error; Product Preparation Error; Product Preparation Issue	Remdesivir			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	17999532	DIRECT	Y	OT			35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S			2 DAY	Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18000460	DIRECT	Y				66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cardiac Arrest; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Dexamethasone			C			Not Reported		
	Enoxaparin			C			Not Reported		
	Furosemide			C			Not Reported		
	Heparin			C			Not Reported		
	Insulin Glargine			C			Not Reported		
	Linezolid			C			Not Reported		
	Losartan			C			Not Reported		
	Meropenem			C			Not Reported		
	Metoprolol Succinate			C			Not Reported		
Nitroglycerin Topical			C		Not Reported				
Norepinephrine Infusion			C		Not Reported				

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Ondansetron	C	Not Reported
Pantoprazole	C	Not Reported
Piperacillin-Tazobactam	C	Not Reported
Propofol Infusion	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Vancomycin	C	Not Reported
Acetaminophen	C	Not Reported
Hydrocodone/Acetaminophen	C	Not Reported
Amlodipine	C	Not Reported
Aspirin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18000529	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Cardiac Arrest; Cardio- Respiratory Arrest; Haemodynamic Instability	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Albuterol Neb			C				Not Reported
	Levaquin 750mg/150ml Iv Q24h			C				Not Reported
	Losartan 100mg 1qd			C				Not Reported
	Solu-Medrol 80 Iv Push			C				Not Reported
	Decadron 6mg Qd			C				Not Reported
	Furosemide 40mg Once			C				Not Reported
	Etomidate 10 Mg Once			C				Not Reported
	Hydrochlorothiazide 25mg 1qd			C				Not Reported
	Heparin 5,000 Units			C				Not Reported
	Lorazepam 1mg			C				Not Reported
	Pantoprazole 40mg Daily			C				Not Reported
	Fentanyl 50mcg Q1hprn			C				Not Reported
	Humalog 6 Units Once			C				Not Reported
	Midazolam			C				Not Reported
	Epinephrine 1mg Iv			C				Not Reported
	Norepinephrine 16mg Iv			C				Not Reported
	Phenylephrine 10mg Iv			C				Not Reported
	Vasopressin 20 Units Iv			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18000543	DIRECT	Y	OT			61 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Remdesivir			S				Not Reported
Aminotransferase	Miralax			C				Not Reported
Increased	Lactated Ringer			C				Not Reported
	Warfarin			C				Not Reported
	Norepinephrine 8 Mg			C				Not Reported
	Insulin Glargine			C				Not Reported
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Gabapentin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18000773	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0479976		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation; Swelling; Thrombotic Thrombocytopenic Purpura	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18000951	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0480889		82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Unknown	Unk		Gilead
	Allopurinol			C				Not Reported
	Methotrexate			C				Not Reported
	Pravastatin			C				Not Reported
	Valsartan			C				Not Reported
	Nabumetone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18001006	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0480755		43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hepatic Enzyme Increased	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18001041	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0480947		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			S	Intravenous (not otherwise specified)	2 G, Once		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1250 Mg, Tid		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Pantoprazole			C				Not Reported
	Atorvastatin			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Albumin			C				Not Reported
	Thiamine			C				Not Reported
	Furosemide			C				Not Reported
	Lantus			C				Not Reported
	Multivitamin With Minerals			C				Not Reported
Ezetimibe			C				Not Reported	
Hydrochlorothiazide;Irbesartan			C				Not Reported	
Isosorbide Mononitrate			C				Not Reported	
Tamsulosin			C				Not Reported	
Ceftriaxone			C				Not Reported	
Enoxaparin			C				Not Reported	

Azithromycin	C	Not Reported
Cefepime	C	Not Reported
Fentanyl	C	Not Reported
Propofol	C	Not Reported
Midazolam	C	Not Reported
Levophed	C	Not Reported
Vasopressin	C	Not Reported
Lactulose	C	Not Reported
Nimbex [Nimesulide]	C	Not Reported
Linezolid	C	Not Reported
Meropenem	C	Not Reported
Hydrocortisone	C	Not Reported
Amiodarone	C	Not Reported
Heparin	C	Not Reported
Rifaximin	C	Not Reported
Phenylephrine	C	Not Reported
Micafungin	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Oxygen	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18001053	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0480857		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Cephalexin [Cefalexin]			C				Not Reported
	Gabapentin			C				Not Reported
	Meloxicam			C				Not Reported
	Metoprolol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Decadron [Dexamethasone]			C				Not Reported
	Enoxaparin			C				Not Reported
	Folic Acid			C				Not Reported
	Thiamine			C				Not Reported
	Doxycycline			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Lactulose			C				Not Reported

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Levophed	C	Not Reported
Acetylcysteine	C	Not Reported
Albumin	C	Not Reported
Fentanyl	C	Not Reported
Rifaximin	C	Not Reported
Heparin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004849	DIRECT	Y	OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Aromatic Inhaler			C				Not Reported
	Benzanotate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Tussionex			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Guanfenesin			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported
	Metoprolol			C				Not Reported
	Nortriptyline			C				Not Reported
	Odnansetron			C				Not Reported
	Potassium Bicarbonate			C				Not Reported
	Temazepam			C				Not Reported
	Terazosin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004869	DIRECT	Y	OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous drip			Gilead

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09-Jul-2020	18004873	DIRECT	Y	OT			47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment; Urinary Tract Infection	Remdesivir			S	Intravenous bolus			Not Reported
	Baclofen 5mg Peg Tid			C				Not Reported
	Benzotropine 1mg Peg Bid			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Docusate 100mg Peg Bid			C				Not Reported
	Enoxaparin 40mg Subcut Daily			C				Not Reported
	Ferrous Sulfate 325mg Peg Daily			C				Not Reported
	Gabapentin 300mg Peg Bid			C				Not Reported
	Heparin 5,000 Unit Subcut Q8h			C				Not Reported
	Lacosamide 150mg Peg Bid			C				Not Reported
	Levetiracetam 1000mg Peg Bid			C				Not Reported
	Levofloxacin 750mg Iv Q24h			C				Not Reported
	Linezolid 600mg Iv Q12h			C				Not Reported
	Magnesium Hydroxide 8% Susp 30ml Oral Bid			C				Not Reported
	Mirtazapine 30mg Peg Qbedtime			C				Not Reported
Olanzapine 20mg Peg Bid			C				Not Reported	
Prazosin 1mg Peg Qbedtime			C				Not Reported	
Senna 8.6mg Peg Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004892	DIRECT	Y	OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Eye Irritation; Infusion Related Reaction; Nausea	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Enoxaparin 40mg Subq Q24h			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004899	DIRECT	Y				82 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Atrial Fibrillation; Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Azithromycin 500 Mg Po Daily			C		Not Reported		
	Ceftriaxone 1 Gram Iv Q24h			C		Not Reported		
	Famotidine 20 Mg Iv Q12h			C		Not Reported		
	Methylprednisolone 20 Mg Iv Q6h			C		Not Reported		
	Fentanyl 50 Mcg/Hr			C		Not Reported		
	Heparin 1200 Unit/Hr			C		Not Reported		
	Norepinephrine 4 Mg/250 MI Titrated			C		Not Reported		
	Propofol 20 Mcg/Kg/Min			C		Not Reported		
	Amiodarone 450 Mg/250 MI Titrated			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004907	DIRECT	Y	OT			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Nausea	Remdesivir			S	Intravenous bolus			Not Reported
	Budesonide 0.5mg Neb Q12h			C		Not Reported		
	Dexamethasone 6mg Iv Daily			C		Not Reported		
	Docusate 100mg Po Bid			C		Not Reported		
	Insulin Glargine 10 Unit Subcut Qbedtime			C		Not Reported		
	Insulin Lispro Sliding Scale			C		Not Reported		
	Senna 8.6mg Po Daily			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004916	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Cirrhosis; Hepatic Steatosis; Hyperlipidaemia	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported
	Ascorbic Acid 500mg Po Daily			C			Not Reported	
	Dexamethasone 6mg Iv Daily			C			Not Reported	

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Lactulose 20g Po Q6h	C	Not Reported
Rifaximin 550mg Po Bid	C	Not Reported
Zinc Sulfate 220mg Po Daily	C	Not Reported

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09-Jul-2020	18004976	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure	Remdesivir			S	Intravenous bolus			Not Reported
	Acorbic Acid 500mg Oral Daily			C				Not Reported
	Azithromycin 500mg Daily			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Clonazepam 0.5mg Oral Bid			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 40mg Subcut Daily			C				Not Reported
	Hydrochlorothiazine 12.5mg Oral Daily			C				Not Reported
	Levothyroxine 137mcg Oral Daily			C				Not Reported
	Methocarbamol 750mg Oral Qid			C				Not Reported
	Valsartan 80mg Oral Daily			C				Not Reported
	Zinc Sulfate 220mg Oral Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004983	DIRECT	Y	OT			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin 500 Mg Iv Q24h			C				Not Reported
	Cefepime 2 Gm Iv Q12h			C				Not Reported
	Dexamethasone 6 Mg Iv Q24h			C				Not Reported
	Famotidine 20 Mg Iv Q12h			C				Not Reported
	Heparin Sodium 5,000 Units Sq Q8h			C				Not Reported
	Magnesium Sulfate 4 Gm Iv			C				Not Reported
	Vancomycin			C				Not Reported
	Hydromorphone Iv			C				Not Reported
	Norepinephrine			C				Not Reported

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09-Jul-2020	18004990	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cardio-Respiratory Arrest	Remdesivir			S	Intravenous bolus			Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Budesonide 0.5mg Nebulized Bid			C				Not Reported
	Cefepime 2mg Iv Q12h			C				Not Reported
	Ceftriaxone 2g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Docusate 100mg Oral Bid			C				Not Reported
	Pantoprazole 40mg Oral Daily			C				Not Reported
	Senna 8.6mg Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18004996	DIRECT	Y	OT			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S				Gilead
	Senna			C				Not Reported
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18005004	DIRECT	Y				46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Condition Aggravated; Nonalcoholic Fatty Liver Disease; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 500 Mg Po Daily			C				Not Reported
	Ceftriaxone 1 Gram Iv Q24h			C				Not Reported
	Dexamethasone 4 Mg Iv Daily			C				Not Reported
	Doxycycline 100 Mg Po Bid			C				Not Reported

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Guaifenesin Er 600 Mg Po Bid
Zinc Sulfate 220 Mg Po Daily

C
C

Not Reported
Not Reported

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09-Jul-2020	18005627	DIRECT	Y				74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S				Not Reported
	Fentanyl			C				Not Reported
	Propotol			C				Not Reported
	Tylenol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Famotidine			C				Not Reported
	Atrvastin			C				Not Reported
	Enoxaparin			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Heparin			C				Not Reported
	Zofran			C				Not Reported
	Calquence			C				Not Reported
	Lasix			C				Not Reported
Potassium Chloride Fluid			C				Not Reported	
Sodium Chloride Fluid			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	18005852	DIRECT	Y				44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Infusion Related Reaction	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17867998	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469207		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase	Remdesivir			S	Intravenous (not	100 Mg, Qd		Gilead

Increased				otherwise specified)					
	Albuterol;Ipratropium	C			Unk				Not Reported
	Famotidine	C			Unk				Not Reported
	Sennosides	C			Unk				Not Reported
	Docusate	C			Unk				Not Reported
	Insulin Lispro	C			Unk				Not Reported
	Epoprostenol	C							Not Reported
	Norepinephrine	C			Unk				Not Reported
	Heparin	C			Unk				Not Reported
	Methylprednisolone	C			Unk				Not Reported
	Midodrine	C			Unk				Not Reported
	Ampicillin	C			Unk				Not Reported
	Metolazone	C			Unk				Not Reported
	Ketamine	C			Unk				Not Reported
	Hydromorphone	C			Unk				Not Reported
	Cisatracurium	C			Unk				Not Reported
	Tylenol	C							Not Reported
	Acetaminophen	C							Not Reported
	Acetazolamide	C							Not Reported
	Ampicillin And Sulbactam	C							Not Reported
	Aspirin [Acetylsalicylic Acid]	C							Not Reported
	Calcium Gluconate	C							Not Reported
	Enoxaparin	C							Not Reported
	Insulin Nph [Insulin Isophane Bovine]	C							Not Reported
	Lorazepam	C							Not Reported
	Oxycodone	C							Not Reported
	Potassium	C							Not Reported
	Prednisone	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17877788	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470621		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Respiratory Failure; Cardiac Arrest; Covid-19; Septic Shock	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Famotidine	C		Unk	Not Reported
	Kayexalate	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Rocuronium	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17877916	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470625		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Hypoxia; Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Convalescent Plasma			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Tocilizumab			C				Not Reported
	Acetaminophen			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Tmp-Smx			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17886205	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0471139		90 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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Increased; Blood Creatinine Increased	Ascorbic Acid	C	Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unk	Not Reported
	Atorvastatin	C	Unk	Not Reported
	Cholecalciferol	C	Unk	Not Reported
	Codeine And Guaifenesin	C	Unk	Not Reported
	Docusate	C	Unk	Not Reported
	Enoxaparin	C	Unk	Not Reported
	Fentanyl	C	Unk	Not Reported
	Furosemide	C	Unk	Not Reported
	Hydralazine	C	Unk	Not Reported
	Insulin	C	Unk	Not Reported
	Levetiracetam	C	Unk	Not Reported
	Levothyroxine	C	Unk	Not Reported
	Multivitamin [Vitamins Nos]	C	Unk	Not Reported
	Pantoprazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17887728	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469658		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Symbicort			C				Not Reported
	Asa			C				Not Reported
	Lipitor [Atorvastatin]			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Zetia			C				Not Reported
	Insulin			C				Not Reported
	Albuterol Sulfate			C				Not Reported
	Bumex			C				Not Reported
	Ferrous Sulfate			C				Not Reported
	Gabapentin			C				Not Reported
	Glipizide			C				Not Reported

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Metoprolol	C	Not Reported
Oxycodone	C	Not Reported
Santyl	C	Not Reported
Toujeo Solostar	C	Not Reported
Losartan	C	Not Reported
Tylenol	C	Not Reported
Proventil Hfa [Salbutamol Sulfate]	C	Not Reported
Ventolin Hfa	C	Not Reported
Aspirin (E.C.)	C	Not Reported
Bisacodyl	C	Not Reported
Dextrose	C	Not Reported
Dyclonine	C	Not Reported
Ezetimibe	C	Not Reported
Heparin	C	Not Reported
Honey	C	Not Reported
Insulin Lispro	C	Not Reported
Magnesium Hydroxide	C	Not Reported
Mirtazapine	C	Not Reported
Morphine	C	Not Reported
Zofran Melt	C	Not Reported
Sodium Chloride	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17892605	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0471871		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Hypoxia; Tachycardia; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Diphenhydramine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Zinc Gluconate			C		Unk		Not Reported

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Prednisone C Unk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17902208	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470939		79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Bilirubin Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C				Not Reported
	Cisatracurium			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Insulin			C				Not Reported
	Ketamine			C				Not Reported
	Methylprednisolone			C				Not Reported
	Norepinephrine			C				Not Reported
	Zosyn			C				Not Reported
	Propofol			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Potassium			C				Not Reported
	Prednisone			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	17964459	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477229		85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

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10-Jul-2020	18006250	DIRECT	Y	OT			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Aspirin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lovenox			C				Not Reported
	Lopressor			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006415	DIRECT		OT			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Clonidine 0.1mg Po Q6h Prn			C				Not Reported
	Alprazolam 0.25mg Po Qhs Prn			C				Not Reported
	Tocilizumab Iv 800mg Once			C				Not Reported
	Ascorbic Acid 500mg Po Bid			C				Not Reported
	Zinc Sulfate 220mg Po Daily			C				Not Reported
	Dexamethasone 6mg Ivp Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006881	DIRECT	Y	OT			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous bolus	Other Frequency:X 1;		Gilead
	Methylprednisilone			C				Not Reported
	Fentanyl			C				Not Reported
	Ceftriaxone			C				Not Reported
	Doxycycline			C				Not Reported

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Enoxaparin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006887	DIRECT	Y				54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Respiratory Disorder; Transaminases Increased	Remdesivir			S	Intravenous drip			Gilead	
	Dexamethasone			C				Not Reported	
	Azithromycin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006892	DIRECT	Y	OT			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006963	DIRECT	Y				75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Acetaminophen 1000 Mg Po Q8h			C				Not Reported	
	Aspirin Chewable 81 Mg Po Daily			C				Not Reported	
	Aztreonam 2,000 Mg Iv Q8h			C				Not Reported	
	Clindamycin 600 Mg Iv Q8h			C				Not Reported	
	Dexamethasone 6 Mg Iv Daily			C				Not Reported	
	Enoxaparin 40 Mg Subq Nightly			C				Not Reported	
	Breo Ellipta 200/25 Mcg 1 Puff			C				Not Reported	

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Inh Daily									
Lactobacillus Capsule Po Twice Daily			C						Not Reported
Lidocaine 5% Transdermal Patch Daily			C						Not Reported
Pantoprazole 40 Mg Iv Daily			C						Not Reported
Polyethylene Glycol 17 G Po Daily			C						Not Reported
Potassium Chloride 40 Meq Iv Once			C						Not Reported
Senna-Docusate 8.6/50 Mg Po Daily			C						Not Reported
Spiriva Inhalation Capsule 18 Mcg Daily			C						Not Reported
Remdesivir Injection			C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006967	DIRECT	Y	OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Dexamethasone Iv			C				Not Reported
	Amiodarone Iv			C				Not Reported
	Phenylephrine Iv			C				Not Reported
	Norepinephrine			C				Not Reported
	Vecuronium			C				Not Reported
	Midazolam Iv			C				Not Reported
	Vasopressin			C				Not Reported
	Propofol			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantoprazole			C				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18006971	DIRECT	Y				68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Abdominal Abscess; Leukocytosis; Peritonitis; Pneumoperitoneum	Tocilizumab Remdesivir Dexamethasone 6mg Po Daily	S S S	Intravenous bolus	Other Frequency:Once;	Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18007445	DIRECT	Y	OT			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Remdesivir			S C			5 DAY	Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18009496	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0481284		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Pulseless Electrical Activity	Remdesivir Tocilizumab Dexamethasone Enoxaparin			S C C C	Unknown	Unk		Gilead Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18010203	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0481436		16 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Dexamethasone			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported

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Ondansetron	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18010787	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0481389		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Renal Impairment	Remdesivir			S	Unknown	Unk		Gilead
	Sulfasalazine			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Doxazosin			C		Unk		Not Reported
	Benazepril			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18010799	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0481317		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012558	DIRECT	Y	DE			83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Covid-19 Pneumonia; Dyspnoea; Tachypnoea	Remdesivir			S	Intravenous bolus			Gilead

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10-Jul-2020	18012559	DIRECT	Y				46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extravasation	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012560	DIRECT	Y	OT			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Malfunction; Product Dose Omission	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012572	DIRECT	Y	DE			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; Asthenia; Blood Bilirubin Increased; Blood Creatinine Increased; Cardiac Arrest; Confusional State; Diarrhoea; Fall; Hypotension; Hypothermia; Nausea; Pulmonary Oedema; Respiration Abnormal; Respiratory Arrest; Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012577	DIRECT	Y	HO			69 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Albuterol Mdi			C				Not Reported
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Lidoderm Patch			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
Rocephin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012582	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Glomerular Filtration Rate Decreased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012588	DIRECT	Y	OT			31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012595	DIRECT	Y	OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Sars-Cov-2	Remdesivir			S	Intravenous bolus			Gilead

Test Positive; Therapy
Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012601	DIRECT	Y	DE			86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Palliative Care	Remdesivir			S	Intravenous drip			Gilead	
	Dexmedetomidine			C				Not Reported	
	Insulin			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Potassium Chloride			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012606	DIRECT	Y	DE			41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous drip			Gilead	
	Cisatracurium			C				Not Reported	
	Fentanyl			C				Not Reported	
	Insulin			C				Not Reported	
	Ketamine			C				Not Reported	
	Midazolam			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012608	DIRECT	Y	DE			82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous drip			Gilead	
	Remdesivir			S	Intravenous drip			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012610	DIRECT	Y	OT			41 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Anakinra			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012616	DIRECT	Y	HO			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Pancreatitis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S		Intravenous (not otherwise specified)		Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Escitalopram			C				Not Reported
	Toprol X L			C				Not Reported
	Protonix			C				Not Reported
	Humalog Sliding Scale			C				Not Reported
Gabapentin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012811	DIRECT	Y				31 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Transaminases Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18012935	DIRECT	Y				60 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir Dexamethasone			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2020	18012653	DIRECT	Y				59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2020	18012654	DIRECT	Y	DE			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2020	18012659	DIRECT	Y	OT			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Infusion Related Reaction	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;	5 DAY	Gilead

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11-Jul-2020	18012667	DIRECT	Y				32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Chills; Transaminases Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:One Time- Loading;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2020	18012675	DIRECT		LT, OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2020	18012622	DIRECT	Y	OT			54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased; Thrombocytopenia	Remdesivir Decadron 6mg Iv Daily Actemra 400mg Iv X One			S C C	Intravenous bolus			Gilead Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2020	18012626	DIRECT		OT			34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir Remdesivir 200 Mg Iv X1 Remdesivir 100 Mg Daily	Y		S C C	Intravenous (not otherwise specified)		5 DAY	Gilead Not Reported Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	17812574	EXPEDITED (15-DAY)		DE, HO, OT	GB-PFIZER INC-2020198894		61 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Multiple Organ Dysfunction Syndrome	Spironolactone			S	Oral	50 Mg, 2x/Day (100mg Per Day)		Pfizer
	Spironolactone			S		Unk		Pfizer
	Furosemide			S	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Furosemide			S	Intravenous (not otherwise specified)	40 Mg, 2x/Day (80 Mg Per Day)		Not Reported
	Furosemide			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Furosemide			S	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 1x/Day		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Ipratropium			C		Unk		Not Reported
	Azithromycin			C		Intravenous (not otherwise specified)	Unk	Not Reported
	Co-Amoxiclav [Amoxicillin;Clavulanate Potassium]			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Midazolam			C		Intravenous (not otherwise specified)	Unk	Not Reported
	Metoclopramide			C		Intravenous (not otherwise specified)	Unk	Not Reported
Metoclopramide			C		Unk		Not Reported	
Morphine			C		Intravenous (not otherwise specified)	Unk	Not Reported	

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		otherwise specified)		
Morphine	C			Not Reported
Salbutamol	C	Respiratory (inhalation)	Unk	Not Reported
Noradrenaline [Norepinephrine]	C		Unk	Not Reported
Rocuronium	C	Intravenous (not otherwise specified)	Unk	Not Reported
Rocuronium	C			Not Reported
Piperacilin/Tazobactam	C		Unk	Not Reported
Erythromycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin	C	Subcutaneous	Unk	Not Reported
Vasopressin	C		Unk	Not Reported
Fentanyl	C	Intravenous (not otherwise specified)	Unk	Not Reported
Mupirocin	C		Unk	Not Reported
Carbocisteine	C		Unk	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Senna [Sennoside A+B]	C		Unk	Not Reported
Sodium Chloride	C		Unk	Not Reported
Vancomycin	C		Unk	Not Reported
Sildenafil	C		Unk	Not Reported
Pabrinex [Ascorbic Acid;Benzyl Alcohol;Nicotinamide;Pyridoxine Hydroch	C	Intravenous (not otherwise specified)	Unk	Not Reported
Budesonide	C	Respiratory (inhalation)	Unk	Not Reported
Enoxaparin	C	Subcutaneous	Unk	Not Reported
Acetylcysteine	C	Respiratory (inhalation)	Unk	Not Reported
Movicol Plain	C		Unk	Not Reported
Prosource Tf	C		Unk	Not Reported

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Milrinone	C	Unk	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	Unk Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	Unk Not Reported
Methylprednisolone	C	Unk	Not Reported
Atracurium	C	Intravenous (not otherwise specified)	Unk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	17892304	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469828		32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S	Unknown	Unk		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Robitussin [Guaifenesin]			C				Not Reported
	Heparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Toprol XL			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Ondansetron			C				Not Reported
	Propofol			C				Not Reported
Normal Saline			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	17927793	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0474348		80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

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Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Ascorbic Acid	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18012114	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	BE-CELLTRION INC.-2020BE024090			Unknown	BEL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Toxic; Respiratory Failure	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Cetirizine			C		Unk		Not Reported
	Thyroxine			C	Oral	Unk		Not Reported
	Calciumcarbonaat			C	Oral	Unk		Not Reported
	Livial			C	Oral	Unk		Not Reported
	Medrol [Methylprednisolone]			C	Oral	Unk		Not Reported
	Omeprazol [Omeprazole]			C		Unk		Not Reported
	Domperidone Flamingo			C	Oral	Unk		Not Reported
	Aldactone [Spironolactone]			C	Oral	Unk		Not Reported
Xanax			C	Oral	Unk		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014120	DIRECT	Y				62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

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Test Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014165	DIRECT	Y	HO, OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea; Hyperhidrosis; Infusion Related Reaction; Nausea; Vomiting	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014188	DIRECT	Y	DE			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Creatinine Increased; Cardio-Respiratory Arrest; Pulseless Electrical Activity	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Ceftriaxone			C				Not Reported
	Fentanyl Drip 20 Mcg/MI			C				Not Reported
	Norepinephrine Drip 8mg/250ml			C				Not Reported
	Propofol Drip 1000mg/100ml			C				Not Reported
	Vasopressin Drip 20 Units/100ml			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic Acid 500mg Tab			C				Not Reported
	Vitamin D3 5000units Cap			C				Not Reported
	Doxycycline 100mg Cap			C				Not Reported
	Enoxaparin 80mg Inj			C				Not Reported
	Famotidine 20mg Inj			C				Not Reported
	Novolog 100units/MI Sliding Scale			C				Not Reported
	Levemir			C				Not Reported
Nitroglycerin 0.4mg S/L Tab			C				Not Reported	
Zinc Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014193	DIRECT	Y	OT			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Blood Calcium Increased	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;	1 DAY		Not Reported
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13-Jul-2020	18014196	DIRECT	Y	OT			83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Glomerular Filtration Rate Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014202	DIRECT	Y				87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014233	DIRECT	Y				48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Chills; Diarrhoea; Dizziness; Fatigue; Presyncope; Sinus Tachycardia; Unresponsive To Stimuli; Vomiting	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)	Frequency: Am			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014245	DIRECT	Y	OT			36 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Metoprolol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014251	DIRECT	Y	OT			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014254	DIRECT	Y	DE			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage Intracranial	Remdesivir			S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014258	DIRECT	Y	DE			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure; Renal Replacement Therapy	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Convalescent Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014263	DIRECT	Y	DE			69 YR	Male	XQZ

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Covalescent Plasma			C				Not Reported
	Hydroxychloroquine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014268	DIRECT	Y	LT, OT			25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Disease Progression	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Heparin			C				Not Reported
	Regular Insulin			C				Not Reported
	Protonix			C				Not Reported
	Lasix			C				Not Reported
	Nystatin			C				Not Reported
	Vancomycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014273	DIRECT	Y				59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Extra Dose Administered; Liver Function Test Increased; Product Dispensing Error	Remdesivir			S				Gilead
	Aspirin 81 Mg Daily			C				Not Reported
	Dexamethasone 6mg Daily			C				Not Reported
	Albuterol Inhaler			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014279	DIRECT	Y	DE			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Death	Remdesivir	S	Intravenous bolus	Gilead
	Covid Antibody Plasma	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014283	DIRECT	Y				63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Tocilizumab (Tocilizumab 20mg/MI Inj, Soln, 4ml)			S	Intravenous (not otherwise specified)	Frequency: Once		Not Reported
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014292	DIRECT	Y	DE			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Disease Complication; Haemorrhagic Stroke	Remdesivir			S				Not Reported
	Aspirin 81 Mg Daily			C				Not Reported
	Calcium Chloride 19 Iv X1			C				Not Reported
	Cefepime 19 Iv Q8h			C				Not Reported
	Peridex Mouth Wash 15 MI Bid			C				Not Reported
	Dexamethasone 6 Mg Lv Daily			C				Not Reported
	Epinephrine 0.1mg/Kg Le1			C				Not Reported
	Famotidine 20 Mg Lv Daily			C				Not Reported
	Furosemide 40 Mg Iv Q12h			C				Not Reported
	Metoclopramide 5 Mg Lv Q8h			C				Not Reported
	Midazolam Lv Continuous Infusion Titrated			C				Not Reported
	Esmolol Iv Continuous Infusion Titrated			C				Not Reported
	Fentanyl Lv Continuous Infusion Titrated			C				Not Reported
	Insulin Lv Continuous Infusion Titrated			C				Not Reported
	Norepinephrine Lv Continuous Infusion Titrated			C				Not Reported
	Hypertonic Saline Lv Continuous Infusion			C				Not Reported

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Ns Continuous Infusion 20ml/Hr
Albumin 5% 250 MI X 2

C
C

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014295	DIRECT	Y				62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014315	DIRECT	Y	HO, LT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014631	DIRECT	Y				59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Device Infusion Issue;	Remdesivir			S				Not Reported
Product Dose Omission;	Azithromycin			C				Not Reported
Wrong Technique In	Ceftriaxone			C				Not Reported
Device Usage Process	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Combivent			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014674	DIRECT	Y	OT				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Gastrointestinal	Remdesivir			S				Not Reported

Haemorrhage; Glomerular
Filtration Rate Decreased;
Therapy Cessation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014675	DIRECT	Y	DE			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; General Physical Health Deterioration; Hypotension; Renal Failure; Renal Replacement Therapy	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014678	DIRECT	Y	OT				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014683	DIRECT	Y	HO			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir Eua			S	Intravenous drip	Other Frequency:One Loading Dose;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014688	DIRECT	Y	OT			55 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014693	DIRECT	Y	OT			90 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S				Not Reported	
	Levophed			C				Not Reported	
	Precedex			C				Not Reported	
	Propofol			C				Not Reported	
	Fentanyl			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014698	DIRECT	Y	OT			21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Maternal Exposure During Pregnancy	Remdesivir			S				Not Reported	
	Acetaminophen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014923	EXPEDITED (15-DAY)			US-GILEAD-2020-0481995		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Storage Error	Remdesivir			S	Unknown			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18017847	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0481381		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Kidney Injury;	Remdesivir	S	Intravenous bolus	200 Mg, Once	Gilead
Vomiting	Doxycycline	C		Unk	Not Reported
	Plasma	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18018077	DIRECT	Y				43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip		3 DAY	Gilead
	Remdesivir	Y		S	Intravenous drip		2 DAY	Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Coreg			C				Not Reported
	Ceftriaxone			C				Not Reported
	Lovenox			C				Not Reported
	Cellcept			C				Not Reported
	Nifedipine			C				Not Reported
	Protonix			C				Not Reported
	Prednisone			C				Not Reported
	Tacrolimus			C				Not Reported
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18018090	DIRECT	Y	OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Serum Ferritin Increased	Remdesivir			S	Intravenous (not otherwise specified)		30 MIN	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18018098	DIRECT	Y				61 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S		Intravenous (not otherwise specified)		Gilead
	Remdesivir	Y		S			Intravenous (not otherwise specified)	
	Azithromycin 500 Mg Daily			C				Not Reported
	Albuterol Hfa Inhaler			C				Not Reported
	Cholecalciferol 2000 Units Daily			C				Not Reported
	Cyanocobalamin 1000 Mcg Daily			C				Not Reported
	Dexamethasone 6 Mg Daily			C				Not Reported
	Dicyclomine 20 Mg Four Times Daily			C				Not Reported
	Enoxaparin 40 Mg Daily			C				Not Reported
	Escitalopram 5 Mg Daily			C				Not Reported
	Famotidine 20 Mg Two Times Daily			C				Not Reported
	Loratadine 10 Mg Daily			C				Not Reported
	Prenatal Plus Vitamin Daily			C				Not Reported
	Pseudoephedrine 30 Mg Four Times Daily			C				Not Reported
	Verapamil 240 Mg Daily			C				Not Reported
	Zinc Sulfate 220 Mg Daily			C				Not Reported
	Acetaminophen 650 Mg Every 4 Hours As Needed			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18018101	DIRECT	Y	OT			92 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18018164	DIRECT	Y	OT			26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir	S	Intravenous drip	Not Reported
	Acetaminophen	C		Not Reported
	Albuterol	C		Not Reported
	Aromatic Inhaler	C		Not Reported
	Dexamethasone	C		Not Reported
	Doxycycline	C		Not Reported
	Enoxaperin	C		Not Reported
	Ipratropium Bromide	C		Not Reported
	Mometasone	C		Not Reported
	Ondansetron	C		Not Reported
	Tocilizumab	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18018360	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18019094	DIRECT	Y	DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus			Gilead
	Actemra			S	Intravenous drip			Genentech

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18019213	DIRECT	Y	OT			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Condition Aggravated; Hypoxia; Sinus Node Dysfunction	Remdesivir			S	Intravenous bolus			Gilead
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported

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Pantoprazole	C	Not Reported
Enoxaparin	C	Not Reported
Insulin Aspart	C	Not Reported
Dexamethasone	C	Not Reported
Potassium Chloride	C	Not Reported
Butalbital/Apap/Caffeine	C	Not Reported
Apap	C	Not Reported
Ondansetron	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17861932	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469014		43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Dyspnoea; Hyperphosphataemia; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ns			C	Intravenous (not otherwise specified)	100 MI/Hr		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported
	D5Irs			C	Intravenous (not otherwise specified)	125 MI/Hr		Not Reported
	Doxycycline			C	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Heparin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin Regular Hm			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin Regular Hm			C			7 Units	
Zosyn			C	Intravenous (not otherwise specified)	2.25 G			Not Reported
Propofol			C	Intravenous (not	Unk			Not Reported

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Albuterol Hfa	C	Respiratory (inhalation)	2 Puff	otherwise specified)	Not Reported
Amlodipine	C	Oral	5 Mg		Not Reported
Ascorbic Acid	C	Oral	500 Mg		Not Reported
Atorvastatin	C	Oral	20 Mg		Not Reported
Bupropion	C	Oral	300 Mg		Not Reported
Buspirone	C	Other	10 Mg		Not Reported
Cholecalciferol	C	Other	1000 Units		Not Reported
Famotidine	C	Intravenous (not otherwise specified)	20 Mg		Not Reported
Novolog	C	Subcutaneous	Unk		Not Reported
Insulin Detemir	C	Subcutaneous	9 Units		Not Reported
Ketamine	C	Intravenous (not otherwise specified)	100 Mg		Not Reported
Lorazepam	C	Intravenous (not otherwise specified)	1 Mg		Not Reported
Midazolam	C	Intravenous (not otherwise specified)	5 Mg		Not Reported
Morphine	C	Intravenous (not otherwise specified)	2 Mg		Not Reported
Rocuronium	C	Intravenous (not otherwise specified)	100 Mg		Not Reported
Thiamine	C	Oral	100 Mg		Not Reported
Zinc Sulfate	C	Oral	220 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17876354	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469633		82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

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Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Eliquis	C	Oral	5 Mg, Bid	Not Reported
Eliquis	C		2.5 Mg, Bid	Not Reported
Albuterol Hfa	C	Respiratory (inhalation)		Not Reported
Amiodarone	C		200 Mg	Not Reported
Amlodipine	C		5 Mg	Not Reported
Atorvastatin	C		40 Mg	Not Reported
Azithromycin	C		500 Mg	Not Reported
Methylprednisolone	C		50 Mg	Not Reported
Metoprolol Succinate	C		25 Mg	Not Reported
Tocilizumab	C		400 Mg	Not Reported
Tocilizumab	C		200 Mg	Not Reported
Pantoprazole	C		40 Mg	Not Reported
Sodium Polystyrene Sulfonate	C		15 G	Not Reported
Zinc Sulfate	C		220 Mg	Not Reported
Nacl	C	Intravenous (not otherwise specified)		Not Reported
Acetaminophen	C		650 Mg	Not Reported
Benzonatate	C		100 Mg	Not Reported
Melatonin	C		3 Mg	Not Reported
Ceftriaxone	C		1000 Mg	Not Reported
Diphenhydramine	C		25 Mg	Not Reported
Furosemide	C		40 Mg	Not Reported
Levothyroxine	C		112 Mcg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17892588	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470679		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Pressure Decreased; Chills; Heart Rate Decreased; Hyperhidrosis; Infusion Related Reaction	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Acetaminophen	C			Not Reported
	Albuterol [Salbutamol]	C			Not Reported
	Azithromycin	C	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1000 Mg	Not Reported
	Heparin	C	Subcutaneous	7500 Units	Not Reported
	Ipratropium Bromide And Albuterol Sulfate	C	Respiratory (inhalation)	1 Puff	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
	Morphine	C			Not Reported
	Ns	C			Not Reported
	Ondansetron	C			Not Reported
	Pravastatin	C			Not Reported
	Thiamine	C			Not Reported
	Iohexol	C			Not Reported
	Quetiapine [Quetiapine Fumarate]	C	Oral	200 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17948842	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475659		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C				Not Reported
	Hydrocortisone			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Vancomycin			C				Not Reported
	Fentanyl			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported

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Heparin	C	Not Reported
Norepinephrine	C	Not Reported
Humalog	C	Not Reported
Zinc	C	Not Reported
Versed	C	Not Reported
Meropenem	C	Not Reported
Micafungin	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Insulin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17949327	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475661		84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Multiple Organ Dysfunction Syndrome	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Heparin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Rocuronium			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Levophed			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Vasopressin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Neosynephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported
Plasma			C					Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17949328	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475657		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Apixaban			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Zinc			C				Not Reported
	Cholecalciferol			C				Not Reported
	Docusate			C				Not Reported
	Selenium			C				Not Reported
	Famotidine			C				Not Reported
	Seroquel			C				Not Reported
	Solumedrol			C				Not Reported
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Plasma			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17963319	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0476755		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Bid		Not Reported

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Aspirin 81	C	Oral	81 Mg, Qd	Not Reported
Dexamethasone	C	Oral	6 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	40 Mg	Not Reported
Azithromycin	C	Oral	500 Mg, Qd	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	17986012	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0479047		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			S	Unknown			Not Reported
	Enoxaparin			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019363	DIRECT	Y				71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Discomfort; Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019365	EXPEDITED (15-DAY)		DE, OT	GB-STRIDES ARCOLAB LIMITED-2020SP008079		84 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Livedo Reticularis	Vancomycin	S	Intravenous (not otherwise specified)	1 Gram, Bid	Strides
	Piperacillin & Tazobactam	S	Intravenous (not otherwise specified)	4.5 Gram, Tid	Not Reported
	Dexamethasone	S	Oral	6 Milligram, Qd	Not Reported
	Remdesivir	S	Intravenous (not otherwise specified)	200, Stat	Not Reported
	Oxygen	C	Unknown	Unk	Not Reported
	Allopurinol	C	Unknown	Unk	Not Reported
	Fexofenadine	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Omeprazole	C	Unknown	Unk	Not Reported
	Dalteparin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019366	DIRECT	Y				41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous bolus		3 DAY	Gilead
	Allopurinol			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Heparin			C				Not Reported
	Lispro			C				Not Reported
	Insulin Nph			C				Not Reported
	Melatonin			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Senna/Docusate			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Hydromorphone			C				Not Reported
	Norepinephrine			C				Not Reported
Propofol			C				Not Reported	

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Acetaminophen	C	Not Reported
Ondansetrol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019372	DIRECT	Y				70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019392	DIRECT	Y	OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation	Remdesivir Eua			S				Not Reported
	Tocilizumab			C				Not Reported
	Zinc			C				Not Reported
	Senna			C				Not Reported
	Rocuronium			C				Not Reported
	Quetiapine			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Pentoxifylline			C				Not Reported
	Pantoprazole			C				Not Reported
	Multivitamins			C				Not Reported
	Levothyroxine			C				Not Reported
	Insulin			C				Not Reported
	Hepaine			C				Not Reported
	Aztreonam			C				Not Reported
	Atorvastatin			C				Not Reported
	Aspirin			C				Not Reported
	Ascorbic Acid			C				Not Reported
Amlodipine			C				Not Reported	
Acetaminophen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019398	DIRECT	Y				42 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Propofol			C				Not Reported
	Sublimaze			C				Not Reported
	Levophed			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019402	DIRECT	Y	OT			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir Eua			S				Not Reported
	Aspirin			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Fentanyl			C				Not Reported
	Folic Acid			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Ketamine			C				Not Reported
	Kepra			C				Not Reported
	Lorazepam			C				Not Reported
	Metronidazole			C				Not Reported
	Multivitamin			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Pentoxifylline			C				Not Reported
Propofol			C				Not Reported	
Thiamine			C				Not Reported	
Vancomycin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019408	DIRECT	Y	HO			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Troponin Increased	Remdesivir			S	Intravenous (not			Gilead

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019547	DIRECT		LT			39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Brain Death; Brain Midline Shift; Brain Oedema; Cardiac Arrest; Cerebral Haemorrhage; Creatinine Renal Clearance Decreased; Pupil Fixed; Unresponsive To Stimuli; Vomiting	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019555	DIRECT	Y	OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Cardio-Respiratory Arrest; Chest Discomfort; Dyspnoea; Hypoxia; Pharyngeal Swelling; Swollen Tongue; Wheezing	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18019894	DIRECT	Y	OT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Na			C				Not Reported

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14-Jul-2020	18020193	DIRECT	Y	OT			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S			5 DAY	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18020200	DIRECT	Y				30 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ast/Alt Ratio Abnormal; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18020210	DIRECT	Y	HO			48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir Actemra Dexamethasone Inj			S C C				Gilead Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18020211	DIRECT	Y	DE			70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pyrexia	Remdesivir Remdesivir Carboxymethylcellulose			S S C	Intravenous drip Intravenous drip			Gilead Gilead Not Reported	

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Ophthalmic Drops									
Cisatracurium			C						Not Reported
Enoxaparin			C						Not Reported
Fentanyl			C						Not Reported
Hydralazine			C						Not Reported
Insulin			C						Not Reported
Norepinephrine			C						Not Reported
Propofol			C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18021105	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482478		86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Insulin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Potassium Chloride			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18021134	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482469		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		500 Mg, Qd		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	2 G, Bid		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg, Bid		Not Reported
	Heparin Sodium			C	Subcutaneous	5000 Units		Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	4 G		Not Reported

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Vancomycin	C	otherwise specified)	Unk	Not Reported
Hydromorphone	C	Intravenous (not otherwise specified)	Unk	Not Reported
Norepinephrine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18022069	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482487		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg		Gilead
	Famotidine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Sennaplant			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18022089	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469452		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Heparin			C				Not Reported
	Hydralazine			C				Not Reported
	Loperamide			C				Not Reported
	Potassium Chloride			C				Not Reported
	Sodium Chloride			C				Not Reported
	Multivitamins [Vitamins Nos]			C				Not Reported
	Ondansetron			C				Not Reported
	Dextromethorphan Hbr & Guaifenesin			C				Not Reported
	Zinc Sulfate			C				Not Reported

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Docusate;Senna C Not Reported
Acetaminophen C Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024034	DIRECT	Y	OT			44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024044	DIRECT	Y				30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Nausea; Vomiting	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid 2000mg Qday			C				Not Reported
	Dexamethasone 6mg Po Qday			C				Not Reported
	Enoxaparin 40mg Subq Q12h			C				Not Reported
	Zinc Sulfate 220mg			C				Not Reported
	Codeine-Guaifenesin 10-100mg Q4h Prn Cough			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024053	DIRECT	Y	OT			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

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14-Jul-2020	18024056	DIRECT	Y	HO			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024064	DIRECT	Y	OT			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024070	DIRECT	Y	OT			96 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024080	DIRECT	Y	OT			89 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Atrioventricular Block First Degree; Atrioventricular Block Second Degree; Bradycardia	Remdesivir Lisinopril Dexamethasone	S C C	Intravenous bolus	Gilead Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024161	DIRECT	Y				88 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024171	DIRECT	Y	OT			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading Dose;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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14-Jul-2020	18024176	DIRECT	Y	OT			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024185	DIRECT	Y	DS, OT			47 YR	Male	USA

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Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Not Reported
	Albuterol Inhaler			C		Not Reported		
	Aspirin 81 Mg			C		Not Reported		
	Vitamin D3 2000 Units			C		Not Reported		
	Dexamethasone 6 Mg			C		Not Reported		
	Famotidine 20 Mg			C		Not Reported		
	Zosyn 3.375 G			C		Not Reported		
	Rocuronium			C		Not Reported		
	Vancomycin			C		Not Reported		
	Zinc Sulfate 220 Mg			C		Not Reported		
Heparin			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024196	DIRECT	Y	OT			28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024205	DIRECT	Y	HO, OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S			Intravenous drip	Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Solu-Medrol			C				Not Reported
	Enoxaparin			C				Not Reported
	Sodium Chloride			C				Not Reported
	Doxycycline			C				Not Reported
	Ceftriaxone			C				Not Reported
	Tocilizumab			C				Not Reported
	Novolog			C				Not Reported
	Dicyclomine			C				Not Reported

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Zofran			C			Not Reported			
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14-Jul-2020	18024217	DIRECT	Y				47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Papule; Rash Pruritic; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024252	DIRECT	Y	OT			78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Benazepril 40 Mg Po Nightly			C				Not Reported	
	Budesonide-Formoterol 160-4.5 Mcg/Actuation 2 Puffs			C				Not Reported	
	Calcium Carbonate 500 Mg Chewable Tablet			C				Not Reported	
	Chlorthalidone 25 Mg Po Daily			C				Not Reported	
	Diltiazem Er 120 Mg Po 2 Times Daily			C				Not Reported	
	Hydrocodone-Acetaminophen 10-325 Mg Po 2 Times Daily Prn			C				Not Reported	
	Pantoprazole 40 Mg Po Daily			C				Not Reported	
	Rivaroxaban 15 Mg Po Daily			C				Not Reported	
	Vitamin D 2000 Units Po 2 Times Daily			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024261	DIRECT	Y	LT			50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Liver Function Test	Remdesivir			S	Intravenous (not			Gilead	

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Increased; Seizure				otherwise specified)					
	Acetaminophen		C						Not Reported
	Alprazolam		C						Not Reported
	Aripiprazole		C						Not Reported
	Ascorbic Acid		C						Not Reported
	Dexamethasone		C						Not Reported
	Enoxaparin		C						Not Reported
	Levofloxacin		C						Not Reported
	Levetiracetam		C						Not Reported
	Sertraline		C						Not Reported
	Zinc Sulfate		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024263	DIRECT	Y	OT			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Cardiac Arrest; Hypotension; Inflammatory Marker Increased; International Normalised Ratio Increased; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mgx1, 100mg/D 4;		Gilead
	Aspirin Ec 81mg Po Daily			C				Not Reported
	Atorvastatin 20mg Po Qhs			C				Not Reported
	Azithromycin 500mg Iv Q24h			C				Not Reported
	Ceftriaxone 1g Iv Once			C				Not Reported
	Dexamethasone 6mg Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Epinephrine Iv Continuous Infusion			C				Not Reported
	Epoprostenol Continuous Neb			C				Not Reported
	Famotidine 20mg Iv Q12h And Q24h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide 20mg Iv Dailly			C				Not Reported
	Lantus Qhs			C				Not Reported
	Insulin Lispro Sliding Scale 4x/D			C				Not Reported
	Midazolam Iv Continuous Infusion			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Phenylephrine Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported

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Rocuronium Iv Pushes Prn For Vent Dyssynchrony	C	Not Reported
Sodium Bicarbonate Infusion	C	Not Reported
Vasopressin Iv Continuous Infusion	C	Not Reported
Vecuronium Iv Continuous Infusion	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024270	DIRECT	Y	DE, LT, OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Creatinine Increased; International Normalised Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg/D, 100mgx4;		Gilead
	Amiodarone Bolus And Infusion			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benzotropine 1mg Ng Q8h			C				Not Reported
	Cefepime 1g Iv Q6h			C				Not Reported
	Ceftriaxone 1g Iv Once			C				Not Reported
	Daptomycin 6 Mg/Kg Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Precedex Infusion			C				Not Reported
	Diazepam 5mg Iv Q6-12h			C				Not Reported
	Enoxaparin Prophy Then Treatment			C				Not Reported
	Fentanyl 25mcg Iv Prn			C				Not Reported
	Insulin Lispro Sliding Scale 4x/Day			C				Not Reported
	Culturelle Capsule Q24h			C				Not Reported
	Meropenem 500mg Iv Q6h			C				Not Reported
	Metoprolol 5mg Iv Q6h			C				Not Reported
	Norepinephrine Infusion			C				Not Reported
	Phenylephrine Infusion			C				Not Reported
	Pip/Tazo 3.375g Iv Q8h			C				Not Reported
	Sodium Bicarbonate Infusion			C				Not Reported
	Vitamin C 1000mg Daily			C				Not Reported
	Zinc Sulfate 220mg Daily			C				Not Reported

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14-Jul-2020	18024360	DIRECT	Y	HO			29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir Acetaminophen Guaifenesin Multivitamin	Y		S C C C				Gilead Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18024375	DIRECT	Y	DE			75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous bolus			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	17882785	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469801		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Aztreonam			C	Intravenous (not otherwise specified)	2 G		Not Reported	
	Furosemide			C	Intravenous (not otherwise specified)	20-40mg		Not Reported	
	Levofloxacin			C	Intravenous (not otherwise specified)	750 Mg		Not Reported	
	Tocilizumab			C	Intravenous (not otherwise specified)	800 Mg		Not Reported	

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Acetaminophen	C	Oral	650 Mg	Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	2.5 Mg	Not Reported
Atropine	C			Not Reported
Clopidogrel	C	Oral	75 Mg	Not Reported
Docusate	C	Oral	100 Mg	Not Reported
Heparin	C	Subcutaneous	5000 Units	Not Reported
Levothyroxine	C	Oral	50 Mcg	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	Unk	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Acetylcysteine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	17887629	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470645		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Pressure Decreased; Heart Rate Irregular	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C	Oral	500 Mg, Bid		Not Reported
	Atorvastatin			C	Oral	40 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Benzonatate			C	Oral	100 Mg, Q8h		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Codeine			C	Oral	15 Mg, Q6h		Not Reported

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Enoxaparin	C	Subcutaneous	75 Mg	Not Reported
Guaifenesin	C	Oral	1200 Mg, Bid	Not Reported
Heparin	C	Subcutaneous	Unk Unk, Bid	Not Reported
Ibuprofen	C	Oral	600 Mg, Once	Not Reported
Losartan	C	Oral	50 Mg, Qd	Not Reported
Metoprolol Succinate	C	Oral	25 Mg, Qd	Not Reported
Metoprolol Tartrate	C	Oral	25 Mg, Bid	Not Reported
Zinc Sulfate	C	Oral	220 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	17892214	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469666		49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Proteinuria; Renal Tubular Necrosis; Rhabdomyolysis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Azithromycin			C	Oral	500 Mg		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G		Not Reported
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Guaifenesin			C	Oral	200 Mg		Not Reported
	Guaifenesin			C	Oral	200 Unk		Not Reported
	Lactated Ringers			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Lokelma			C		10 G		Not Reported
	Lokelma			C		10 Unk		Not Reported
	Ns			C		500 MI		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Albuterol;Ipratropium			C		2		Not Reported
	Albuterol;Ipratropium			C		3		Not Reported

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Etomidate	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Midazolam	C	Intravenous (not otherwise specified)	Unk	Not Reported
Rocuronium	C	Intravenous (not otherwise specified)	150 Mg	Not Reported
Atracurium	C	Intravenous (not otherwise specified)	Unk	Not Reported
Hydromorphone	C		Unk	Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	2750 Mg	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	2250 Unk	Not Reported
Famotidine	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Metoclopramide	C	Intravenous (not otherwise specified)	10 Mg	Not Reported
Oxycodone	C	Oral	10 Mg	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bumetanide	C	Intravenous (not otherwise specified)	5 Mg	Not Reported
Chlorothiazide	C	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Sodium Bicarbonate	C	Intravenous (not otherwise specified)	150 Meq	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	17940034	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0473153		78 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amlodipine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Atorvastatin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Diltiazem			C				Not Reported
	Gabapentin			C				Not Reported
	Glimepiride			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Isosorbide Dinitrate			C				Not Reported
	Levothyroxine			C				Not Reported
	Methylprednisolone			C				Not Reported
Metoclopramide			C				Not Reported	
Pantoprazole			C				Not Reported	
Zinc Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18021510	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0481896		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment; Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18021816	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482431		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Eye Irritation; Nausea	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Enoxaparin			C				Not Reported

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15-Jul-2020	18024742	DIRECT	Y	DE			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Pulmonary Oedema; Agitation; Atrial Fibrillation; Lung Infiltration; Obstructive Airways Disorder; Pulse Absent; Rales; Respiratory Failure; Respiratory Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Metoprolol			C				Not Reported
	Amiodarone			C				Not Reported
	Furosemide			C				Not Reported
	Etomidate			C				Not Reported
	Rocuronium			C				Not Reported
	Midazolam			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Atorvastatin			C				Not Reported
	Insulin Determir			C				Not Reported
	Insulin Lispro			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18024764	DIRECT		HO			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Arrest	Remdesivir			S	Intravenous bolus			Gilead
	Azithromycin 500 Mg Ivpb Once			C				Not Reported
	Azithromycin 250 Mg Po Daily			C				Not Reported
	Azithromycin 500 Mg Ivpb Every 24 Hours			C				Not Reported
	Ceftriaxone 1 Gram Ivpb Every 12 Hours			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18024782	DIRECT	Y	DE			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous bolus	Other Frequency:X1;		Gilead

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Actemra		S	Intravenous bolus		Other Frequency:X1;			Genentech		
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15-Jul-2020	18024787	DIRECT	Y	OT			51 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
International Normalised Ratio Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4;		Gilead		
	Acetaminophen 325mg Q6h Prn Pain 1-3. Fever			C				Not Reported		
	Azithromycin 500mg Iv Daily			C				Not Reported		
	Ceftriaxone 1g Iv Daily			C				Not Reported		
	Dexamethasone 6mg Iv Daily			C				Not Reported		
	Enoxaparin 30mg Subq Q12h			C				Not Reported		
	Lantus Qhs			C				Not Reported		
	Insulin Lispro Sliding Scale 4x/D			C				Not Reported		
	Norepinephrine Iv Infusion			C				Not Reported		
	Tocilizumab 400mg Iv X 1			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jul-2020	18024788	DIRECT	Y	OT			22 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead		
	Dexamethasone			C				Not Reported		
	Ceftriaxone			C				Not Reported		
	Azithromycin			C				Not Reported		
	Covid Convalescent Plasma			C				Not Reported		
	Albuterol			C				Not Reported		
	Fluticasone			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jul-2020	18024789	DIRECT	Y				21 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

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Liver Function Test Increased	Remdesivir	S	Intravenous bolus	Gilead
	Remdesivir	C		Not Reported

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15-Jul-2020	18024790	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead
	Acetaminophen 650 Po Q6h Prn			C				Not Reported
	Ascorbic Acid 500mg Qd			C				Not Reported
	Atenolol 25mg Qd			C				Not Reported
	Atorvastatin 20 Qpm			C				Not Reported
	Bicalutamide 50mg Qd			C				Not Reported
	Dexamethasone 6mg Iv Q 24			C				Not Reported
	Famotidine 20 Mg Qd			C				Not Reported
	Heparin 5000 Sc Q8			C				Not Reported
	Tocilizumab 100 MI Iv Once			C				Not Reported
	Levothyroxine 100mcg Qs			C				Not Reported
	Ondansteron 4mg Q8 Prn			C				Not Reported
	Zinc Sulfate 220 Mg Qd			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18024809	DIRECT	Y				74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Liver Function Test Increased; Ventricular Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18024816	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir Eua Product			S	Intravenous bolus			Gilead
	Dexamethasone 6 Mg Iv Daily			C				Not Reported

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Tocilizumab 400 Mg Iv X2	C	Not Reported
Cisatracurium 37.5 Mg/Hr Iv	C	Not Reported
Continuous		
Fentanyl 50 Mcg/Hr Iv	C	Not Reported
Continuously		
Propofol 50 Mcg/Kg/Min Iv	C	Not Reported
Continuously		
Norepinephrine 5 Mcg/Min Iv	C	Not Reported
Continuously		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18024817	DIRECT	Y				32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18024833	DIRECT	Y	DE			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18026374	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0482857		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis	Remdesivir			S	Unknown	200 Mg, Qd		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18026584	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482356		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased Remdesivir S Intravenous drip 200 Mg, Qd Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18026641	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470338		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Blood Bilirubin Increased; Blood Creatinine Increased;	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
Jugular Vein Thrombosis; Pneumonia; Respiratory Disorder; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral	650 Mg		Not Reported
	Acetaminophen			C	Oral	975 Mg		Not Reported
	Acetaminophen			C	Other	975 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Acetaminophen			C	Other	650 Mg		Not Reported
	Albuterol Hfa			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Docusate			C				Not Reported
	Duloxetine			C				Not Reported
	Enoxaparin			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Haloperidol			C				Not Reported
	Hydroxyzine			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Lorazepam			C				Not Reported
	Midazolam			C				Not Reported

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Norepinephrine	C	Not Reported
Ondansetron	C	Not Reported
Oxycodone	C	Not Reported
Polyethylene Glycol 3350	C	Not Reported
Pregabalin	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Senna S	C	Not Reported
Succinylcholine	C	Not Reported
[Suxamethonium]		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18027006	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482904		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Dexamethasone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18027028	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477223			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Respiratory Failure; Suspected Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18027438	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482916		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhagic Stroke	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported	
	Calcium Chloride			C		Unk		Not Reported	

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Cefepime	C	Unk	Not Reported
Peridex [Chlorhexidine Gluconate]	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Epinephrine	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Metoclopramide	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Esmolol	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Insulin	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Hypertonic Saline Solution	C	Unk	Not Reported
Normal Saline	C	Unk	Not Reported
Albumin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18028282	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0472223		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Vitamin D3			C				Not Reported
	Clonidine			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported

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Midodrine	C	Not Reported
Multivitamins [Vitamins Nos]	C	Not Reported
Potassium Chloride	C	Not Reported
Potassium Phosphate Dibasic	C	Not Reported
Sodium Chloride	C	Not Reported
Sodium Phosphate	C	Not Reported
Sulfamethoxazole And	C	Not Reported
Trimethoprim		
Thiamine	C	Not Reported
Oxycodone	C	Not Reported
Fentanyl	C	Not Reported
Acyclovir [Aciclovir]	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029374	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482872		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Aztreonam			C	Intravenous (not otherwise specified)	2 G Q8hr		Not Reported
	Clindamycin			C		Unk		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Lidocaine			C		Unk		Not Reported
	Enoxaparin [Enoxaparin Sodium]			C		Unk		Not Reported
	Breo Ellipta			C		Unk		Not Reported
	Lactobacillus			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Polyethylene Glycol 3350			C		Unk		Not Reported

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Potassium Chloride	C	Unk	Not Reported
Docusate;Sennoside A+B	C	Unk	Not Reported
Spiriva	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029500	DIRECT	Y	DE			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Unresponsive To Stimuli	Remdesivir			S				Not Reported
	Apixaban			C				Not Reported
	Benzonatate			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxycycline			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C				Not Reported
	Apap-Codeine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029545	DIRECT	Y	DE			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock	Remdesivir	Y		S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Merrem			C				Not Reported
	Montelukast			C				Not Reported
	Senna			C				Not Reported
	Spirolactone			C				Not Reported
	Vancomycin			C				Not Reported
	Amiodarone			C				Not Reported

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15-Jul-2020	18029550	DIRECT	Y	HO			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Ofirmev 1000mg/100ml			C				Not Reported
	Acetaminophen Oral			C				Not Reported
	Ascorbic Acid 500mg			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Etomidate			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Ketorolac			C				Not Reported
	Lorazepam			C				Not Reported
	Melatonin			C				Not Reported
	Midazolam			C				Not Reported
	Pantoprazole			C				Not Reported
Propofol			C				Not Reported	
Vecuronium			C				Not Reported	
Zinc Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029557	DIRECT	Y	HO			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous bolus			Gilead
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
Lorazepam			C				Not Reported	

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Melatonin	C	Not Reported
Maalox+Lidocaine	C	Not Reported
Maalox	C	Not Reported
Midazolam	C	Not Reported
Montelukast	C	Not Reported
Cimetidine	C	Not Reported
Pantoprazole	C	Not Reported
Promethazine	C	Not Reported
Propofol	C	Not Reported
Sucralfate	C	Not Reported
Levothyroxine	C	Not Reported
Zinc Sulfate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029588	DIRECT	Y	OT			79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029595	DIRECT	Y	OT			61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029605	DIRECT	Y				71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State;	Remdesivir			S	Intravenous drip			Gilead

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Pyrexia; Unresponsive To Stimuli	Dexamethasone	C	Not Reported
	Ceftriaxone	C	Not Reported
	Breo Ellipta	C	Not Reported
	Protonix	C	Not Reported
	Mirapex	C	Not Reported
	Incruse Ellipta	C	Not Reported
	Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029631	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Glargine Insulin			C				Not Reported
	Lispro Insulin			C				Not Reported
	0.9% Nacl			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029641	DIRECT	Y	OT			25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)		4 DAY	Gilead
	Dexamethasone Iv			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Vancomycin Iv			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029648	DIRECT	Y	DE			74 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albumin			C				Not Reported
	Promethazine W/Codeine			C				Not Reported
	D5w			C				Not Reported
	Dig			C				Not Reported
	Norco			C				Not Reported
	Kcl			C				Not Reported
	Lorazepam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Sod Bicarb			C				Not Reported
	Ns			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ca Gluconate			C				Not Reported
	Ceftazidime			C				Not Reported
	Vanco			C				Not Reported
	Amio			C				Not Reported
	Mag Sulfate			C				Not Reported
	Metronidazole			C				Not Reported
	Azithromycin			C				Not Reported
	Pip/Tazo			C				Not Reported
	Tocilizumab			C				Not Reported
	Vanco			C				Not Reported
	Meropenem			C				Not Reported
	K Phos			C				Not Reported
	Acetaminophen			C				Not Reported
	Bumex			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin Dm			C				Not Reported
	Haldol			C				Not Reported
	Reg Insulin			C				Not Reported
	Reglan			C				Not Reported
	Metoprolol			C				Not Reported
	Zofran			C				Not Reported
	Proamatine			C				Not Reported
	Atropine			C				Not Reported
	Epi			C				Not Reported
	Ketorolac			C				Not Reported

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Midazolam C Not Reported
Succinylcholine C Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18029681	DIRECT	Y	OT			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)		2 DAY	Gilead
	Ondansetron			C				Not Reported
	Pantoprazole			C				Not Reported
	Duloxetine			C				Not Reported
	Atorvastatin			C				Not Reported
	Montelukast			C				Not Reported
	Dexamethasone			C				Not Reported
	Apixaban			C				Not Reported
	Insulin Aspart			C				Not Reported
	Meropenem			C				Not Reported
	Gabapentin			C				Not Reported
	Propofol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Lactated Ringers			C				Not Reported
	Vancomycin			C				Not Reported
Heparin			C				Not Reported	
Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18030037	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482899		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Unknown	100 Mg		Gilead
	Dexamethasone			C				Not Reported
	Oxygen			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18030692	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483267		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Oxygen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18035551	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Physical Product Label Issue; Product Administration Error; Product Label Confusion; Product Use Complaint	Remdesivir Injection			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Injection			S	Intravenous (not otherwise specified)	Powder For Reconstitution		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	17896499	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0469667		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Death; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Vancomycin			S	Intravenous (not otherwise specified)	1500 Mg		Not Reported
	Genvoya			C	Oral	1 Dosage Form, Qd		Gilead
	Biktarvy			C	Oral	1 Dosage Form, Qd		Gilead

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Enoxaparin	C	Subcutaneous	30 Mg	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	17957797	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0476807		85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Hydralazine			C				Not Reported
	Metoprolol			C				Not Reported
	Thiamine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	17969655	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477743		91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Death; Dyspnoea; Haemoptysis; Pulmonary Congestion	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg Iv X1, Then 100 Mg Iv X 4 Days		Gilead
	Levofloxacin			C		Unk		Not Reported
	Warfarin			C				Not Reported
	Hydromorphone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18027827	EXPEDITED (15-DAY)			US-GILEAD-2020-0482378			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Product Storage Error	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg		Gilead
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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031319	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir Dexamethasone			S C				Gilead Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031353	DIRECT	Y	OT			67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead
	Acetaminophen(Tylenol) Tablet 650 Mg			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Ceftriaxone 1 G In Ns			C				Not Reported
	Azithromycin 500 Mg In Ns			C				Not Reported
	Heparin 7,500 Unit Inj			C				Not Reported
	Dextromethorphan-Guainfenesin 20mg			C				Not Reported
	Levothyroxin Tablet 137 Mcg			C				Not Reported
	Ondansetron Disintegrating Tablet 4 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jul-2020	18031361	DIRECT	Y	OT			40 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031365	DIRECT	Y	OT			88 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir	Y		S			4 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031451	EXPEDITED (15-DAY)			US-GILEAD-2020-0482855			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intercepted Product Preparation Error	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031615	DIRECT	Y				67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Papular; Scab	Remdesivir For Injection			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031625	DIRECT	Y	DE			47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Coagulopathy; Disseminated Intravascular Coagulation; Ischaemic Hepatitis; Liver Disorder; Liver Function	Remdesivir Listed On Previous Medwatch			S C				Gilead Not Reported

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Test Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031630	DIRECT	Y				77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir				S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031742	DIRECT	Y				31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir				S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031745	DIRECT	Y	OT			39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Erythema; Infusion Site Extravasation	Remdesivir				S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031962	DIRECT	Y				59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Choking Sensation; Cough; Dyspnoea; Nausea	Remdesivir Enoxaparin				S C	Intravenous bolus			Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031968	DIRECT	Y	OT			72 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4;		Gilead
	Dexamethasone 6mg Iv Q6h Then Daily			C			Not Reported	
	Enoxaparin 30mg Sq Q12h			C			Not Reported	
	Famotidine 20mg Po Q12h			C			Not Reported	
	Culturelle 1 Cap Daily			C			Not Reported	
	Vitamin C 1 Gram Po Daily			C			Not Reported	
	Zinc Sulfate 220mg Po Daily			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18031980	DIRECT	Y	DE			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Renal Failure; Respiratory Failure; Septic Shock	Remdesivir			S		Other Frequency:X 1 Dose;		Gilead
	Methylprednisolone			C			Not Reported	
	Cefepime			C			Not Reported	
	Ascorbic Acid			C			Not Reported	
	Azithromycin			C			Not Reported	
	Protonix			C			Not Reported	
	Zinc Sulfate			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18032087	DIRECT	Y	OT			37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported
	Albuterol			C				Not Reported
	Benzonatate			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Bio-K Plus			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18032093	DIRECT	Y	OT			60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oxygen Saturation Decreased; Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mgx4d;		Gilead
	Aspirin Ec 81mg Po Daily			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benzonatate 100mg Q8h			C				Not Reported
	Carvedilol 6.25mg Bid			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Famotidine 20mg Po Q12h			C				Not Reported
	Culturelle 1 Cap Po Daily			C				Not Reported
	Vitamin C 1000mg Daily To Bid			C				Not Reported
	Zinc Sulfate 200mg Po Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18032103	DIRECT	Y	DE			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Hypoxia; Pulse Absent	Remdesivir Under Emergency Use Authorization	Y		S	Intravenous bolus		1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18033239	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483276		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Benzotropine [Benzatropine]			C				Not Reported

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Cefepime	C	Not Reported
Ceftriaxone	C	Not Reported
Daptomycin	C	Not Reported
Dexamethasone	C	Not Reported
Precedex	C	Not Reported
Diazepam	C	Not Reported
Enoxaparin	C	Not Reported
Fentanyl	C	Not Reported
Insulin Lispro	C	Not Reported
Culturelle	C	Not Reported
Meropenem	C	Not Reported
Metoprolol	C	Not Reported
Norepinephrine	C	Not Reported
Phenylephrine	C	Not Reported
Piperacillin / Tazobactam	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Vitamin C [Ascorbic Acid]	C	Not Reported
Zinc Sulfate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034928	DIRECT	Y	DE			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Cardio-Respiratory Arrest	Remdesivir			S	Intravenous drip			Gilead
	Albuterol			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Nph			C				Not Reported
	Novolog Insulin			C				Not Reported
	Ipratropium			C				Not Reported
	Thiamine			C				Not Reported
	Hydrocodone/Acetaminophen			C				Not Reported
	Fentanyl Continuous Infusion			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
Potassium Phosphate			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034929	DIRECT	Y	OT			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034932	DIRECT	Y	OT			57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Inflammatory Marker Increased; Pneumonia Staphylococcal; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4d;		Gilead
	Azithromycin 500mg Iv Daily			C				Not Reported
	Carbamazepine 200mg Po Q12h			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Enoxaparin 40mg Subq Q12h			C				Not Reported
	Famotidine 20mg Iv Q12h			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Meropenem 1g Iv Q6h			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Propofol Infusion			C				Not Reported
	Risperidone 0.5mg Po Qhs			C				Not Reported
	Tocilizumab 400mg X 1			C				Not Reported
	Vancomycin Varying Doses			C				Not Reported
	Vitamin C 1000mg Daily			C				Not Reported
Zinc Sulfate 220mg Po Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034933	DIRECT	Y				57 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir Tocilizumab	Y		S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034934	DIRECT	Y				62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Renal Impairment	Remdesivir Azithromycin Ceftriaxone Cefepime Vancomycin Norepinephrine	Y		S C C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034935	DIRECT	Y				57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir Actemra	Y		S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034936	DIRECT	Y				75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Dispensing Error; Product Preparation Issue	Remdesivir Injection			S	Intravenous drip			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034938	DIRECT	Y				55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dispensing Error; Product Preparation Issue	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034939	DIRECT	Y				69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Pneumonia Pseudomonal; Systemic Candida	Remdesivir	Y		S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034940	DIRECT	Y				55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered; Product Dispensing Error; Product Label Issue; Product Preparation Issue	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034941	DIRECT	Y	DE			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip	Other Frequency:200 Mg X1, 100 Mg;		Gilead
	Dexamethasone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034942	DIRECT	Y	DE			72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction; Cardiac Arrest; Oxygen Saturation Decreased	Remdesivir Cefepime 2g Iv Q12h Dexamethasone 6 Mg Iv Qdaily Enoxaparin 1 Mg/Kg Sc Q12h			S C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034943	DIRECT	Y	OT			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Sodium Chloride 0.45% Iv Acetaminophen Po Albuterol Inhaler Regular Insulin Sq Dexamethasone Iv Losartan Docusate Zinc Sulfate Po Ascorbic Acid Po Cholecalciferol Po Multivitamin W/ Minerals Po Rivaroxaban Ceftriaxone Iv Azithromycin Iv Furosemide Iv Push	Y		S C C C C C C C C C C C C C C C	Intravenous bolus	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034944	DIRECT	Y	OT			70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glomerular Filtration Rate	Remdesivir	Y		S	Intravenous (not			Gilead	

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Decreased

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034949	DIRECT	Y	DE			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Diarrhoea; Headache; Respiratory Distress	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C				Not Reported
	Lovenox			C				Not Reported
	Furosemide			C				Not Reported
	Iohexol			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported
	Ativan			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034950	DIRECT	Y	DE			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hepatic Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Apixaban 5 Mg Po Bid			C				Not Reported
	Ascorbic Acid 500 Mg Po Daily With Food			C				Not Reported
	Azithromycin 500 Mg Po Q24h			C				Not Reported
	Ceftriaxone 1 Gm Iv Daily			C				Not Reported
	Cholecalciferol 1,000 Iu Po Daily			C				Not Reported
	Daptomycin 450 Mg Iv Q24h			C				Not Reported
	Dexamethaxone 6 Mg Iv Daily			C				Not Reported
	Enoxaparin 90 Mg Sq Q12h			C				Not Reported
	Escitalopram 10 Mg Po Daily			C				Not Reported
	Guaifenesin Er 600 Mg Po Bid			C				Not Reported
	Levothyroxine 25 Mcg Po Daily			C				Not Reported
	Metoprolol 12.5 Mg Po Bid			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported
	Fentanyl 25 Mcg Iv Q1hr Prn			C				Not Reported
	Dyspena							

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Sodium Bicarbonate 150
Meq/1000 MI D5 Iv Solution 50
MI/Hr

C

Not Reported

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16-Jul-2020	18034951	DIRECT	Y	OT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18035164	DIRECT	Y				91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	17878094	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470901		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	17878265	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470883		70 YR	Male	USA

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Acute Kidney Injury; Covid-19 Pneumonia; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydroxychloroquine Actavis			C				Not Reported
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Isosorbide Mononitrate			C				Not Reported
	Metoprolol			C				Not Reported
	Rosuvastatin			C				Not Reported
	Sevelamer			C				Not Reported
	Sodium Polystyrene Sulfonate			C				Not Reported
Plasma			C				Not Reported	
Oxygen			C				Not Reported	
Eliquis			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	17925062	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2020238576		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use	Levofloxacin			S		Unk		Pfizer
	Levofloxacin			S				Pfizer
	Meropenem			S		Unk		Pfizer
	Meropenem			S				Pfizer
	Tigecycline			S		Unk		Pfizer
	Tigecycline			S				Pfizer
	Isavuconazonium Sulfate			S		Unk		Unknown
	Isavuconazonium Sulfate			S				Unknown
	Remdesivir			S		Intravenous (not otherwise specified)	200 Mg	Not Reported
	Remdesivir			S				Not Reported
Remdesivir			S				Not Reported	

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Colimycine [Colistin Sulfate]	S	Unk	Not Reported
Colimycine [Colistin Sulfate]	S		Not Reported
Voriconazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	17925759	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0474420		77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Potassium Increased; Blood Pressure Decreased; Death; Haematocrit Decreased; Haemoglobin Decreased; Thrombocytopenia; Vomiting	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Acetaminophen			C				Not Reported
	Chlorhexidine			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Docusate;Senna			C				Not Reported
	Fentanyl			C				Not Reported
	Haloperidol			C				Not Reported
	Hydrocortisone			C				Not Reported
	Insulin Regular Hm			C				Not Reported
	Ketamine			C				Not Reported
	Levetiracetam			C				Not Reported
	Lorazepam			C				Not Reported
	Metronidazole			C				Not Reported
	Midazolam			C				Not Reported
	Milk Of Magnesia			C				Not Reported
	Pantoprazole			C				Not Reported
	Quetiapine			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Sodium Chloride			C				Not Reported
	Sodium Polystyrene Sulfonate			C				Not Reported
	Trazodone			C				Not Reported
	Valproic Acid			C				Not Reported
	Vasopressin			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	17951126	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475719		82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone Plasma			C				Not Reported
	Ceftriaxone			C				Not Reported
	Emend [Aprepitant]			C				Not Reported
	Zofran [Ondansetron]			C				Not Reported
	Compazine [Prochlorperazine Maleate]			C				Not Reported
	Oxygen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18020525	NON-EXPEDITED		DE, OT	US-SA-2020SA179325			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haemorrhage	Plavix			S	Unknown	Unk		Sanofi
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Low Molecular Weight Heparin			S	Unknown	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Baricitinib			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035516	DIRECT	Y	OT			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Lung Infiltration	Remdesivir	Y	S	Intravenous drip	Gilead
	Rocephin		C		Not Reported
	Azithromycin		C		Not Reported
	Vancomycin		C		Not Reported
	Zosyn		C		Not Reported
	Dexamethasone		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035517	DIRECT	Y	OT			70 YR	Male	AFG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Disease Complication; Pneumonia	Remdesivir			S	Intravenous drip			Gilead
	Azithromycin			C				Not Reported
	Zosyn			C				Not Reported
	Solumedrol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035597	DIRECT	Y	OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous drip			Gilead
	Solumedrol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035639	DIRECT	Y				30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:200mgx1,100m gx4;		Gilead
	Acetaminophen 500mg Tab			C				Not Reported
	Ondansetron 4mg Iv			C				Not Reported
	Dexamethasone 6mg Iv			C				Not Reported
	Enoxaparin 40mg Syringe			C				Not Reported
	Mucinex Dm 600/30mg Tab Sr			C				Not Reported

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Acetaminophen 325mg Tab

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035719	DIRECT	Y	OT			1 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Rocephin Zosyn Azithromycin Rocephin	Y		S C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035725	DIRECT	Y	DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035926	DIRECT	Y	OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Hypersensitivity; Feeling Abnormal; Headache; Pharyngeal Swelling; Refusal Of Treatment By Patient	Remdesivir Remdesivir Ascorbic Acid Azithromycin Ceftriaxone Cholecalciferol Dexamethasone Enoxaparin Furosemide Pantoprazole			S S C C C C C C C C	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Other Frequency:Once; Other Frequency:Once;		Gilead Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Polyethylene Glycol 3350	C	Not Reported
Zinc Sulfate	C	Not Reported
Codeine-Guaifenesin	C	Not Reported
Promethazine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18035933	DIRECT	Y	OT			89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Related Reaction; Infusion Site Extravasation; Infusion Site Swelling	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18036176	DIRECT	Y	OT			44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Oxygen Saturation Decreased; Platelet Count Increased; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mgx4d;	4 DAY	Gilead
	Acetaminophen Q6h Prn Fever			C				Not Reported
	Azithromycin 500mg Iv Daily			C				Not Reported
	Benzonatate 200mg Q8h			C				Not Reported
	Ceftriaxone 1g Iv Daily			C				Not Reported
	Enoxaparin 30mg Subq Q12h			C				Not Reported
	Famotidine 20mg Po Q12h			C				Not Reported
	Advair Hfa 115/21 2 Puff Bid			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Spiriva 18mcg Inhaled Daily			C				Not Reported
	Vitamin C 1000mg Po Daily			C				Not Reported
	Zinc Sulfate 200mg Po Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18036194	DIRECT	Y	OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Sars-Cov-2 Test Positive	Remdesivir	S	Intravenous (not otherwise specified)	Other Frequency:Once;	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)		Gilead
	Acetaminophen	C			Not Reported
	Dexamethasone	C			Not Reported
	Docusate	C			Not Reported
	Enoxaparin	C			Not Reported
	Lamotrigine	C			Not Reported
	Lithium	C			Not Reported
	Pantoprazole	C			Not Reported
	Pramipexole	C			Not Reported
	Senna	C			Not Reported
	Trazodone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18036257	DIRECT	Y	HO			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18036332	DIRECT	Y	OT			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Amlodipine			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported

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Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Vasopressin	C	Not Reported

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17-Jul-2020	18037300	EXPEDITED (15-DAY)		DE, OT	GB-IBIGEN-2020.09028		84 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Livedo Reticularis	Oxygen			C				Not Reported
	Piperacillin & Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid		Not Reported
	Allopurinol			C				Not Reported
	Fexofenadine			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			S	Oral	6 Mg, Qd		Not Reported
	Omeprazole			C				Not Reported
	Dalteparin			C				Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18037988	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0483702		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin (E.C.)			C				Not Reported
	Metformin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported

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Enoxaparin	C	Not Reported
Epinephrine	C	Not Reported
Epoprostenol	C	Not Reported
Famotidine	C	Not Reported
Fentanyl	C	Not Reported
Furosemide	C	Not Reported
Lantus	C	Not Reported
Insulin Lispro	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Phenylephrine	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Vasopressin	C	Not Reported
Vecuronium	C	Not Reported
Tocilizumab	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18038118	EXPEDITED (15-DAY)			US-GILEAD-2020-0483220			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Overdose	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	200 Mg, Once		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18038968	EXPEDITED (15-DAY)		DE, OT	GB-BAUSCH-BL-2020-020115		84 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Livedo Reticularis	Dexamethasone			S	Oral			Valeant
	Piperacillin And Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Not Reported

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Oxygen	C		Not Reported
Allopurinol	C		Not Reported
Fexofenadine	C		Not Reported
Atorvastatin	C	Unknown	Not Reported
Omeprazole	C	Unknown	Not Reported
Dalteparin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18038969	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483273		75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18039487	EXPEDITED (15-DAY)			US-GILEAD-2020-0483949		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Issue	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18039530	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483230		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased;	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead
Prothrombin Time Prolonged;	Remdesivir			S	Intravenous bolus	Unk		Gilead
Thrombocytopenia	Remdesivir			S	Intravenous bolus	Unk		Gilead
	Decadron [Dexamethasone]			C		6 Mg, Qd		Not Reported
	Actemra			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18040312	EXPEDITED (15-DAY)			US-GILEAD-2020-0483260		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead	
	Azithromycin			C		Unk		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Dexamethasone			C		Unk		Not Reported	
	Enoxaparin			C		Unk		Not Reported	
	Combivent			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18040633	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483659		85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Blood Bilirubin Increased; Blood Creatinine Increased; Cardiac Arrest; Hypotension; Hypothermia; Respiratory Arrest; Unresponsive To Stimuli	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead	
	Dexamethasone			C		6 Mg, Qd		Not Reported	
	Plasma, Fresh Frozen Oxygen			C				Not Reported	
	Furosemide			C		Unk		Not Reported	
	Valsartan			C		Unk		Not Reported	
	Sodium Chloride 0.9%			C		500 MI		Not Reported	
	Normal Saline			C		75 MI/Hr		Not Reported	
	Albumin (Ljudski) 20%			C		Unk		Not Reported	

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17-Jul-2020	18040850	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483686		88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous bolus	100 Mg, Once		Gilead
	Lisinopril			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042660	DIRECT	Y				62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042664	DIRECT	Y	HO			32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Tylenol 650mg			C				Not Reported
	Azithromycin 500mg			C				Not Reported
	Dexamethasone 6mg			C				Not Reported
	Enoxaparin 40mg			C				Not Reported
	Furosemide 40mg			C				Not Reported
	Levalbuterol			C				Not Reported
	Rocephin 1gm			C				Not Reported
	Morphine 2mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042688	DIRECT	Y	OT			97 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Creatinine Increased	Remdesivir	S	Intravenous drip	Other Frequency:Once;	Gilead
	Carboxymethylcellulose	C			Not Reported
	Ophthalmic Drops				
	Ceftaroline	C			Not Reported
	Premarin Vaginal Cream	C			Not Reported
	Enoxaparin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042704	DIRECT	Y				60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Laboratory Test Abnormal; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042711	DIRECT	Y	HO			82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous drip		4 DAY	Gilead
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported
	Duloxetine			C				Not Reported
	Etomidate			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ipratropium			C				Not Reported
	Levetiracetam			C				Not Reported
	Lorazepam			C				Not Reported
	Memantine			C				Not Reported
	Meropenem			C				Not Reported
	Oxybutynin			C				Not Reported
	Succinylcholine			C				Not Reported
	Propofol			C				Not Reported
	Gapabentin			C				Not Reported
	Fentanyl			C				Not Reported

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Midazolam	C	Not Reported
Norepinephrine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042717	DIRECT	Y				86 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Creatinine Renal Clearance Decreased	Remdesivir			S	Intravenous drip		1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042722	DIRECT	Y	DE			1 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Acute Kidney Injury; Cardiac Arrest; Decreased Appetite; Encephalopathy; Lethargy; Malaise; Nausea; Pneumonia; Pyrexia; Respiratory Distress; Respiratory Failure; Septic Shock	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Azithromycin 500 Mg Iv Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Enoxaparin 40 Mg Sq Once Daily			C				Not Reported
	Lasix 20 Mg Iv Bid 9a, 5p			C				Not Reported
Lasix 40 Mg Iv X 1			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042760	DIRECT	Y	OT			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Unfractionated Heparin			C				Not Reported

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Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Linezolid	C	Not Reported
Mycophenolate	C	Not Reported
Tacrolimus	C	Not Reported
Dexmedetomidine	C	Not Reported
Fentanyl	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Sodium Bicarbonate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042765	DIRECT	Y				26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation; Pain; Peripheral Swelling; Skin Discolouration	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042778	DIRECT	Y	OT			43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Laboratory Test Abnormal	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042796	DIRECT	Y	DE			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hepatic Enzyme Increased; Leukocytosis; Pneumonia Aspiration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Hydroxychloroquine 400 Mg X 1			C				Not Reported
	Levetiracetam 500 Mg Iv Q12hr			C				Not Reported
	Zosyn 3.375 Gm Iv Q8hr			C				Not Reported

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Vancomycin 1250 Mg Iv Q18h	C	Not Reported
Dexamethasone 20 Mg Iv Daily	C	Not Reported
Amlodipine 5 Mg Po Once Daily	C	Not Reported
Aspirin 81 Mg Po Once Daily	C	Not Reported
Atorvastatin 80 Mg Po Daily	C	Not Reported
Donepezil 10 Mg Po W/ Breakfast	C	Not Reported
Enoxaparin 40 Mg Sq Once Daily	C	Not Reported
Enoxaparin 100 Mg Sq Q12hr	C	Not Reported
Enoxaparin 90 Mg Sq Q12hr	C	Not Reported
Fluoxetine 20 Mg Po Once Daily	C	Not Reported
Metoprolol 25 Mg Po Q12hr	C	Not Reported
Tamsulosin 0.4 Mg Po Once Daily	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042800	DIRECT	Y	DE			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Hypoxia; Pulmonary Function Test Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg Iv X 1			C				Not Reported
	Azithromycin 500 Mg Po Once Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Enoxaparin 40 Mg Sq Once Daily			C				Not Reported
	Enoxaparin 80 Mg Sq Once Daily			C				Not Reported
	Methylprednisolone 60 Mg Iv Q12hr			C				Not Reported
	Zinc Sulfate 220 Mg Po Bid			C				Not Reported
	Lantus 15 Units Sq Daily			C				Not Reported
	Lantus 20 Untis Sq Bid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042831	DIRECT	Y	OT			1 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Hypersensitivity; Rash; Swelling	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 Mg Iv X 1			C				Not Reported
	Azithromycin 500 Mg Po Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Ceftriaxone 1 Gm Iv Once Daily			C				Not Reported
	Diphenhydramine 25 Mg Iv X 1 Stat			C				Not Reported
	Enoxaparin 60 Mg Sq Q12hrs			C				Not Reported
	Methylprednisolone 60 Mg Iv Q6hr			C				Not Reported
	Zinc Sulfate 220 Mg Po Bid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042835	DIRECT	Y					Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Liver Function Test Increased	Remdesivir	Y		S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042845	DIRECT	Y	DE			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Amlodipine 10 Mg			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Dexamethasone 10 Mg Iv Once Daily			C				Not Reported
	Hydroxychloroquine 400 Mg Po Daily			C				Not Reported
	Hydroxchloroquine 400 Mg Po Q12hrs			C				Not Reported

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Enoxaparin 50 Mg Sq Q12hrs	C	Not Reported
Enoxaparin 100 Mg Sq Q12hrs	C	Not Reported
Enoxaparin 100 Mg Sq Once Daily	C	Not Reported
Enoxaparin 80 Mg Sq Once Daily	C	Not Reported
Enoxaparin 70 Mg Sq Q12hrs	C	Not Reported
Meropenem 1 Gm Q8hr	C	Not Reported
Meropenem 500 Mg Q8hr	C	Not Reported
Vancomycin 1 Gm Iv Q12hrs	C	Not Reported
Vancomycin 750 Mg Iv Q12hrs	C	Not Reported
Zinc Sulfate 220 Mg Po Bid	C	Not Reported
Methylprednisolone 40 Mg Iv Q12hr	C	Not Reported
Lantus 10 Units Sq Bid	C	Not Reported
Lantus 16-24 Units Sq Bid	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042848	DIRECT	Y	OT			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Laboratory Test Abnormal	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042873	DIRECT	Y	DE			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Injury; Pulseless Electrical Activity	Remdesivir	Y		S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2020	18042876	DIRECT	Y	DE			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Enterobacter	Remdesivir	Y		S				Not Reported
	Actemra			C				Not Reported

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Pneumonia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2020	18038171	EXPEDITED (15-DAY)		DE, OT	GB-AUROBINDO-AUR-APL-2020-035246		84 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Livedo Reticularis	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	13.5 Gram, Once A Day (4.5 G, Tid)		Aurobindo
	Dexamethasone			S	Oral	6 Milligram, Once A Day		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	2 Gram, Two Times A Day (1 G, Bid)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk (200, Stat)		Not Reported
	Oxygen			C	Unknown	Unk		Not Reported
	Allopurinol			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Dalteparin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2020	18042881	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2020	18042886	DIRECT	Y				73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Infusion Site	Remdesivir	S	Not Reported
Extravasation; Peripheral Swelling			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2020	18042888	DIRECT	Y				64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dialysis; Renal Failure	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2020	18042948	DIRECT	Y	OT			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophne 650mg Q4h Prn			C				Not Reported
	Ascorbic Acid 1000 Mg Po Bid			C				Not Reported
	Atorvastatin 80 Mg Once Daily			C				Not Reported
	Benzonatate 200 Mg Po Q8h			C				Not Reported
	Docusate 200 Mg Po Bid			C				Not Reported
	Enoxaparin 90 Mg Sc Q12h			C				Not Reported
	Famotidine 20 Mg Iv/Po Q12h			C				Not Reported
	Fentanyl Iv Continuous Infusion			C				Not Reported
	Insulin Glargine 40 Units Sc Bedtime			C				Not Reported
	Methylprednisolone 40 Mg Iv Q6h			C				Not Reported
	Midazolam Iv Continuous Infusion			C				Not Reported
	Norepinephrine Iv Continuous Infusion			C				Not Reported
	Rocuronium Continuous Iv Infusion			C				Not Reported
	Sertraline 50 Mg Po Daily			C				Not Reported
	Thiamine Mononitrate 100 Mg Po Daily			C				Not Reported
Zinc Sulfate 220 Mg Po Bid			C				Not Reported	

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19-Jul-2020	18042892	DIRECT	Y	OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Dexamethasone			C				Not Reported	
	Cefepime			C				Not Reported	
	Propofol			C				Not Reported	
	Fentanyl			C				Not Reported	
	Diltiazem			C				Not Reported	
	Norepinephrine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2020	18042893	DIRECT	Y	OT			40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Eye Irritation; Lacrimation Increased; Photophobia	Remdesivir (Eua) 100 Mg In Sodium Chloride 0.9 % 250 MI lvpb			S	Intravenous drip			Gilead	
	Ceftriaxone 1g Q24h			C				Not Reported	
	Doxycycline 100 Mg Bid			C				Not Reported	
	Heparin 5000 Units Subq Bid			C				Not Reported	
	Acetaminophen 1000 Mg Q8h			C				Not Reported	
	Senna 17.2 Mg			C				Not Reported	
	Dextromethorphan-Guaifenesin (Robitussin-Dm) 10-100 Mg/5 MI Liquid 5 M			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2020	18042921	DIRECT	Y				42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2020	18042929	DIRECT	Y	OT			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vecuronium			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2020	18042938	DIRECT	Y				89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Lip Erythema; Lip Swelling; Lung Opacity; Oxygen Saturation Decreased; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone Oral Tablet			C				Not Reported
	Enoxaparin 30 Mg Syringe			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	17866588	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0470040		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S		Intravenous (not otherwise specified)	100 Mg, Qd	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	17976144	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478171		31 YR	Male	USA

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Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Oxygen			C	Nasal	5 L, Q1minute		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044292	DIRECT	Y	OT			26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Decreased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Sulfamethoxazole/Trimethoprim			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044297	DIRECT	Y	OT			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Isosorbide			C				Not Reported
	Levothyroxine			C				Not Reported
	Potassium			C				Not Reported
	Aspirin			C				Not Reported
	Apixaban			C				Not Reported
	Ceftriaxone			C				Not Reported
	Iohexol			C				Not Reported
	Acetaminophen			C				Not Reported
	Furosemide			C				Not Reported

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Cefepime									Not Reported
Vancomycin									Not Reported

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20-Jul-2020	18044300	DIRECT	Y	DE			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Metabolic Acidosis; Pulseless Electrical Activity; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Melatonin			C				Not Reported
	Morphine			C				Not Reported
	Ocular Lubricant			C				Not Reported
	Ceftriaxone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Albumin			C				Not Reported
	Lactated Ringers			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044306	DIRECT	Y				42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044312	DIRECT	Y	DE			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood	Remdesivir (Gs-574)			S	Intravenous (not			Gilead

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Creatinine Increased;
Blood Urea Increased

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044317	DIRECT					40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen 650 Mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044322	DIRECT	Y	HO			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044453	DIRECT	Y				76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous drip			Not Reported
	Dexamethasone			C				Not Reported
	Rivaroxaban			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044487	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Atorvastan			C				Not Reported
	Azithromycin			C				Not Reported

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Ceftriaxone	C	Not Reported
Norepinephrine Drip	C	Not Reported
Fentanyl Drip	C	Not Reported
Pitressin Drip	C	Not Reported
Propofol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044522	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484016		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure; Respiratory Failure; Septic Shock	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Methylprednisolone			C				Not Reported
	Cefepime			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Protonix [Omeprazole]			C				Not Reported
	Zinc Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18044535	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0483671		29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Guaifenesin			C		Unk		Not Reported
	Multivitamin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18045226	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0483668		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Bilirubin Increased; Liver	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

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Function Test Increased Remdesivir S Intravenous (not otherwise specified) 100 Mg, Qd Gilead

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20-Jul-2020	18045238	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2020274304		84 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Hypotension; Livedo Reticularis; White Blood Cell Count Decreased	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid 3x/Day		Pfizer
	Vancomycin Hcl			S	Intravenous (not otherwise specified)	2 G, 2x/Day		Pfizer
	Dexamethasone			S	Oral	6 Mg, Qd (Daily)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	200 Unk (Stat)		Not Reported
	Oxygen			C		Unk		Not Reported
	Allopurinol			C		Unk		Not Reported
	Fexofenadine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Dalteparin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18045538	EXPEDITED (15-DAY)			US-GILEAD-2020-0483336			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Preparation Issue	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18045788	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483629		74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Glomerular Filtration Rate Decreased	Remdesivir	S	Unknown	Unk	Gilead
	Propofol	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Famotidine	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Piperacillin / Tazobactam	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Zofran [Ondansetron]	C		Unk	Not Reported
	Calquence	C		Unk	Not Reported
	Lasix [Furosemide]	C		Unk	Not Reported
	Potassium Chloride	C		Unk	Not Reported
	Sodium Chloride	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18045905	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483722		88 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047692	DIRECT	Y				76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Prescribing Error; Wrong Product Administered	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047736	DIRECT	Y	HO			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Remdesivir	Y		S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported
	Plavix			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin			C				Not Reported
	Lasix			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol XI			C				Not Reported
	Proton Ix			C				Not Reported
	Lovenox			C				Not Reported
	Levaquin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047739	DIRECT	Y	RI			28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Dose Omission; Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047771	DIRECT	Y				80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; International Normalised Ratio Increased; Ischaemic Hepatitis	Remdesivir			S	Intravenous bolus			Gilead
	Meropenem			C				Not Reported

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20-Jul-2020	18047777	DIRECT	Y				87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extra Dose Administered; Product Prescribing Error	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047781	DIRECT	Y				57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Diprivan			C				Not Reported	
	Heparin			C				Not Reported	
	Versed			C				Not Reported	
	Zemuron			C				Not Reported	
	Sublimaze			C				Not Reported	
	Sodium Chloride 0.45%			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047785	DIRECT	Y	OT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead	
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Tocilizumab			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047790	DIRECT	Y	OT			59 YR	Male	USA

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Transaminases Increased	Remdesivir 200mg			S	Intravenous bolus	200mg X1 Then 100mg Daily X4		Gilead
	Atorvastatin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047806	DIRECT	Y	LT			75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone 6 Mg Po			C				Not Reported
	Famotidine 20 Mg Po			C				Not Reported
	Rocuronium 50 Mg Iv			C				Not Reported
	Midazolam 2 Mg Iv			C				Not Reported
	Propofol			C				Not Reported
Succinylcholine 100 Mg Iv			C			Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047826	DIRECT	Y	OT				Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; International Normalised Ratio Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18047831	DIRECT	Y	OT			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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20-Jul-2020	18047838	DIRECT	Y				44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Discomfort; Infusion Site Extravasation; Infusion Site Pain	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18048292	DIRECT	Y	OT			46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Second Degree	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	17872381	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020- 0469304		79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Plaquinol			C	Oral	Unk		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Doxycycline			C	Oral	Unk		Not Reported	
	Vancomycin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Vitamin C [Ascorbic Acid]			C		Unk		Not Reported	
	Torseamide			C	Oral			Not Reported	
	Cardizem Cd			C	Oral			Not Reported	

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Lipitor [Atorvastatin]	C	Oral		Not Reported
Protonix [Omeprazole]	C			Not Reported
Metoprolol	C			Not Reported
Prednisone	C	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	C	Intravenous (not otherwise specified)	400 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	17975234	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0477746		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infection; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	6mg		Not Reported
	Enoxaparin			C	Subcutaneous	70 Mg, Bid		Not Reported
	Iohexol			C	Intravenous (not otherwise specified)	90ml		Not Reported
	Multivitamins;Minerals			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	17979289	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478652		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S		Unk		Gilead
	Amlodipine			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Carvedilol			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

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Cefuroxime	C	Unk	Not Reported
Clopidogrel	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Probiotic [Bifidobacterium Infantis;Lactobacillus Acidophilus]	C	Unk	Not Reported
Lisinopril	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Pravastatin	C	Unk	Not Reported
Acetaminophen	C	Unk	Not Reported
Haldol [Haloperidol]	C	Unk	Not Reported
Hydralazine	C	Unk	Not Reported
Effer K	C	Unk	Not Reported
Magnesium	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18048688	DIRECT	Y				53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18048691	DIRECT	Y				41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported

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Azithromycin	C	Not Reported
Benzonatate	C	Not Reported
Ceftriaxone	C	Not Reported
Codeine-Guaifenasin	C	Not Reported
Dexamethasone	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported
Peg 3350	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18048696	DIRECT	Y	OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Pulseless Electrical Activity	Remdesivir			S	Intravenous bolus			Gilead
	Tylenol			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18048902	DIRECT		DE			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Covid-19; Diarrhoea; Drug Withdrawal Syndrome; Fibrin D Dimer Increased; Nausea; Pulseless Electrical Activity; Respiratory Distress; Serum Ferritin Increased; Vomiting	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18048962	DIRECT	Y	HO			58 YR	Male	USA

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		5 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049335	DIRECT	Y	OT			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049365	DIRECT	Y	OT			83 YR	Male	PRI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Dexamethasone			C		Not Reported			
	Doxycycline			C		Not Reported			
	Norepinephrine			C		Not Reported			
	Cefepime			C		Not Reported			
	Midazolam			C		Not Reported			
Enoxaparin			C	Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049368	DIRECT	Y	OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Azithromycin			C		Not Reported			

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21-Jul-2020	18049671	DIRECT	Y	OT			20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
	Azithromycin 500mg Iv Q24h			C				Not Reported	
	Ceftriaxone 2g Iv Q24h			C				Not Reported	
	Dexamethasone 6mg Po Q24h			C				Not Reported	
	Enoxaparin 40mg Sq Q24h			C				Not Reported	
	Tocilizumab 400mg Iv Once			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049679	DIRECT	Y	DS, HO			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Artery Occlusion; Cerebral Infarction	Remdesivir			S	Intravenous bolus		5 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049688	DIRECT	Y				33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills	Remdesivir	Y		S	Intravenous bolus			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049743	DIRECT		HO			79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049788	DIRECT		OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased	Remdesivir Simvastatin			S C					Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18049795	DIRECT	Y	DS			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead
	Aspirin 81 Mg			C					Not Reported
	Cetylpyridinium Chloride			C					Not Reported
	Chlorhexidine			C					Not Reported
	Cisatracurium			C					Not Reported
	Dexamethasone			C					Not Reported
	White Petrolatum-Mineral Oil			C					Not Reported
	Ophthalmic Ointment								
	Diltiazem			C					Not Reported
	Enoxaparin			C					Not Reported
	Famotidine			C					Not Reported
	Fentanyl			C					Not Reported
	Furosemide			C					Not Reported
	Heparin			C					Not Reported
	Insulin Lispro			C					Not Reported
	Multivitamin With Iron-Mineral			C					Not Reported
	Mupirocin			C					Not Reported
	Polyethylene Glycol Packet			C					Not Reported
	Sennosides			C					Not Reported
	Unjury			C					Not Reported

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Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported

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21-Jul-2020	18050438	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483985		22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Transaminases Increased	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Albuterol [Salbutamol Sulfate]			C		Unk		Not Reported
	Fluticasone			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18050599	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484234		58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Hypertension; Hypoxia; Pulmonary Function Test Decreased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Azithromycin			C	Oral	500 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	80 Mg, Qd		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	60 Mg		Not Reported

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Zinc Sulfate	C	Oral	220 Mg, Bid	Not Reported
Lantus	C	Subcutaneous	15 Units	Not Reported
Lantus	C	Subcutaneous	20 Units	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18050743	EXPEDITED (15-DAY)		DE, HO	BE-SEBELA IRELAND LIMITED-2020SEB00086		68 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Toxic; Respiratory Failure	Imuran			S		Unk		Sebela
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S		Unk		Not Reported
	Aldactone			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Cetirizine			C		Unk		Not Reported
	Domperidone			C		Unk		Not Reported
	Livial			C		Unk		Not Reported
	Thyroxine			C		Unk		Not Reported
	Medrol			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18050980	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0484178		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

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21-Jul-2020	18052100	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0484063			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19	Remdesivir			S	Unknown				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Jul-2020	18052350	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484228		67 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead	
	Tylenol			C		650 Mg			Not Reported	
	Albuterol Hfa			C		Unk			Not Reported	
	Ceftriaxone			C		1 G			Not Reported	
	Ns			C		Unk			Not Reported	
	Azithromycin			C		500 Mg			Not Reported	
	Heparin			C		Subcutaneous	7500 Unit			Not Reported
	Dextromethorphan;Guaifenesin			C		20 Mg			Not Reported	
	Levothyroxin			C		137 Mcg			Not Reported	
Ondansetron			C	4 Mg			Not Reported			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053342	DIRECT	Y	OT			75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053359	DIRECT	Y	RI			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Haemodialysis; Paralysis; Renal Failure; Sepsis; Therapy Cessation	Remdesivir			S				Not Reported
	Calcium Chloride			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Lantus			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053364	DIRECT	Y	DE			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hypotension	Remdesivir			S	Oral			Gilead
	Lovenox			C				Not Reported
	Atorvastatin			C				Not Reported
	Propofol			C				Not Reported
	Phytonadione			C				Not Reported
	Zosyn			C				Not Reported
	Peg			C				Not Reported
	Morphine			C				Not Reported
	Lidocaine			C				Not Reported
	Fentanyl			C				Not Reported
	Epinephrine			C				Not Reported
	Furosemide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053368	DIRECT	Y	DE, HO, LT			84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S				Not Reported

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Aminotransferase
Increased

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21-Jul-2020	18053390	DIRECT	Y				64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Rivaroxaban			S	Oral			Janssen
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cholecalciferol			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin			C				Not Reported
	Pantoprazole			C				Not Reported
	Risperidone			C				Not Reported
	Tiotropium			C				Not Reported
Zinc Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053433	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation; Skin Disorder	Remdesivir Eua 100mg			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone Iv			C				Not Reported
	Enoxaparin Sq			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053436	DIRECT	Y	DE			97 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Creatinine Renal	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

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Clearance Decreased	Carboxymethylcellulose	C	Not Reported
	Ophthalmic Drops		
	Ceftaroline	C	Not Reported
	Premarin Vaginal Cream	C	Not Reported
	Dexamethasone	C	Not Reported
	Enoxaparin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18053466	DIRECT	Y	HO			83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Blood Glucose Decreased; Dysarthria; Dyspnoea; Hyperglycaemia; Lethargy; Lung Infiltration; Mental Status Changes; Pyrexia; White Blood Cell Count Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18054434	DIRECT	Y	DE			59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiac Arrest; Heart Rate Decreased	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Benzonatate			C				Not Reported
	Calcitriol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine			C				Not Reported
	Clopidogrel			C				Not Reported

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Dexamethasone	C	Not Reported
Diphenhydramine	C	Not Reported
Epoetin Alfa-Epbx	C	Not Reported
Fluconazole	C	Not Reported
Furosemide	C	Not Reported
Insulin Detemir	C	Not Reported
Insulin, Regular	C	Not Reported
Isosorbide Mononitrate	C	Not Reported
Melatonin	C	Not Reported
Metolazone	C	Not Reported
Midodrine	C	Not Reported
Mupirocin	C	Not Reported
Norepinephrine	C	Not Reported
Ondansetron	C	Not Reported
Pantoprazole	C	Not Reported
Propafenone	C	Not Reported
Sevalamer Carbonate	C	Not Reported
Terazosin	C	Not Reported
Trazodone	C	Not Reported
Vancomycin	C	Not Reported
Venlafaxine	C	Not Reported
Clortimazole	C	Not Reported
Insuline Aspart	C	Not Reported
Metoprolol Succinate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18054894	DIRECT	Y	RI			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir (Eua) (Remdesivir (Eau))			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18054943	DIRECT	Y				83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir (Eua) (Remdesivir (Eau))			S	Intravenous (not otherwise specified)			Not Reported

Aminotransferase
Increased; Liver Function
Test Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18054997	DIRECT	Y				51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir (Eua) (Remdesivir (Eau))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18055037	DIRECT	Y	RI			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	Remdesivir (Eua) (Remdesivir (Eau))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18055038	DIRECT	Y	DE			89 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Disease Progression; Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir (Eua) (Remdesivir (Eau))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2020	18055058	DIRECT	Y	DE			71 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Disease Progression; Glomerular Filtration Rate Decreased; Renal Failure	Remdesivir (Eua) (Remdesivir (Eau))			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	17925133	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0474418		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Covid-19; Dyspnoea	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C		Unk		Not Reported
	Acetaminofen			C		Unk		Not Reported
	Ipratropium Bromide/Albuterol Sulfate			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Bisacodyl			C		Unk		Not Reported
	Carvedilol			C		Unk		Not Reported
	Cefazolin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
Lidocaine			C		Unk		Not Reported	

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Metoprolol	C	Unk	Not Reported
Scopolamine [Hyoscine]	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	17952578	EXPEDITED (15-DAY)			US-GILEAD-2020-0476285		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18015900	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0480805		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Decadron [Dexamethasone]			C		Unk		Not Reported
	Digoxin			C				Not Reported
	Fentanyl			C		Unk		Not Reported
	Lasix [Furosemide]			C				Not Reported
	Heparin [Heparin Sodium]			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Diprivan			C		Unk		Not Reported
	Herceptin			C				Not Reported
	Perjeta			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054154	DIRECT	Y	OT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054171	DIRECT	Y	OT			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ertapenem			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Tamsulosin			C				Not Reported
	Furosemide			C				Not Reported
	Acetaminophen			C				Not Reported
	Morphine			C				Not Reported
	Ondansetron			C				Not Reported
	Oxycodone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Budesonide			C				Not Reported
	Dexamethasone			C				Not Reported
	Finasteride			C				Not Reported
	Atorvastatin			C				Not Reported
	Escitalopram			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054175	DIRECT	Y	CA			31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Death; Maternal	Remdesivir			S				Not Reported

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Drugs Affecting Foetus;	Levophed	C	Not Reported
Maternal Exposure Timing	Heparin Drip	C	Not Reported
Unspecified	Fentanyl Drip	C	Not Reported
	Lovenox	C	Not Reported
	Ceftriaxone	C	Not Reported
	Nimbex	C	Not Reported
	Dexamethasone	C	Not Reported
	Precedex	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054179	DIRECT	Y	DE			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardio-Respiratory Arrest; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)		7 DAY	Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Multivitamin			C				Not Reported
	Ergocalciferol			C				Not Reported
	Zosyn			C				Not Reported
	Zyvox			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Versed			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054194	DIRECT	N					Prefer not to disclose	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054412	DIRECT	Y	OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased	Remdesivir	Y	S	Intravenous (not otherwise specified)	Gilead
	Albuterol		C		Not Reported
	Albuterol-Ipratropium		C		Not Reported
	Ascorbic Acid		C		Not Reported
	Azithromycin		C		Not Reported
	Cholecalciferol		C		Not Reported
	Dexamethasone		C		Not Reported
	Doxycycline		C		Not Reported
	Famotidine		C		Not Reported
	Melatonin		C		Not Reported
	Potassium Chloride		C		Not Reported
	Ceftriaxone		C		Not Reported
	Thiamine		C		Not Reported
	Zinc Sulfate		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054585	DIRECT					66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054623	DIRECT	Y	OT			43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054795	DIRECT	Y				48 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			S	Intravenous bolus	Other Frequency:Once Dose;		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054800	DIRECT	Y				30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once-Loading Dose;		Gilead
	Vancomycin			C				Not Reported
	Levofloxacin			C				Not Reported
	Azithromycin			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054852	DIRECT	Y				66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tocilizumab			C				Not Reported
	Amiodarone Drip			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Cisatracurium Drip			C				Not Reported
	Diltiazem Drip			C				Not Reported
	Enoxaparin			C				Not Reported
	Epoprostenol Neb			C				Not Reported
	Ketamine Drip			C				Not Reported
	Lorazepam Inj			C				Not Reported
	Methylprednisolone Sod Succ Inj			C				Not Reported
	Midazolam Drip			C				Not Reported
	Norepinephrine Drip			C				Not Reported

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Pantoprazole Inj	C	Not Reported
Piperacillin-Tazobactam Ivpb	C	Not Reported
Rivaroxaban	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054927	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484197		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Benzonatate			C				Not Reported
	Dexamethasone			C				Unknown
	Enoxaparin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Bio-K Plus			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054937	DIRECT	Y				63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Piperacillin-Tazobactam			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc Gluconate			C				Not Reported
	Lovenox			C				Not Reported
	Insulin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055094	DIRECT	Y	OT			77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased	Remdesivir			S	Intravenous (not			Gilead

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055099	DIRECT	Y	DE			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Remdesivir			S	Intravenous drip			Gilead	
	Remdesivir			S	Intravenous drip			Gilead	
	Dimethicone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055100	DIRECT	Y	DE			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Glomerular Filtration Rate Decreased; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Hydroxychloroquine			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Azithromycin			C				Not Reported	
	Piperacillin/Tazobactam			C				Not Reported	
	Amiodarone			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Cicatracurium			C				Not Reported	
	Dexmedetomidine			C				Not Reported	
	Epoprostanol			C				Not Reported	
	Fentanyl			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055115	DIRECT	Y	DE			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Convalescent Plasma	C		Not Reported
	Dexamethasone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055119	DIRECT	Y				49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Transaminases Increased	Remdesivir Dexamethasone Lovenox	Y		S C C				Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055121	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir Azithromycin	Y		S C	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055167	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484150		40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir Remdesivir Rocephine Azithromycin			S S C C	Intravenous bolus	200 Mg, Once 100 Mg, Qd		Gilead Gilead Not Reported Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055195	DIRECT	Y	OT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tacrolimus			C		Not Reported		
	Aspirin			C		Not Reported		
	Benzonatate			C		Not Reported		
	Dexamethasone			C		Not Reported		
	Enoxaparin			C		Not Reported		
	Famotidine			C		Not Reported		
	Mycophenolate			C		Not Reported		
	Nifedipine XI			C		Not Reported		
Bld-2660/Placebo			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055197	DIRECT	Y	OT			45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055237	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484419		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055242	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484409		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Brain Injury; Death; Pulseless Electrical Activity	Remdesivir	S	Intravenous (not otherwise specified)	Unk	Gilead
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055247	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Gilead
	Tocilizumab 800 Mg Iv			C				Not Reported
	Cholecalciferol			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc			C				Not Reported
	Dexamethasone 6 Mg Iv Daily			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefepime			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide			C				Not Reported
	Carvedilol			C				Not Reported
	Enoxaparin			C				Not Reported
Finasteride			C				Not Reported	
Furosemide			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055254	DIRECT	Y	OT			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Pantopraxole			C				Not Reported
	Zinc Sulfate			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055312	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484440		71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Bid		Gilead
	Plasma			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055323	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484424		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Death; Enterobacter Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Actemra			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055324	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0484475		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Death	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Oxygen	C			Not Reported
	Plasma	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Lasix [Furosemide]	C		20 Mg, Bid	Not Reported
	Lasix [Furosemide]	C		40 Mg, Once	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18055403	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484435		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Hepatic Enzyme Increased; Hypoxia; Leukocytosis; Pneumonia Aspiration	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydroxychloroquine			C		400 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Plasma			C		Unk		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	1250 Mg		Not Reported
	Zosyn			C	Intravenous (not otherwise specified)	3.375 G, Q8h		Not Reported
	Levetiracetam			C	Intravenous (not otherwise specified)	500 Mg, Bid		Not Reported
Amlodipine			C	Oral	5 Mg, Qd		Not Reported	

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Aspirin 81	C	Oral	81 Mg, Qd	Not Reported
Atorvastatin	C	Oral	80 Mg, Qd	Not Reported
Donepezil	C	Oral	10 Mg	Not Reported
Enoxaparin	C	Subcutaneous	40 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	100 Mg, Bid	Not Reported
Enoxaparin	C	Subcutaneous	90 Mg, Bid	Not Reported
Fluoxetine	C	Oral	20 Mg, Once	Not Reported
Metoprolol	C	Oral	25 Mg, Bid	Not Reported
Tamsulosin	C	Oral	0.4 Mg, Qd	Not Reported
Epinephrine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18056373	NON-EXPEDITED		DE, OT	US-SA-2020SA189495			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Subdural Haemorrhage	Plavix			S	Unknown			Sanofi
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Heparin (Salt Not Specified)			S	Unknown			Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18056545	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484152		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Blood Creatinine Increased; Inflammatory Marker Increased; Liver Function Test Increased; Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
Staphylococcal	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Carbamazepine			C		Unk		Not Reported

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Ceftriaxone	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Fentanyl	C	Unk	Not Reported
Meropenem	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Risperidone	C	Unk	Not Reported
Tocilizumab	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Vitamin C [Ascorbic Acid]	C	Unk	Not Reported
Zinc Sulfate	C	Unk	Not Reported
Clonazepam	C		Not Reported
Metformin	C		Not Reported
Metoprolol Tartrate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18056597	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484192		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Famotidine			C	Oral	20 Mg		Not Reported
	Culturelle			C	Oral	1 Dosage Form, Qd		Not Reported
	Vitamin C Acid			C	Oral	1 G, Qd		Not Reported
	Zinc Sulfate			C	Oral	220 Mg, Qd		Not Reported
	Dexamethasone			C				Not Reported

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22-Jul-2020	18056841	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484422		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Death; Diarrhoea; Drug Withdrawal Syndrome; Nausea; Oxygen Saturation Decreased; Pulseless Electrical Activity; Vomiting	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Bid		Gilead
	Enoxaparin				C		Unk		Not Reported
	Oxygen				C	Nasal	12 L High Flownasal Cannula		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18056972	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484177		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Pneumonia Pseudomonal; Systemic Candida	Remdesivir				S	Unknown	Unk		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18057091	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484405		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen				C		Unk		Not Reported
	Amlodipine				C		Unk		Not Reported
	Azithromycin				C				Not Reported
	Ceftriaxone				C		Unk		Not Reported
	Dexamethasone				C		Unk		Not Reported
	Dexmedetomidine				C		Unk		Not Reported
	Enoxaparin				C		Unk		Not Reported

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Fentanyl	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Vasopressin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18057110	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484418		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Laboratory Test Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18057123	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484429		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Docusate			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Lamotrigine			C				Not Reported
	Lithium			C				Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pramipexole			C				Not Reported
	Senna			C		Unk		Not Reported

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Trazodone		C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18057147	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484437		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18057167	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484479		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Acetaminophen			C				Not Reported	
	Albuterol [Salbutamol]			C		Unk		Not Reported	
	Apixaban			C		Unk		Not Reported	
	Aspirin [Acetylsalicylic Acid]			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Benzonatate			C		Unk		Not Reported	
	Calcitriol			C		Unk		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Chlorhexidine			C		Unk		Not Reported	
	Clopidogrel			C				Not Reported	
	Clotrimazole			C		Unk		Not Reported	
	Dexamethasone			C		Unk		Not Reported	
	Diphenhydramine			C		Unk		Not Reported	
	Epoetin Alfa Epbx			C		Unk		Not Reported	
	Fluconazole			C		Unk		Not Reported	

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Furosemide	C		Not Reported
Insulin Aspart	C	Unk	Not Reported
Insulin Detemir	C	Unk	Not Reported
Insulin Regular [Insulin Porcine]	C	Unk	Not Reported
Isosorbide Mononitrate	C		Not Reported
Melatonin	C	Unk	Not Reported
Metolazone	C		Not Reported
Metoprolol Succinate	C		Not Reported
Midodrine	C		Not Reported
Mupirocin	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Ondansetron	C	Unk	Not Reported
Pantoprazole	C		Not Reported
Propafenone	C		Not Reported
Sevelamer Carbonate	C	Unk	Not Reported
Terazosin	C		Not Reported
Trazodone	C		Not Reported
Vancomycin	C	Unk	Not Reported
Venlafaxine	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18057283	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484715		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058379	DIRECT	Y	OT			70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Aspartate Aminotransferase Increased	Remdesivir	Y	S	Intravenous bolus		Gilead
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058380	DIRECT	Y	LT			29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058418	DIRECT	Y				63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cholecalciferol			C			Not Reported	
	Dexamethasone			C			Not Reported	
	Vitamin C			C			Not Reported	
	Zinc			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058424	DIRECT	Y				22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertension; Infusion Related Reaction; Oxygen Saturation Decreased; Pyrexia	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058427	DIRECT	Y	DE, LT			91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Alanine Aminotransferase Increased Remdesivir S Intravenous (not otherwise specified) Other Frequency:Once - Loading Dose; Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058431	DIRECT	Y	HO			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Atorvastatin 40 Mg			S C	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058438	DIRECT	Y	DE			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Hypotension; Hypoxia; Mental Status Changes; Oxygen Saturation Decreased	Remdesivir Dexamethasone 6 Mg Combivent Azithromycin 500 Mg Iv Ceftriaxone 1 Gm Iv			S C C C C	Intravenous bolus			Gilead Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058451	DIRECT	Y				56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058454	DIRECT	Y				67 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058458	DIRECT	Y				50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Vitamin C			C				Not Reported
	Zinc			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Ketamine			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported
	Rosuvastatin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058463	DIRECT	Y	OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous drip			Gilead
	Dexamethasone			C				Not Reported
	Levofloxacin			C				Not Reported
	Azithromycin			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058472	DIRECT	Y				45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058478	DIRECT	Y				86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Drug Administration Rate; Product Preparation Issue	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058482	DIRECT	Y				82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058488	DIRECT	Y	DE			33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paralysis; Respiratory Failure	Remdesivir			S	Intravenous bolus			Gilead	
	Cefepime 2 Gm Iv			C				Not Reported	
	Dexamethasone 2 Mg			C				Not Reported	
	Famotidine 20 Mg			C				Not Reported	
	Metronidazole 500 Mg			C				Not Reported	
	Vancomycin Iv			C				Not Reported	

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22-Jul-2020	18058493	DIRECT	Y	OT			59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Macular; Rash Maculo-Papular	Remdesivir			S	Intravenous drip			Gilead
	Ciprofloxacin			S	Intravenous drip			Not Reported
	Senna 8.6mg			C				Not Reported
	Divalproex 500mg Dr			C				Not Reported
	Docusate Sodium 250mg			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Pantoprazole 20mg Tablet			C				Not Reported
	Haloperidol 5mg Tablet			C				Not Reported
	Acetaminophen 500mg Tablet			C				Not Reported
Enoxaparin 40mg Sc			C				Not Reported	
Metoprolol 50mg Ir			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058500	DIRECT	Y	HO			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058507	DIRECT	Y	OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY	Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Atorvastatin 40 Mg Oral Daily			C				Not Reported
	Ascorbic Acid 3000 Mg Oral Bid			C				Not Reported
	Cholecalciferol 25 Mcg Oral Daily			C				Not Reported

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Dexamethasone 6 Mg Daily Iv	C	Not Reported
Furosemide 40 Mg Iv Bid	C	Not Reported
Zinc 220 Mg Daily Oral	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058533	DIRECT	Y				47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058540	DIRECT	Y	OT			67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	17914969	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0473383		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; General Physical Health Deterioration; Pneumothorax; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Ascorbic Acid			C	Intravenous (not otherwise specified)	1500 Mcg		Not Reported
	Atorvastatin			C	Oral	10 Mg		Not Reported
	Aztreonam			C	Intravenous bolus	2 G		Not Reported
	Bisacodyl			C	Oral	5 Mg		Not Reported
	Buspirone			C	Oral	10 Mg		Not Reported
	Carbidopa-Levodopa-B			C	Oral	25 Mg - 100 Mg		Not Reported

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Celebrex	C	Oral	100 Mg	Not Reported
Clonazepam	C	Oral	0.5 Mg	Not Reported
Digoxin	C	Oral	62.5 Mcg	Not Reported
Depakote	C			Not Reported
Lovenox Hp	C	Subcutaneous	60 Mg	Not Reported
Fentanyl 3 Day Hmt	C		200 Mcg	Not Reported
Guaifenesin	C	Oral	600 Mg	Not Reported
Metoprolol	C			Not Reported
Propofol	C	Intravenous (not otherwise specified)	10 Mcg	Not Reported
Risperidone	C	Oral	0.5 Mg	Not Reported
Oxygen	C			Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	360 Mcg	Not Reported
Cetirizine	C	Oral	10 Mg	Not Reported
Peridex [Chlorhexidine Gluconate]	C	Oral	15 MI	Not Reported
Cyanocobalamin	C	Oral	500 Mcg	Not Reported
Decadron [Dexamethasone Acetate]	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
Senokot S	C	Oral	1 Dosage Form	Not Reported
Pepcid [Famotidine]	C	Intravenous (not otherwise specified)	20 Mg	Not Reported
Fluticasone	C	Respiratory (inhalation)	220 Mcg	Not Reported
Magnesium Citrate	C		30 MI	Not Reported
Solu-Medrol	C	Intravenous (not otherwise specified)	30 Mg	Not Reported
Midodrine	C	Oral	5 Mg	Not Reported
Montelukast	C	Oral	10 Mg	Not Reported
Pyridoxine	C	Oral	20 Mg	Not Reported
Sodium Bicarbonate	C	Intravenous (not otherwise specified)	50 Meq	Not Reported

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Thiamine	C	Intravenous bolus	200 Mg	Not Reported
Zanaflex	C	Oral	4 Mg	Not Reported
Trazodone	C			Not Reported
Depacon	C	Intravenous (not otherwise specified)	150 Mg	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	750 Mg	Not Reported
Effexor Sr	C	Oral	150 Mg	Not Reported
Fiorinal [Acetylsalicylic Acid;Butalbital;Caffeine]	C			Not Reported
Dexmedetomidine	C	Intravenous (not otherwise specified)	400 Mcg	Not Reported
Epinephrine	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
Norepinephrine	C	Intravenous (not otherwise specified)	15 Mg	Not Reported
Vasopressin	C	Intravenous (not otherwise specified)	40 Units	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18000931	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0480838		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Ammonium Lactate			C	Topical	1 App		Not Reported
	Clonazepam			C	Oral	0.5 Mg, Bid		Not Reported
	Dexamethasone			C	Oral	6 Mg, Qd		Not Reported
	Divalproex Sodium			C	Oral	125 Mg, Tid		Not Reported
	Levetiracetam			C	Oral	1000 Mg		Not Reported
	Mirtazapine A			C	Oral	15 Mg		Not Reported
	Lactulose			C	Oral	40 G, Bid		Not Reported

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Melatonin		C	Oral	15 Mg			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18058096	EXPEDITED (15-DAY)			US-GILEAD-2020-0484800		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation Error	Remdesivir			S	Unknown			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18058774	EXPEDITED (15-DAY)		DE, OT	GB-MYLANLABS-2020M1064915		84 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Livedo Reticularis	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid		Not Reported	
	Remdesivir			S	Intravenous (not otherwise specified)	200, Stat		Mylan	
	Vancomycin			S	Intravenous (not otherwise specified)	1 G, Bid		Mylan	
	Dexamethasone			S	Oral	6 Mg, Qd		Mylan	
	Oxygen			C		Unk		Mylan	
	Allopurinol			C		Unk		Mylan	
	Fexofenadine			C				Mylan	
	Atorvastatin			C				Mylan	
	Omeprazole			C				Mylan	
	Dalteparin			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059145	DIRECT	Y	OT			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Decreased; Aspartate Aminotransferase	Remdesivir			S	Intravenous (not otherwise specified)		4 DAY	Gilead	

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Decreased; Hepatotoxicity	Tamsulosin 0.4 Mg Daily	C	Not Reported
	Metoprolol Succinate 25 Mg Daily	C	Not Reported
	Insulin Glargine & Lispro	C	Not Reported
	Lisinopril 5 Mg Daily	C	Not Reported
	Enoxaparin 30 Mg Q12h	C	Not Reported
	Aspirin 325 Mg Daily	C	Not Reported
	Allopurinol 300 Mg Daily	C	Not Reported
	Acetaminophen 650 Mg Q4h Prn (1 Dose Given)	C	Not Reported
	Atorvastatin 80 Mg Daily	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059208	EXPEDITED (15-DAY)			US-GILEAD-2020-0484718			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Product Administration Duration	Remdesivir			S	Unknown			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059300	DIRECT	Y	DE			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Oxygen Saturation Decreased; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clopidogrel			C				Not Reported
	Dexamethasone			C				Not Reported
	Donepezil			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Isosorbide			C				Not Reported
	Lorazepam			C				Not Reported
	Metoprolol			C				Not Reported
	Quetiapine			C				Not Reported

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Morphine	C	Not Reported
Haloperidol	C	Not Reported
Ondansetron	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059532	DIRECT	Y				47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir Dexamethasone			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059728	DIRECT	Y	HO			17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059746	DIRECT	Y				34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059811	DIRECT	Y				87 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

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23-Jul-2020	18059877	DIRECT	Y				55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059882	DIRECT	Y				75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18060296	DIRECT	Y	OT			49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir Norco Acetaminophen			S C C				Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18060302	DIRECT	Y	OT			46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Transfusion	Remdesivir Acetaminophen Levophed			S C C				Not Reported Not Reported Not Reported	

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23-Jul-2020	18061063	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484797		91 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061107	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484795		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Dimethicone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061137	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484791		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Plasma Dexamethasone			C				Not Reported	
				C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061316	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484733		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Transaminases Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Dexamethasone	C		Unk	Not Reported
	Isosorbide	C		Unk	Not Reported
	Levothyroxine	C		Unk	Not Reported
	Potassium	C		Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Unk	Not Reported
	Apixaban	C		Unk	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Iohexol	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Cefepime	C		Unk	Not Reported
	Vancomycin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061558	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484363		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cefepime			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Unfractionated Heparin			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Linezolid			C		Unk		Not Reported
	Mycophenolate			C		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Dexmedetomidine			C		Unk		Not Reported

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Fentanyl	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Sodium Bicarbonate	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061613	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482969		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061654	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484374		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Azithromycin			C		Unk Mg		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Diphenhydramine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Zinc Sulphate			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18061839	EXPEDITED (15-DAY)		OT	ES-ASTELLAS-2020US023406		22 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Hypokalaemia; Hypotensive Crisis; Nausea; Vomiting	Amphotericin B, Liposome	S	Unknown	Unk Unk, Unknown Freq.	Astellas
	Remdesivir	S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.	Not Reported
	Linezolid	C	Unknown	Unk Unk, Unknown Freq.	Not Reported
	Meropenem	C	Unknown	Unk Unk, Unknown Freq.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064217	DIRECT	Y				62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064224	DIRECT	Y				39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Trazodone			C				Not Reported
	Famotidine			C				Not Reported
	Albuterol			C				Not Reported
	Norco			C				Not Reported
	Acetaminophen			C				Not Reported
	Thiamine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Lovenox			C				Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064231	DIRECT	Y	DE, HO, LT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Liver Function Test Increased	Remdesivir	Y	S	Intravenous drip	Gilead
	Amiodarone		C		Not Reported
	Azithromycin		C		Not Reported
	Chlorhexidine		C		Not Reported
	Dexamethasone		C		Not Reported
	Famotidine		C		Not Reported
	Heparin		C		Not Reported
	Insulin Glargine		C		Not Reported
	Piperacillin-Tazobactam		C		Not Reported
	Thiamine		C		Not Reported
	Norepinephrine		C		Not Reported
	Propofol		C		Not Reported
	Vasopressin		C		Not Reported
	Fentanyl		C		Not Reported
	Midazolam		C		Not Reported
	Sodium Bicarbonate		C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064238	DIRECT	Y	DE			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Anuria; Candida Infection; Pneumonia Pseudomonal; Septic Shock; Streptococcal Infection	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064294	DIRECT	Y	DE, OT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemodialysis; Renal Impairment	Remdesivir For Injection			S	Intravenous (not otherwise specified)			Gilead
	Toclizumab			C				Not Reported

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23-Jul-2020	18064343	DIRECT	Y	DE			90 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Pain; Respiratory Failure; Sedation	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064778	DIRECT	Y	RI			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flushing; Hyperhidrosis; Hypertension; Oxygen Saturation Decreased	Remdesivir 200mg			S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir 100mg			S	Intravenous (not otherwise specified)			Gilead	
	Atracurium			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Chlorhexidine Gluconate			C				Not Reported	
	Sennosides			C				Not Reported	
	Docusate			C				Not Reported	
	Albuterol			C				Not Reported	
	Rocuronium			C				Not Reported	
Dexamethasone Sodium Phosphate			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18064943	DIRECT	Y	RI			47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir 100mg			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Frequency: Once		Gilead	

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Remdesivir 100mg	S	Intravenous (not otherwise specified)	Gilead
Rocephin	C		Not Reported
Azithromycin	C		Not Reported
Dexamethasone Sodium Phosphate	C		Not Reported
Fentanyl	C		Not Reported
Magnesium Sulfate	C		Not Reported
Norepinephrine	C		Not Reported
Pantoprazole	C		Not Reported
Potassium Chloride	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	17971419	EXPEDITED (15-DAY)		DE, HO, LT	FR-AUROBINDO-AUR-APL-2020-031896		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Ineffective For Unapproved Indication; Off Label Use	Levofloxacin			S	Unknown	Unk		Aurobindo
	Levofloxacin			S				Aurobindo
	Meropenem			S	Unknown	Unk		Aurobindo
	Meropenem			S				Aurobindo
	Voriconazole			S	Unknown	Unk		Aurobindo
	Colimycine [Colistin Sulfate]			S	Unknown	Unk		Not Reported
	Colimycine [Colistin Sulfate]			S				Not Reported
	Isavuconazonium Sulfate			S	Unknown	Unk		Not Reported
	Isavuconazonium Sulfate			S				Not Reported
	Tigecycline			S	Unknown	Unk		Not Reported
	Tigecycline			S				Not Reported
	Remdesivir			S	Intravenous drip	200 Milligram (Loading Dose)		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	17996635	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478717		63 YR	Male	USA

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Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Dexamethasone			C	Oral	6 Mg, Qd		Not Reported
	Plasma			C		Unk		Not Reported
	Enoxaparin			C		40 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	40 Unk		Not Reported
	Acetaminophen			C	Oral	650 Mg, Q4hr, As Needed		Not Reported
	Omeprazole			C				Not Reported
	Tamsulosin			C	Oral	0.4 Mg, Qd		Not Reported
Pantoprazole			C	Oral	20 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18062555	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485076		20 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18062589	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485054		51 YR	Male	USA

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Blood Creatinine Increased	Remdesivir			S	Intravenous drip	100 Mg Daily		Gilead
	Rocephin [Ceftriaxone]			C		Unk	Not Reported	
	Azithromycin			C		Unk	Not Reported	
	Vancomycin			C		Unk	Not Reported	
	Zosyn			C		Unk	Not Reported	
	Dexamethasone			C		Unk	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065426	DIRECT	Y	HO			1 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065496	DIRECT	N					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Decreased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065586	DIRECT	Y				20 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Gilead
	Trazadone 25 Mg			C		Not Reported		
	Dexamethasone 6 Mg			C		Not Reported		
	Acetaminophen			C		Not Reported		

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24-Jul-2020	18065608	DIRECT	Y	OT				Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir				S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065617	DIRECT	Y					Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Interrupted	Remdesivir				S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065620	DIRECT	Y	OT			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir		Y		S	Intravenous drip			Gilead
	Azithromycin				C				Not Reported
	Rocephin				C				Not Reported
	Dexamethasone				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065740	DIRECT	Y	DE			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Remdesivir				S				Not Reported
	Vancomycin				C				Not Reported
	Apixaban				C				Not Reported
	Cefepime				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18065824	DIRECT	Y	OT			78 YR	Female	USA

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Infusion Site Erythema; Infusion Site Extravasation; Infusion Site Swelling	Remdesivir	Y		S	Intravenous drip			Gilead
	Thiamine 100 Mg			C				Not Reported
	Terazosin 1 Mg			C				Not Reported
	Olanzapine 2.5 Mg In Am And 5mg In Pm			C				Not Reported
	Nystatin Powder			C				Not Reported
	Mirtazapine 15 Mg			C				Not Reported
	Insulin Lispro			C				Not Reported
	Folic Acid 1mg			C				Not Reported
	Enoxaparin 40 Mg Qc			C				Not Reported
	Donepezil 10 Mg Daily			C				Not Reported
	Dexamethasone 6mg Oral Tab			C				Not Reported
	Clonidine 0.1 Mg Every 12h			C				Not Reported
	Citalopram 20mg			C				Not Reported
	Cholecalciferol 1000 Units Po			C				Not Reported
	Bupropion XI 300mg			C				Not Reported
	Atorvastatin 20mg			C				Not Reported
	Aspirin Ec 81mg			C				Not Reported
Alprazolam 0.5mg Bid			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066173	DIRECT	Y	DE			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Hypoxia; Oxygen Saturation Decreased	Remdesivir			S	Intravenous drip	Other Frequency:Once Then 100mg Da;		Gilead
	Ascorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Furosemide			C				Not Reported
	Lorazepam			C				Not Reported
	Meropenem			C				Not Reported
	Doxycycline			C				Not Reported
	Methylprednisolone			C				Not Reported
Vancomycin			C				Not Reported	

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24-Jul-2020	18066227	DIRECT	Y	OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypovolaemic Shock	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Amiodarone			C				Not Reported
	Amlodipine			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Carvedilol			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Furosemide			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Lansoprazole			C				Not Reported
	Vasopressin			C				Not Reported
	Potassium Chloride			C				Not Reported
Epinephrine			C				Not Reported	
Fentanyl			C				Not Reported	
Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066233	DIRECT	Y				69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066239	DIRECT	Y				60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Therapy Interrupted	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Tocilizumab	C		Not Reported
	Zinc Sulfate	C		Not Reported
	Dexamethasone	C		Not Reported
	Ascorbic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066243	DIRECT	Y	DE			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulse Absent; Respiratory Arrest; Sars-Cov-2 Test Positive	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066285	DIRECT	Y				71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066287	DIRECT	Y	OT			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ascorbic Acid			C				Not Reported

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Azithromycin	C	Not Reported
Ceftriaxone	C	Not Reported
Enoxaparin	C	Not Reported
Pravastatin	C	Not Reported
Lisinopril	C	Not Reported
Levothyroxine	C	Not Reported
Bisoprolol	C	Not Reported
Aspirin	C	Not Reported
Pantoprazole	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066290	DIRECT	Y				66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Montelukast 10 Mg			C				Not Reported
	Lisinopril			C				Not Reported
	Combivent Respimat			C				Not Reported
	Insulin Lispro			C				Not Reported
	Gabapentin 300 Mg			C				Not Reported
	Enoxaparin			C				Not Reported
	Duloxetine 60 Mg			C				Not Reported
	Dexamethasone 6 Mg			C				Not Reported
	Symbicort			C				Not Reported
	Atorvastatin			C				Not Reported
	Aspirin Chewable			C				Not Reported
	Amlodipine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18066297	DIRECT	Y	DE			89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Breath Sounds Absent; Pulse Absent	Remdesivir			S				Gilead

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24-Jul-2020	18066300	DIRECT	Y	DE			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Cardiac Arrest; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Tocilizumab			C				Not Reported
	Sodium Bicarbonate Infusion			C				Not Reported
	Vasopressin			C				Not Reported
	Phenylephrine			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Epinephrine			C				Not Reported
	Albumin 25%			C				Not Reported
	Cefepime			C				Not Reported
	Vancomycin			C				Not Reported
	Heparin Sq			C				Not Reported
	Enoxaparin Treatment Dosing			C				Not Reported
Enoxaparin Ppx Dosing			C				Not Reported	
Famotidine			C				Not Reported	
Insulin			C				Not Reported	
Furosemide			C				Not Reported	

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24-Jul-2020	18066305	DIRECT	Y				69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Throat Tightness	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Clonidine			C				Not Reported
	Dexamethasone			C				Not Reported

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Heparin	C	Not Reported
Hydralazine	C	Not Reported
Insulin Lispro	C	Not Reported
Isosorbide Mononitrate	C	Not Reported
Levothyroxine	C	Not Reported
Metoprolol Succinate XI	C	Not Reported
Oxybutynin	C	Not Reported
Pantoprazole Ec	C	Not Reported
Polyethylene Glycol	C	Not Reported
Rosuvastatin	C	Not Reported
Senna	C	Not Reported
Tamsulosin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18067776	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0485221		84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18068101	EXPEDITED (15-DAY)			US-GILEAD-2020-0484476			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Storage Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18068860	EXPEDITED (15-DAY)		DS, HO, OT	US-GILEAD-2020-0484987		39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Artery Occlusion	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead

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24-Jul-2020	18068864	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485562		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Cholecalciferol			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Vitamin C [Ascorbic Acid]			C				Not Reported	
	Zinc			C				Not Reported	

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24-Jul-2020	18068869	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485223		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Tocilizumab			C				Not Reported	
	Amiodarone			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Azithromycin			C				Not Reported	
	Cisatracurium			C				Not Reported	
	Diltiazem			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Epoprostenol			C				Not Reported	
	Ketamine			C				Not Reported	
	Lorazepam			C				Not Reported	
	Methylprednisolone			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Piperacillin & Tazobactam			C				Not Reported	
	Rivaroxaban			C				Not Reported	

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24-Jul-2020	18068870	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485506		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18070936	DIRECT	Y	OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Lyophilized Powder	Y		S	Intravenous bolus	Other Frequency:Once;		Gilead	
	Albuterol/Ipratropium			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Doxycycline			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Benzonatate			C				Not Reported	
	Iohexol			C				Not Reported	

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24-Jul-2020	18070943	DIRECT	Y	OT			77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Arrest	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead	
	Methylprednisolone 60 Mg Iv Q12h			C				Not Reported	
	Dexamethasone 6mg Po Daily			C				Not Reported	
	Enoxpararin 1 Mg/Kg Sc Bid			C				Not Reported	

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24-Jul-2020	18070950	DIRECT	Y				61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir Metoprolol 12.5 Mg Heparin 500 Sq Doxazosin 2 Mg Dexamethasone 6 Mg Clopidogrel Aspirin 81			S C C C C C C	Intravenous bolus		4 DAY	Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18070955	DIRECT	Y	DE			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction	Remdesivir Acetaminophen Etomidate Propofol Rocuronium Lorazepam Midazolam Fentanyl Lansoprazole Methylprednisolone Insulin Norepinephrine Ascorbic Acid (Iv) Enoxaparin Carvedilol Tocilizumab Amlodipine Losartan Aspirin Furosemide Albuterol			S C				Not Reported Not Reported	

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Metolazone		C		Not Reported					
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24-Jul-2020	18070989	DIRECT	Y				51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18071052	DIRECT	Y	DE			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Calcium Decreased; Blood Chloride Increased; Blood Creatinine Increased; Blood Glucose Increased; Blood Magnesium Increased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Urea Increased; Carbon Dioxide Decreased; Cardiac Arrest; Glomerular Filtration Rate Increased; Haematocrit Decreased; Red Blood Cell Count Decreased; Sars-Cov-2 Test Positive; White Blood Cell Count Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Convalescent Plasma X 2 Units At Other Hosp			C				Not Reported	
	Tocilizumab 800 Mg X 1 At Other Hosp			C				Not Reported	
	Amiodarone 200 Mg Po Q12hr			C				Not Reported	
	Azithromycin 500 Mg Feed Tube Daily			C				Not Reported	
	Dexamethasone 10 Mg Iv Once Daily			C				Not Reported	
	Dexamethasone 6 Mg Iv Daily			C				Not Reported	
	Enoxaparin 100 Mg Sq Q12hrs			C				Not Reported	
	Famotodine 20 Mg Iv Bid			C				Not Reported	
	Lantus Up To 20 Untis Sq Bid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2020	18071078	DIRECT	Y				49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Alanine Aminotransferase Increased; Liver Function Test Increased	Remdesivir (Eua)	S	Intravenous (not otherwise specified)	Gilead
	Dexmedetomidine In Ns 400 Mcg/100 MI (4 Mcg/MI) Iv Premix (Precedex In	C		Not Reported
	Fentanyl (Pf) In Ns 10 Mcg/MI Iv Soln	C		Not Reported
	Heparin (Porcine) In D5w 25,000 Unit/250 MI(100 Unit/MI) Iv Premix	C		Not Reported
	Insulin Regular Human Sliding Scale Inj (Humulin R/Novolin R)	C		Not Reported
	Ipratropium 17 Mcg/Actuation Mdi 2 Puff (Atrovent Hfa)	C		Not Reported
	Melatonin Rap Dis Tablet 10 Mg	C		Not Reported
	Metronidazole In Nacl Iv Premix 500 Mg (Flagyl)	C		Not Reported
	Midazolam In Ns 1 Mg/MI Iv Soln	C		Not Reported
	Ascorbic Acid Ivpb 1,500 Mg	C		Not Reported
	Phenylephrine 100 Mg In	C		Not Reported
	Sodium Chloride 0.9% 250 MI Iv Soln	C		Not Reported

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24-Jul-2020	18071081	DIRECT	Y	DE			45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Tylenol			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Nimbex			C				Not Reported
	Ryanodex			C				Not Reported
	Lovenox			C				Not Reported
	Insulin			C				Not Reported

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24-Jul-2020	18071087	DIRECT	Y	DE			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Glucose Increased; Blood Urea Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S		Intravenous (not otherwise specified)		Gilead
	Dexamethasone 5 Mg Iv Once Daily			C				Not Reported
	Carvedilol 3.125 Mg Po Bid			C				Not Reported
	Valproate Sodium 500 Mg Po Hs			C				Not Reported
	Ticagrelor 90 Mg Po Q12hr			C				Not Reported
	Thiamine 100 Mg Po Once Daily			C				Not Reported
	Spironolactone 25 Mg Po Daily			C				Not Reported
	Entresto 24/26 Po Bid			C				Not Reported
	Pantoprazole 40 Mg Po Once Daily			C				Not Reported
	Megestrol 400 Mg Po Bid			C				Not Reported
	Furosemide 40 Mg Iv Once Daily			C				Not Reported
	Fluconazole 100 Mg Po Once Daily			C				Not Reported
	Ezetimibe 10 Mg Po Once Daily			C				Not Reported
	Enoxaparin 80 Mg Sq Q12hr			C				Not Reported
	Atorvastatin 80 Mg Po Hs			C				Not Reported
	Asa 81 Mg Po Once Daily			C				Not Reported
	Albuterol Mdi Rt Bid			C				Not Reported
	Clinimix E 2.75%-5%			C				Not Reported
	Tpn Custom			C				Not Reported

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24-Jul-2020	18071657	DIRECT	Y				53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Therapy Cessation	Remdesivir			S				Not Reported
	Cyclosporine			C				Not Reported
	Decadron			C				Not Reported

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24-Jul-2020	18073245	DIRECT	Y	OT			86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Bacterial Infection; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Disease Progression; Procalcitonin Increased; Respiratory Failure; White Blood Cell Count Increased	Remdesivir 100mg/MI			S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Acetaminophen			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Fluticasone			C				Not Reported
	Budesonide Neb			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Methimazole			C				Not Reported
	Ceftriaxone			C				Not Reported
	Vancomycin			C				Not Reported
	Acetylcysteine			C				Not Reported
	Omnipaque			C				Not Reported
	Methyprednisolone			C				Not Reported
	Thiamin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Atorvastatin			C				Not Reported
	Avithromycin			C				Not Reported
	Aspirin			C				Not Reported
	Melatonin			C				Not Reported

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25-Jul-2020	18071093	DIRECT	Y	OT			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
White Blood Cell Count Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albuterol-Ipratropium			C				Not Reported
	Dexamethasone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2020	18071098	DIRECT	Y	OT			35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once As Ld.;		Gilead
	Acetaminophen 650 Mg Po Q6h Prn			C				Not Reported
	Albuterol 2 Puff Q4h			C				Not Reported
	Ascorbic Acid 1000 Mg Po Daily			C				Not Reported
	Clozapine 100 Mg Po Bid			C				Not Reported
	Robitussin Ac 10 MI Po Q8h Prn Cough			C				Not Reported
	Dexamethasone 6 Mg Iv Bid			C				Not Reported
	Duloxetine 30 Mg Po Daily			C				Not Reported
	Enoxaparin 40 Mg Sc Bid			C				Not Reported
	Famotidine 20 Mg Po Bid			C				Not Reported
	Labetalol 100 Mg Po Bid			C				Not Reported
	Lisinopril 10 Mg Po Daily			C				Not Reported
	Spironolactone 25 Mg Po Daily			C				Not Reported
	Thiamine Mononitrate 100 Mg Po Daily			C				Not Reported
Topiramate 100 Mg Po Bedtime			C				Not Reported	
Zinc Sulfate 220 Mg Po Daily			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2020	18071103	DIRECT	Y	OT			83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Alfuzosin			C				Not Reported
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydralazine			C				Not Reported
	Insulin			C				Not Reported
	Melatonin			C				Not Reported

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Methylprednisolone C Not Reported
Sennosides C Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2020	18071109	DIRECT	Y	OT			41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Furosemide			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Ketamine			C				Not Reported
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Levofloxacin			C				Not Reported
	Norepinephrine			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2020	18071115	DIRECT	Y	DE			84 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2020	18071156	DIRECT	Y				53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

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25-Jul-2020	18071160	DIRECT	Y				65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Aspirin			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Guafenisin			C				Not Reported	
	Ketorolac			C				Not Reported	
	Tramadol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2020	18071165	DIRECT	Y	OT			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2020	18072868	DIRECT	Y	DE			81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulse Absent; Respiratory Arrest; Subcutaneous Emphysema	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead	
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Other Route:lv		Gilead	
	Acetaminophen			C	Oral			Not Reported	
	Albuterol			C		Other Dose:2 Puffs;Other Frequency:Q6-8 Hr;		Not Reported	
	Ascorbic Acid (Vitamin C)			C	Oral			Not Reported	

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Atorvastatin	C	Oral		Not Reported
Azithromycin	C		Other Route:lv	Not Reported
Azithromycin	C	Oral		Not Reported
Cefazolin	C		Other Route:lv	Not Reported
Cefepime	C		Other Route:lv	Not Reported
Chlorhexidine	C	Oral		Not Reported
Cholecalciferol (Vitamin D3)	C	Oral	Other Frequency:Once Or Bid;	Not Reported
Dexamethasone	S		Other Frequency:Q 12-24 Hr;Other Route:lv	Not Reported
Donepezil	C	Oral		Not Reported
Enoxaprin	S	Subcutaneous	Other Dose:40-60 Mg;Other Frequency:Q 12-24 Hr;	Not Reported
Fentanyl	C		Other Frequency:Continuous;Other Route:lv	Not Reported
Furosemide	C		Other Frequency:X 3 Doses;Other Route:lv	Not Reported
Guaifenesin	C	Oral		Not Reported
Hydrocodone- Acetaminophen	C	Oral	Other Frequency:Q 6-12 Hr;	Not Reported
Insulin Aspart	C	Subcutaneous	Other Dose:0-10 Units;Other Frequency:Ac & Hs Prn;	Not Reported
Insulin Detemir	C	Subcutaneous	Other Dose:8-25 Units;	Not Reported
Insulin, Regular	C	Subcutaneous	Other Dose:0-10 Units;Other Frequency:Q 4 Hr Prn;	Not Reported
Losartan	C	Oral		Not Reported
Meclizine	C	Oral		Not Reported
Melatonin	C	Oral		Not Reported
Methylprednisolone Sodium	C		Other Dose:40-125	Not Reported

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Succinate				Mg;Other Route:Iv	
Mupirocin	C	Nasal			Not Reported
Norepinephrine	C			Other Dose:0.02-0.16 Mcg/Kg/M;Other Frequency:Continuous;Other Route:Iv	Not Reported
Ondansetron	C			Other Route:Iv	Not Reported
Propofol	C			Other Frequency:Continuous;Other Route:Iv	Not Reported
Senna - Docusate 8.5 - 50	C	Oral			Not Reported
Vancomycin	C			Other Frequency:Intermittent Dose;Other Route:Iv	Not Reported
Zinc Sulfate	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	17868186	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0469280		85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Tylenol			C				Not Reported
	Zosyn			C		Unk		Not Reported
	Doxycycline			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Clopidogrel			C		Unk		Not Reported
	Albuterol [Salbutamol]			C		Unk		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	Unk		Not Reported
	Acetaminophen			C		Unk		Not Reported
	Albumin			C		Unk		Not Reported

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Amino Acids Nos	C	Unk	Not Reported
Ascorbic Acid	C	Unk	Not Reported
Calcium & Vitamin D [Calcium;Colecalciferol]	C	Unk	Not Reported
Fat Emulsions	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Haloperidol	C	Unk	Not Reported
Insulin Regular Hm	C	Unk	Not Reported
Levalbuterol [Levosalbutamol]	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported
Multivitamin And Mineral	C	Unk	Not Reported
Ns	C	Unk	Not Reported
Potassium Chloride	C	Unk	Not Reported
Sodium Chloride	C	Unk	Not Reported
Sodium Phosphate	C	Unk	Not Reported
Tpn [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos]	C	Unk	Not Reported
Zinc Sulfate	C	Unk	Not Reported
Kinevac	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	17882674	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469816		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	200mg X 1, 100mg X 1		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Melatonin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Ceftriaxone			C				Not Reported
	Enoxaparin			C				Not Reported

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Morphine	C		Not Reported
Pantoprazole	C		Not Reported
Insulin	C		Not Reported
Zinc	C		Not Reported
Ascorbic Acid	C		Not Reported
Sucralfate	C		Not Reported
Decadron [Dexamethasone]	C	Unk	Not Reported
Decadron [Dexamethasone]	C	Unk	Not Reported
Diltiazem	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	17882697	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0469673		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Covid-19 Pneumonia; Hypovolaemia; Pneumonia Staphylococcal; Renal Tubular Necrosis; Sepsis; Septic Shock	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk		Gilead
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported
	Etomidate			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	40 Mg		Not Reported
	Heparin			C	Subcutaneous	7500 Units		Not Reported
	Lorazepam			C	Oral	4 Mg		Not Reported
Metoclopramide			C	Intravenous (not otherwise specified)	10 Mg		Not Reported	
Vecuronium			C	Intravenous (not otherwise specified)	10 Mg		Not Reported	

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Azithromycin	C	otherwise specified)	Intravenous (not otherwise specified)	500 Mg	Not Reported
Cefazolin	C	otherwise specified)	Intravenous (not otherwise specified)	2 G	Not Reported
Cefepime	C	otherwise specified)	Intravenous (not otherwise specified)	2 G	Not Reported
Dexmedetomidine	C	otherwise specified)	Intravenous (not otherwise specified)	Unk	Not Reported
Diltiazem	C	otherwise specified)	Intravenous (not otherwise specified)	Unk	Not Reported
Metoprolol	C	otherwise specified)	Intravenous (not otherwise specified)	2.5 Mg	Not Reported
Propofol	C	otherwise specified)	Intravenous (not otherwise specified)	Unk	Not Reported
Vancomycin	C	otherwise specified)	Intravenous (not otherwise specified)	1750 Mg	Not Reported
Potassium Chloride	C	otherwise specified)	Intravenous (not otherwise specified)	40 Meq	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18040153	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0483271		90 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Death	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Levophed			C		Unk		Not Reported
	Precedex			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported

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27-Jul-2020	18045095	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484021		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Oxygen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072744	DIRECT	Y	OT			53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hypersensitivity	Remdesivir Eua	Y		S				Gilead	
	Insulin Nph 5 Units			C				Not Reported	
	Atorvastatin 20mg			C				Not Reported	
	Pantoprazole 40mg			C				Not Reported	
	Aspirin 81mg			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072756	DIRECT	Y	OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072768	DIRECT	Y				70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead	

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072778	DIRECT	Y	OT			46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir				S	Intravenous drip			Gilead
	Dexamethasone				C				Not Reported
	Enoxaparin				C				Not Reported
	Azithromycin				C				Not Reported
	Ceftriaxone				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072790	DIRECT	Y				57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir		Y		S	Intravenous (not otherwise specified)			Gilead
	Levophed				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072809	DIRECT	Y	OT			77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir				S	Intravenous drip			Gilead
	Atorvastatin				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072842	DIRECT	Y	OT			77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir				S	Intravenous (not			Gilead

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otherwise specified)

Famotidine	C	Not Reported
Gammunex	C	Not Reported
Insulin Lispro	C	Not Reported
Methylprednisone	C	Not Reported
Potassium Chloride	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072846	DIRECT					76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072852	DIRECT	Y	HO			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Creatinine Renal Clearance Increased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone 6 Mg Iv Convalescent Plasma			C				Not Reported
				C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072951	DIRECT	Y	DE, OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertension; Slow Response To Stimuli; Tachycardia	Remdesivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Injection			S	Intravenous (not otherwise specified)	Frequency Daily X 4 Days 4 DAY		Gilead
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Propofol			C				Not Reported
	Fentanyl			C				Not Reported
	Diltiazem			C				Not Reported

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Hydralazine	C	Not Reported
Labetalol	C	Not Reported
Metoprolol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18073621	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485716		71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Hydroxychloroquine			C				Not Reported
	Cholecalciferol			C				Not Reported
	Azithromycin			C				Not Reported
	Piperacillin & Tazobactam			C				Not Reported
	Amiodarone			C				Not Reported
	Atorvastatin			C				Not Reported
	Cisatracurium			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Propofol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18074246	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485069			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Bradycardia; Fluid Overload	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Propofol			C		Unk		Not Reported
	Versed			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18076581	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486049		72 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Covid-19	Remdesivir			S	Unknown	Unk		Gilead
	Acetaminophen			C				Not Reported
	Etomidate			C				Not Reported
	Propofol			C				Not Reported
	Rocuronium			C				Not Reported
	Lorazepam			C				Not Reported
	Midazolam			C				Not Reported
	Fentanyl			C				Not Reported
	Lansoprazole			C				Not Reported
	Methylprednisolone			C				Not Reported
	Insulin			C				Not Reported
	Norepinephrine			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Enoxaparin			C				Not Reported
	Carvedilol			C				Not Reported
	Tocilizumab			C				Not Reported
	Amlodipine			C				Not Reported
	Losartan			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077392	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485708		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Cholecalciferol			C				Not Reported
	Vitamin C [Ascorbic Acid]			C				Not Reported
	Zinc			C				Not Reported
	Dexamethasone			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Cefepime			C				Not Reported
	Amlodipine			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide			C				Not Reported
	Carvedilol			C				Not Reported
Enoxaparin			C				Not Reported	

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	Finasteride Furosemide			C C				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077503	EXPEDITED (15-DAY)			US-GILEAD-2020-0479527		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Storage Error; Product Temperature Excursion Issue	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077545	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0486092		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Septic Shock	Remdesivir			S	Unknown	Completed An Extended 10-Day Course In 2020		Gilead	
	Dexamethasone			C		Completed A 10 Day Course In 2020		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077663	EXPEDITED (15-DAY)		OT	SK-BAUSCH-BL-2020-021078		38 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder	Dexamethasone			S	Oral			Valeant	
	Metamizol (Metamizole)			S	Oral			Not Reported	
	Moxifloxacin			S	Oral			Not Reported	
	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077728	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0485681		45 YR	Female	USA

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Death	Remdesivir			S	Unknown	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077754	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485067		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Solu-Medrol			C	Intravenous (not otherwise specified)	200 Mg, Qd		Not Reported	
	Solu-Medrol			C	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077843	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485590		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Atorvastatin			C		Unk		Not Reported	
	Acetaminophen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18077932	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485701		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

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Piperacillin And Tazobactam	C	Unk	Not Reported
Cholecalciferol	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Vitamin C Flavour	C	Unk	Not Reported
Zinc Gluconate	C	Unk	Not Reported
Lovenox [Enoxaparin Sodium]	C	Unk	Not Reported
Insulin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078185	DIRECT	Y	OT			26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Therapy Cessation	Remdesivir			S			3 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078194	DIRECT	Y	OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead
	Tocilizumab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078205	DIRECT	Y	HO, LT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead

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Remdesivir	S	Intravenous drip	Gilead
Losartan	C		Not Reported
Sotalol	C		Not Reported
Metoclopramide	C		Not Reported
Tocilizumab	C		Not Reported
Ambien	C		Not Reported
Levothyroxine	C		Not Reported
Fiorcet	C		Not Reported
Solu-Medrol	C		Not Reported
Acetaminophen	C		Not Reported
Ceftriaxone	C		Not Reported
Doxycycline	C		Not Reported
Atorvastatin	C		Not Reported
Robitussin Ac	C		Not Reported
Levemir	C		Not Reported
Albuterol	C		Not Reported
Cyanocobalamin	C		Not Reported
Potassium Chloride	C		Not Reported
Oxybutynin	C		Not Reported
Citalopram	C		Not Reported
Lovenox	C		Not Reported
Pantoprazole	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078218	DIRECT	Y	HO, LT			27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Albuterol			C				Not Reported
	Sodium Chloride			C				Not Reported
	Azithromycin			C				Not Reported
	Lovenox			C				Not Reported
	Cefepime			C				Not Reported
	Solu-Medrol			C				Not Reported
	Levemir			C				Not Reported
	Novolog			C				Not Reported
	Pantoprazole			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078228	DIRECT		DE				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Cardiac Arrest; Condition Aggravated; Septic Shock	Remdesivir			S	Intravenous bolus			Gilead
	Dexamethason			C				Not Reported
	Cisatracurium			C				Not Reported
	Norepinephrine			C				Not Reported
	Midazolam Infusion			C				Not Reported
	Dexmedetomidine			C				Not Reported
Fentanyl			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078249	DIRECT	Y	DE			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Anxiety; Bilevel Positive Airway Pressure; Respiratory Failure; Unresponsive To Stimuli	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078277	DIRECT	Y	HO			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir	Y		S	Intravenous bolus			Gilead
	Iv Vancomycin			C				Not Reported
	Iv Piperacillin-Tazobactam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078287	DIRECT	Y	OT			91 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Renal Failure	Remdesivir Dexamethamethsone Lovenox Glimepiride Irbesartan Ivermectin Azithromycin	Y	S C C C C C C	Intravenous drip	Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078366	DIRECT	Y				9 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Administration Error; Product Preparation Issue	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078376	DIRECT	Y				89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		3 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078388	DIRECT	Y	OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Lovenox			C				Not Reported
	Decadron			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078397	DIRECT	Y				83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous drip		3 DAY	Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078408	DIRECT	Y	HO			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
	Azithromycin 500mg Iv Daily			C				Not Reported	
	Furosemide 40mg Iv Twice Daily			C				Not Reported	
	Acetaminophen As Needed			C				Not Reported	
	Albuterol/Ipratropium Neb Four Times Daily			C				Not Reported	
	Ascorbic Acid 500mg Oral Three Times Daily			C				Not Reported	
	Budesonide Neb			C				Not Reported	
	Ceftriaxone 2gm Ivpb Daily			C				Not Reported	
	Cholecalciferol 1,000units Daily			C				Not Reported	
	Doxycycline 100mg Ivpb Twice Daily			C				Not Reported	
	Enoxaparin 40mg Sub Q Daily			C				Not Reported	
	Fentanyl Infusion			C				Not Reported	
	Methylprednisolone 60mg Ivpb Q6h			C				Not Reported	
	Midazolam Infusion			C				Not Reported	
	Norepinephrine Infusion			C				Not Reported	
	Pantoprazole 40mg Iv Daily			C				Not Reported	
	Thiamine 200mg Iv Daily			C				Not Reported	
	Vecuronium Infusion			C				Not Reported	

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Zinc Sulfate 220mg Oral Twice Daily

C

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078420	DIRECT	Y				46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Erythema; Infusion Site Swelling; Injection Site Extravasation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078433	DIRECT	Y	HO			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased; Therapy Interrupted	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen As Needed			C				Not Reported
	Albuterol/Ipratropium Neb 4 Times Daily			C				Not Reported
	Amlodipine 10mg At Bedtime			C				Not Reported
	Ascorbic Acid 500mg Tablet Twice Daily			C				Not Reported
	Aspirin 81mg Daily			C				Not Reported
	Atenolol 50mg Tablet Daily			C				Not Reported
	Atorvastatin 40mg Daily			C				Not Reported
	Budesonide 0.5mg Neb Twice Daily			C				Not Reported
	Clopidogrel 75mg Tablet Daily			C				Not Reported
	Enoxaparin 40mg Sub Q Daily			C				Not Reported
	Famotidine 20mg Tablet Twice Daily			C				Not Reported
	Fentanyl Infusion			C				Not Reported
	Furosemide 40mg Iv Twice Daily			C				Not Reported
	Lactobacillus 1 Capsule Daily			C				Not Reported
Linezolid 600mg Iv Q12h			C				Not Reported	
Meropenem 1g Iv Q12h			C				Not Reported	

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Methylprednisolone 40mg Iv Q6h	C	Not Reported
Midazolam Infusion	C	Not Reported
Thiamine 200mg Iv Twice Daily	C	Not Reported
Zinc Sulfate 220mg Po Twice Daily	C	Not Reported
Norepinephrine Infusion	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078441	DIRECT	Y	OT			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Apixaban 5mg Bid			C				Not Reported
	Bupropion 50mg Tid			C				Not Reported
	Duloxetine 30mg Daily			C				Not Reported
	Apripirazole 5mg Bid			C				Not Reported
	Insulin Glargine 15units Hs			C				Not Reported
	Levothyroxine 100mcg Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078450	DIRECT	Y				70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Azithromycin 500 My Po Daily			C				Not Reported
	Ceftriaxone 1 Gm Iv Q24h			C				Not Reported
	Enoxaparin 40 Mg Sq Q12h			C				Not Reported
	Furosime 20 Mg Ivpush Daily			C				Not Reported
	Methylprednisolone 20 Mg Iv Q6h			C				Not Reported
	Prednisone 40 Mg Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078470	DIRECT	Y	OT			61 YR	Female	USA

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Renal Injury	Remdesivir Fentanyl Drip Norepinephrine Drip Propofol Drip Rocuronium Drip			S C C C C	Intravenous bolus	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078474	DIRECT	Y	OT			44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078481	DIRECT		OT			78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078538	DIRECT	Y	OT			23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir Azithromycin 250mg Daily Famotidine 20mg Bid Ceftriaxone 1gm Q 24h			S C C C	Intravenous bolus	Other Frequency:Once;		Gilead Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18078545	DIRECT	Y				88 YR	Male	USA

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International Normalised Ratio Increased	Remdesivir			S	Intravenous drip			Gilead
	Rivaroxaban			S	Oral		1 YR	Janssen
	Remdesivir			C				Not Reported
	Rivaroxaban			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18079270	DIRECT	Y	DE			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoeic Attack; Brain Death; Confusional State; Fatigue; Lethargy; Myasthenia Gravis Crisis; Pulse Absent	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Alprazolam			C				Not Reported
	Dexamethasone			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Diphenhydramine			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Hydrocortisone Sodium Succinate			C				Not Reported
	Mupirocin			C				Not Reported
	Mycophenolate			C				Not Reported
	Norepinephrine			C				Not Reported
Vitamin D			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18079401	DIRECT	Y	DE			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Condition Aggravated; Oxygen Saturation Decreased	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not			Gilead

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	otherwise specified)	
Acetaminophen	C	Not Reported
Albuterol	C	Not Reported
Alprazolam	C	Not Reported
Amlodipine	C	Not Reported
Ascorbic Acid (Vitamin C)	C	Not Reported
Atorvastatin	C	Not Reported
Chlorhexidine	C	Not Reported
Cholecciferol (Vitamin D3)	C	Not Reported
Clonidine	C	Not Reported
Dexamethasone	C	Not Reported
Diphenhydramine	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported
Gabapentin	C	Not Reported
Hydralazine	C	Not Reported
Levofloxacin	C	Not Reported
Lorazepam	C	Not Reported
Mupirocin	C	Not Reported
Ondansetron	C	Not Reported
Patiomer Calcium Sorbitex	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Sodium Bicarbonate In Dextrose 5%	C	Not Reported
Sucralfate	C	Not Reported
Timolol Maleate 0.5%	C	Not Reported
Zinc Sulfate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18079480	DIRECT	Y	DE			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir Solution 100 Mg Vial Y			S	Intravenous (not otherwise specified)	Frequency: Once		Gilead
	Remdesivir Solution 100 Mg Vial Y			S	Intravenous (not otherwise specified)			Gilead
	Bupropion			C				Not Reported
	Chlorhexidine			C				Not Reported
	Citalopram			C				Not Reported

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Dexamethasone	C	Not Reported
Diphenhydramine	C	Not Reported
Enoxaparin	C	Not Reported
Furosemide	C	Not Reported
Insulin, Regular	C	Not Reported
Melatonin	C	Not Reported
Mupirocin	C	Not Reported
Nifedipine	C	Not Reported
Quetiapine	C	Not Reported
Tamsulosin	C	Not Reported
Zolpidem	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18085061	DIRECT	Y	OT			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Abnormal	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	17931173	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474765		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Death; Pulseless Electrical Activity; Respiratory Disorder	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Lorazepam			C	Intravenous (not otherwise specified)	1.5 Mg		Not Reported
	Magnesium Sulfate			C		Unk		Not Reported
	Metoprolol Tartrate			C	Intravenous (not	5 Mg		Not Reported

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Potassium Chloride	C	otherwise specified)	Unk	Not Reported
Sodium Chloride 0.9%	C		Unk	Not Reported
Hydralazine	C	Intravenous (not otherwise specified)	10 Mg	Not Reported
Morphine	C	Intravenous (not otherwise specified)	4 Mg	Not Reported
Vecuronium	C		Unk	Not Reported
Epinephrine	C		Unk	Not Reported
Phenylephrine	C		Unk	Not Reported
Propofol	C		Unk	Not Reported
Sodium Bicarbonate	C		100 Meq	Not Reported
Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
Pantoprazole	C	Intravenous (not otherwise specified)	40 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	17933655	EXPEDITED (15-DAY)		DE, DS, OT	US-GILEAD-2020-0474767		77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Duoneb			C	Respiratory (inhalation)	3 MI		Not Reported
	Pantoprazole			C	Oral	40 Mg		Not Reported
	Sodium Chloride			C				Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Titrated		Not Reported

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Cefepime	C	Intravenous (not otherwise specified)	2 G	Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	2 Puffs	Not Reported
Insulin	C	Intravenous (not otherwise specified)	10 Units	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	17971034	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0477731		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Heart Rate Decreased; Hepatic Enzyme Increased; Hypotension; Liver Disorder; Pulseless Electrical Activity; Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			S	Intravenous (not otherwise specified)	0.5 Mg, Q1minute		Not Reported
	Ivermectin			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported
	Plasma			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Clinimix E			C				Not Reported
	Norepinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Propofol			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Vasopressin			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Ascorbic			C				Not Reported
Chlorhexidine			C				Not Reported	
Cholecalciferol			C				Not Reported	
Enoxaparin			C				Not Reported	
Epinephrine			C				Not Reported	
Etomidate			C				Not Reported	
Famotidine			C				Not Reported	

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Heparin	C	Not Reported
Solu-Medrol	C	Not Reported
Metoprolol	C	Not Reported
Petrolatum/Mineral Oil	C	Not Reported
Ondansetron	C	Not Reported
Rocuronium	C	Not Reported
Kayexalate	C	Not Reported
Zinc Sulfate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	17992213	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0479521		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Lispro			C				Not Reported
	Lisinopril			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)			Not Reported
	Cisatracurium			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Epinephrine			C				Not Reported
	Epoprostenol			C				Not Reported
	Hydromorphone			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol [Salbutamol]			C				Not Reported
	Alprazolam			C				Not Reported
	Benzonatate			C				Not Reported

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28-Jul-2020	18014563	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482006		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Diamox [Acetazolamide]			C				Not Reported
	Insulin Human			C				Not Reported
	Cefepime			C				Not Reported
	Rocephine			C				Not Reported
	Dexamethasone			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Metoprolol			C				Not Reported
	Furosemide			C				Not Reported
	Acetazolamide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18078490	DIRECT	Y	OT			87 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18078499	DIRECT	Y	OT			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Cardiac Arrest; Liver Function Test Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18078998	EXPEDITED (15-DAY)		DS, OT	US-GILEAD-2020-0485015		51 YR	Male	USA

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Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cetylpyridinium Chloride			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Cisatracurium			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	White Petrolatum			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Insulin Lispro			C		Unk		Not Reported
	Multivitamin Iron			C		Unk		Not Reported
	Mupirocin			C		Unk		Not Reported
	Polyethylene Glycol 3350			C		Unk		Not Reported
Sennosides			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18081104	EXPEDITED (15-DAY)		DE	IE-PFIZER INC-2020280589		43 YR	Male	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication	Vancomycin Hcl			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Meropenem			S		1 G, 3x/Day		Pfizer
	Piperacillin & Tazobactam			S		4.5 G, 4x/Day		Not Reported

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Co-Amoxiclave	S	Intravenous (not otherwise specified)	1.2 G, 3x/Day	Not Reported
Clarithromycin	S		500 Mg, 2x/Day	Not Reported
Remdesivir	S		Unk	Not Reported
Salbutamol	C		Unk (Inhaler)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18081722	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486573		86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Death; Respiratory Disorder; Superinfection Bacterial	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Acetaminophen			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Thiamin [Thiamine]			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Fluticasone			C		Unk		Not Reported
	Budesonide			C		Unk		Not Reported
	Vitamin D [Colecalciferol]			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Methimazole			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Vancomycin			C		Unk		Not Reported
	Acetylcysteine			C		Unk		Not Reported

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Omnipaque	C	Unk	Not Reported
Plasma	C		Not Reported
Oxygen	C		Not Reported

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28-Jul-2020	18082608	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485063		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Remdesivir			S	Intravenous drip	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous drip	100 Mg, Qd		Gilead
	Zosyn			C		Unk		Not Reported
	Solumedrol			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18082610	EXPEDITED (15-DAY)		CA, OT	US-GILEAD-2020-0486085		31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Endotracheal Intubation; Foetal Death; Maternal Exposure During Pregnancy	Remdesivir			S	Unknown	Unk		Gilead
	Heparin			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Lovenox [Levofloxacin]			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Nimbex [Nimesulide]			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Precedex			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18082674	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485073		1 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Rocephin [Ceftriaxone Sodium]	C		Unk	Not Reported
	Rocephin [Ceftriaxone Sodium]	C		Unk	Not Reported
	Zosyn	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18083224	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485103		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S				Gilead
	Atorvastatin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Pitressin [Vasopressin]			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl Citrate			C	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18084069	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0485112		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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				otherwise specified)					
		Azithromycin		C					Not Reported
		Levofloxacin		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18084128	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486098		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Unknown	Unk		Gilead	
	Norco			C		7 Doses		Not Reported	
	Acetaminophen			C		500 Mg, 2 Doses		Not Reported	
	Oxygen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18084211	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0486110		46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead	
	Acetaminophen			C		Unk		Not Reported	
	Levophed			C		Unk		Not Reported	
	Tocilizumab			C		Unk		Not Reported	
	Plasma			C		Unk		Not Reported	
	Dexamethasone			C				Not Reported	
	Azithromycin			C				Not Reported	
	Rocephin			C				Not Reported	
	Oxygen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18084673	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486571		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Covid-19 Pneumonia; Subcutaneous Emphysema	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)	Gilead
	Acetaminophen	C		Unk	Not Reported
	Albuterol [Salbutamol]	C		Unk	Not Reported
	Ascorbic Acid	C		Unk	Not Reported
	Atorvastatin	C		Unk	Not Reported
	Azithromycin	C		Unk	Not Reported
	Cefazolin	C		Unk	Not Reported
	Cefepime	C		Unk	Not Reported
	Chlorhexidine	C		Unk	Not Reported
	Cholecalciferol	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported
	Donepezil	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Guaifenesin	C		Unk	Not Reported
	Hydrocodone/Acetaminophen	C		Unk	Not Reported
	Insulin Aspart	C		Unk	Not Reported
	Insulin, Regular	C		Unk	Not Reported
	Losartan	C		Unk	Not Reported
	Meclizine [Meclozine]	C		Unk	Not Reported
	Melatonin	C		Unk	Not Reported
	Methylprednisolone Sodium Succinate	C		Unk	Not Reported
	Mupirocin	C		Unk	Not Reported
	Norepinephrine	C		Unk	Not Reported
	Ondansetron	C		Unk	Not Reported

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Propofol	C	Unk	Not Reported
Senna-S [Docusate Sodium;Sennoside A+B]	C	Unk	Not Reported
Vancomycin	C	Unk	Not Reported
Zinc Sulfate	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085150	DIRECT	Y	DE			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection; Hepatic Failure; Renal Failure; Staphylococcal Infection; Staphylococcal Infection	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085180	DIRECT	Y	DE			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085188	DIRECT	Y	OT				Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hepatic Function Abnormal; Renal Impairment	Remdesivir			S				Not Reported

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28-Jul-2020	18085199	DIRECT	Y	DE			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Palliative Care	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085208	DIRECT	Y	DE			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Respiratory Distress	Remdesivir			S				Not Reported
	Docusate 100 Mg Po Bid			C				Not Reported
	Lovenox 70 Mg Iv Bid			C				Not Reported
	Insulin Sliding Scale			C				Not Reported
	Insulin Aspart 7 Units Sub Q Tid			C				Not Reported
	Wiht Meals							
	Lantus Subq 17 Units Nightly			C				Not Reported
	Ativan 1 Mg Iv X1			C				Not Reported
	Losartan 25 Mg Po Daily			C				Not Reported
	Morphine 1 Mg Iv X1			C				Not Reported
	Morphine 4 Mg Iv X1			C				Not Reported
	Protonix 20 Mg Iv Daily			C				Not Reported
	Senna 1 Tablet Nightly			C				Not Reported
	Thiamine 100 Mg Iv Daily			C				Not Reported
	Precedex Titrated			C				Not Reported
Morphine Pca			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085231	DIRECT	Y				59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus			Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported

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Ondansetron	C		Not Reported
Vancomycin	C		Not Reported
Heparin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085362	DIRECT	Y	DE			29 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Injury; Cardiac Arrest; Haemodialysis; Hypotension; Mental Status Changes; Renal Failure; Respiratory Failure; Tachycardia	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085373	DIRECT	Y	HO			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir Remdesivir	Y		S C	Intravenous drip	Other Frequency:Once;		Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085406	DIRECT	Y	HO, OT			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085562	DIRECT	Y	HO			69 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Kidney Injury	Remdesivir	Y	S	Intravenous drip	Other Frequency:Once;	Gilead
	Remdesivir		C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085591	DIRECT	Y	OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous bolus			Gilead
	Albuterol Inhalation			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide Neb			C				Not Reported
	Fluticasone Nasal			C				Not Reported
	Furosemide			C				Not Reported
	Guaifenesin			C				Not Reported
	Hydralazine Inj			C				Not Reported
	Lorazepam			C				Not Reported
	Losartan			C				Not Reported
	Melatonin			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Ivermectin			C				Not Reported
	Thiamin			C				Not Reported
	Vancomycin			C				Not Reported
	Amlodipine			C				Not Reported
	Ascorbic Acid Iv			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Famotidine			C				Not Reported
	Heparin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085602	DIRECT	Y	DE			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Liver Disorder; Shock;	Remdesivir	Y		S	Intravenous bolus			Gilead
	Cisatracurium			C				Not Reported

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Staphylococcal Sepsis	Norepinephrine	C	Not Reported
	Nafcillin	C	Not Reported
	Midazolam Drip	C	Not Reported
	Fentanyl Drip	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085661	DIRECT	Y	OT			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus			Gilead
	Gabapentin 300mg Tid			C				Not Reported
	Insulin Glargine 35 Units Bid			C				Not Reported
	Pantoprazole 40mg Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085672	DIRECT	Y	DE, OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gilead
	Amiodarone lypb			C				Not Reported
	Azithromycin 500mg Q24h			C				Not Reported
	Enoxaparin 73mg Q12h			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085683	DIRECT	Y	HO			54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium	Remdesivir	Y		S				Gilead
	Dexamethasone			C				Not Reported

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28-Jul-2020	18085716	DIRECT	Y	OT			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Ecchymosis; Infusion Site Bruising; Infusion Site Extravasation; Infusion Site Pain; Localised Oedema	Remdesivir Ceftriaxone	Y		S C	Intravenous drip			Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085726	DIRECT	Y	OT			58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir Dexamethasone Enoxaparin			S C C				Gilead Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085736	DIRECT	Y	DE			59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acinetobacter Bacteraemia; Device Related Thrombosis; General Physical Health Deterioration; Haemofiltration; Hypotension; Klebsiella Bacteraemia; Pulmonary Embolism; Shock; Therapy Interrupted; Transaminases Increased	Remdesivir Dexamethasone Fentanyl Infusion Midazolam Infusion Epoprostenol Nebulization Norepinephrine Infusion Cisatracurium Infusion	Y		S C C C C C C	Intravenous bolus			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085747	DIRECT	Y				60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Transaminases Increased	Remdesivir	Y		S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085776	DIRECT	Y	DE			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Cardio-Respiratory Arrest; General Physical Health Deterioration; Hypotension; Unresponsive To Stimuli	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S		Intravenous (not otherwise specified)		Gilead
	Ascobic Acid			C				Not Reported
	Cholescliferol			C				Not Reported
	Dexamehasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Humulin 70/30			C				Not Reported
	Insulin Lispro Sliding Scale			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085784	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486567		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Death; Myasthenia Gravis Crisis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)		Gilead
	Remdesivir			S		100 Mg, Qd (Maintenance Dose)		Gilead
	Acetaminophen			C		Unk		Not Reported

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Alprazolam	C	Unk	Not Reported
Dexamethasone	C	Unk	Not Reported
Dexmedetomidine	C		Not Reported
Diphenhydramine	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Hydrocortisone Sodium Succinate	C	Unk	Not Reported
Mupirocin	C	Unk	Not Reported
Mycophenolate	C	Unk	Not Reported
Norepinephrine	C	Unk	Not Reported
Vitamin D [Colecalciferol]	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085785	DIRECT	Y	OT			45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation; Eye Pain; Infusion Related Reaction; Infusion Site Erythema; Infusion Site Swelling; Lacrimation Increased; Rash Erythematous; Therapy Interrupted; Vision Blurred	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085795	DIRECT	Y	OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Remdesivir			S	Intravenous drip			Not Reported
	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085849	DIRECT	Y	HO			69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085859	DIRECT	Y	HO			49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085876	DIRECT	Y	DE			89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Albumin Decreased; Blood Bilirubin Increased; Blood Calcium Decreased; Blood Creatinine Increased; Blood Glucose Increased; Blood Lactate Dehydrogenase Increased; Blood Magnesium Increased; Blood Phosphorus Increased; Blood Potassium Increased; Blood Sodium Decreased;	Remdesivir Convalescent Plasma Dexamethasone 6 Mg Iv Once Daily Amiodarone Iv Drip Amlodopine 5 Mg Po Bid Aspirin 81 Mg Ec Po Once Daily Atorvastatin 40 Mg Po Daily At Hs Cefepime 2 Gm Iv Ceftolozane/Tazobactam 0.75 Gm Iv Clopidogrel 75 Mg Po Once Daily Enoxaparin 60 Mg Sq Q 12hr Ezetimibe 10 Mg Po Daily Famotidine 20 Mg Po Daily	Y		S C C C C C C C C C C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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C-Reactive Protein Increased; Haemoglobin Decreased; Hyperphosphatasaemia; Pneumonia Pseudomonal; Procalcitonin Increased; Protein Total Decreased; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Increased; Refusal Of Treatment By Relative; Renal Impairment; Somnolence; White Blood Cell Count Increased	Meropenem Iv Renally Adjusted Metoprolol 25 Mg Po Q8hr Pravastatin 20 Mg Po Once Daily	C C C	Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085898	DIRECT	Y	HO			71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Atracurium			C				Not Reported
	Chlorhexidine			C				Not Reported
	Famotidine			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085938	DIRECT	Y	OT			89 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ampicillin/Sulbactam			C				Not Reported

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Dexamethasone	C	Not Reported
Famotidine	C	Not Reported
Heparin 5000u	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18085947	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Haemodialysis; Hypotension; Hypoxia; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once Daily			C				Not Reported
	Ascorbic Acid 1000 Mg Po Q12h			C				Not Reported
	Aspirin 81 Mg Po Daily			C				Not Reported
	Atorvastatin 80 Mg Po Hs			C				Not Reported
	Azithromycin 500 Iv X 1, Then 250 Mg Po Once Daily			C				Not Reported
	Cefepime 1 Gm Iv Q6hr			C				Not Reported
	Cholecalciferol 2, 0000 Units Po Daily			C				Not Reported
	Clopidogrel 75 Mg Po Once Daily			C				Not Reported
	Cyanocobalamin 1,000 Mcg Po Once Daily			C				Not Reported
	Enoxaparin 40 Mg Sq Q12hr			C				Not Reported
	Enoxaparin 100 Mg Sq Q12hr			C				Not Reported
	Famotidine 10 Mg Po Once Daily			C				Not Reported
	Famotidine 20 Mg Po Once Daily			C				Not Reported
	Meropenem 500 Mg Iv Renally Dosed			C				Not Reported
	Thiamine 100 Mg Po Once Daily			C				Not Reported
	Zinc Sulfate 220 Mg Po Daily			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	18086678	DIRECT	Y	HO, RI			6 DAY	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qt Prolonged	Remdesivir Iv 0.4 Mg/ML	Y		S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	17942222	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0474770		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Decreased; Condition Aggravated; Death; Disseminated Intravascular Coagulation; Hypothermia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atorvastatin			C		Unk	Not Reported	
	Aspirin (E.C.) [Aspirin]			C		Unk	Not Reported	
	Cefepime			C		Unk	Not Reported	
	Enoxaparin			C		Unk	Not Reported	
	Duoneb			C		Unk	Not Reported	
	Pantoprazole			C		Unk	Not Reported	
	Valacyclovir Hcl			C		Unk	Not Reported	
	Acetaminophen			C		Unk	Not Reported	
	Propofol			C		Unk	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18055651	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484380		97 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Death	Remdesivir			S	Intravenous drip	200 Mg, Once		Gilead
	Carboxymethylcellulose Sodium			C		Unk	Not Reported	
	Ceftaroline			C		Unk	Not Reported	
	Premarin			C		Vaginal	Unk	Not Reported
	Enoxaparin			C		Unk	Not Reported	

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Dexamethasone	C	Unk	Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18082333	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486234		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18082535	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486581		74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)		Gilead
	Bupropion			C		Unk		Not Reported
	Chlorhexidine			C		Unk		Not Reported
	Citalopram			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Diphenhydramine			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Insulin, Regular			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported
	Mupirocin			C		Unk		Not Reported
	Nifedipine			C		Unk		Not Reported
Quetiapine			C		Unk		Not Reported	

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Tamsulosin	C	Unk	Not Reported
Zolpidem	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18085583	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486599		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aortic Dissection; Death; Depressed Level Of Consciousness; Hypertension; Hypoxia; Tachycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Enoxaparin			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Diltiazem			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Labetalol			C		Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
Plasma			C		Unk		Not Reported	
Oxygen			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18085960	DIRECT	Y	OT			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Pressure Decreased; Disseminated Intravascular Coagulation; Therapy Non-Responder	Remdesivir	Y		S	Intravenous drip	Other Frequency:200mg X 1,100mg Qd;		Gilead
	Atracurium			C				Not Reported
	Atropine			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

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Hydrocortisone Sod Succ	C	Not Reported
Insulin Glargine	C	Not Reported
Insulin Lispro	C	Not Reported
Insulin Nph	C	Not Reported
Melatonin	C	Not Reported
Piperacillin-Tazobactam	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Vancomycin	C	Not Reported
Dopamine	C	Not Reported
Hydromorphone	C	Not Reported
Insulin Regular	C	Not Reported
Isoproterenol	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Vasopressin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18085980	DIRECT	Y	OT			27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sinus Bradycardia	Remdesivir			S			5 DAY	Not Reported
	Actemra			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087217	DIRECT					79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperkalaemia	Remdesivir			S			5 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087222	DIRECT	Y	DE			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087224	DIRECT		OT			28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087255	DIRECT	Y	OT			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Renal Impairment	Remdesivir			S				Not Reported
	Furosemide			C				Not Reported
	Norepinephrine			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087258	DIRECT	Y	OT			41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Vomiting	Remdesivir			S	Intravenous bolus		5 DAY	Gilead
	Ascorbic Acid			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Insulin Aspart			C				Not Reported
	Insulin Detemir			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Codeine-Guaifenesin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087261	DIRECT	Y	DE			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Clostridium Difficile Colitis; Remdesivir S Intravenous (not otherwise specified) Gilead
Hypotension; Pneumonia;
Respiratory Failure

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29-Jul-2020	18087267	DIRECT	Y	DE			41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Hydroxychloroquine			S	Oral		5 DAY	Not Reported
	Ns Fluid			C				Not Reported
	Albumin 25%			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Potassium Chloride Ivpb			C				Not Reported
	Propofol			C				Not Reported
	Remdesivir			S				Not Reported
	Sodium Bicarbonate Large Volume			C				Not Reported
	Acetaminophen 500mg Tablet			C				Not Reported
	Ascorbic Acid Tablet			C				Not Reported
	Cholecalciferol 5000 Unit Tablet			C				Not Reported
	Dexamethasone 6mg Po Daily			C				Not Reported
	Docusate			C				Not Reported
	Enoxaparin 40mg Sq Q24h			C				Not Reported
	Enoxaparin 60mg Sq Q12h			C				Not Reported
	Etomidate Iv			C				Not Reported
	Furosemide 20mg Ivp			C				Not Reported
	Furosemide 40mg Ivp			C				Not Reported
	Insulin Aspart			C				Not Reported
	Ivermectin 12 Po X 1			C				Not Reported
	Ondansetron Ivp			C				Not Reported
	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087333	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486207		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine	Remdesivir			S	Intravenous (not	200 Mg, Once		Gilead

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Increased					otherwise specified)				
	Remdesivir		S		Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Rocephin [Ceftriaxone Sodium]		C			Unk			Not Reported
	Azithromycin		C			Unk			Not Reported
	Dexamethasone		C			Unk			Not Reported
	Sodium Phosphate		C			Unk			Not Reported
	Fentanyl Citrate		C			Unk			Not Reported
	Magnesium Sulfate		C			Unk			Not Reported
	Norepinephrine Bitartrate		C			Unk			Not Reported
	Pantoprazole		C			Unk			Not Reported
	Potassium Chloride		C			Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087532	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0486136		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Atracurium			C				Not Reported
	Insulin Glargine			C				Not Reported
	Chlorhexidine Gluconate			C				Not Reported
	Sennosides			C				Not Reported
	Docusate			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Rocuronium B Brau			C				Not Reported
	Dexamethasone Sodium Phosphate			C				Not Reported
	Piperacillin			C				Not Reported
	Fentanyl			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087678	EXPEDITED (15-DAY)		CA, DE, OT	US-GILEAD-2020-0486660			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Anomaly; Foetal Exposure During Pregnancy	Remdesivir			S	Transplacental	Unk		Gilead
	Levophed			C	Transplacental	Unk		Not Reported
	Heparin			C	Transplacental	Drip		Not Reported
	Fentanyl			C	Transplacental	Unk		Not Reported
	Lovenox [Levofloxacin]			C	Transplacental	Unk		Not Reported
	Ceftriaxone			C	Transplacental	Unk		Not Reported
	Nimbex [Nimesulide]			C	Transplacental	Unk		Not Reported
	Dexamethasone			C	Transplacental	Unk		Not Reported
	Precedex			C	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18088069	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486162		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Dysphagia; General Physical Health Deterioration	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Dexamethasone			C	Intravenous (not otherwise specified)	5 Mg, Qd		Not Reported
	Carvedilol			C	Oral	3.125 Mg, Bid		Not Reported
	Valproate Sodium			C		500 Mg		Not Reported
	Ticagrelor			C	Oral	90 Mg Q12h		Not Reported
	Spirolactone			C	Oral	25 Mg, Qd		Not Reported
	Entresto			C	Oral	24/26		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported

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Megestrol	C	Oral	400 Mg, Bid	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
Fluconazole	C	Oral	100 Mg, Qd	Not Reported
Ezetimibe	C	Oral	10 Mg, Qd	Not Reported
Enoxaparin	C	Subcutaneous	80 Mg Q12hr	Not Reported
Atorvastatin	C	Oral	80 Mg	Not Reported
Asa	C	Oral	81 Mg, Once	Not Reported
Albuterol [Salbutamol]	C	Respiratory (inhalation)	Unk, Bid	Not Reported
Clinimix E	C		Unk	Not Reported
Tpn [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos]	C		Unk	Not Reported
Thiamine	C	Oral	Unk Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18088776	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486244		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Dose Omission	Remdesivir			S	Unknown	200 Mg, Once		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead
	Remdesivir			S	Unknown	100 Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18089307	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486950		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Amiodarone			C				Not Reported
	Azithromycin			C				Not Reported
	Enoxaparin			C				Not Reported

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Covid-19; Glomerular
Filtration Rate Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18089362	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486238		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure; Sars-Cov-2 Test Positive	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S				Gilead
	Azithromycin			C		Unk		Not Reported
	Rocephin			C		Unk		Not Reported
	Dexamethasone			C	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18089399	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486606		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Metoprolol [Metoprolol Fumarate]			C				Not Reported
	Heparin			C				Not Reported
	Doxazosin			C				Not Reported
	Dexamethasone			C				Not Reported
	Clopidogrel			C				Not Reported
	Aspirin 81			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18089522	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0486614		20 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous bolus	100 Mg, Qd		Gilead

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Aminotransferase Increased	Trazodone	C	Unk	Not Reported
	Dexamethasone	C	Unk	Not Reported
	Acetaminophen	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18089790	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0486578		91 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Lovenox			C		Unk		Not Reported
	Glimepiride			C		Unk		Not Reported
	Irbesartan			C		Unk		Not Reported
	Ivermectin			C		Unk		Not Reported
	Azithromycin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090945	DIRECT	Y				27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Nausea; Tachycardia; Vomiting	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Not Reported
	Normal Saline Infusion			C				Not Reported
	Acetaminophen 1000mg Tab			C				Not Reported
	Acetaminophen 650mg Tab			C				Not Reported
	Aspirin 81mg Chewable Tab			C				Not Reported
	Azithromycin 500mg Tab			C				Not Reported
	Ceftriaxone 1g In 100ml Ns			C				Not Reported
	Enoxaparin 40mg Syringe			C				Not Reported
	Risaquad Capsule			C				Not Reported
	Methylprednisolone 40mg Iv			C				Not Reported
	Montelukast 10mg Tab			C				Not Reported
	Zofran 4mg Inj			C				Not Reported
	Potassium Chloride Cr 40meq			C				Not Reported

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Zinc Sulfate			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090946	DIRECT	Y	DE			58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S		Other Frequency:Once;		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090948	DIRECT	Y	DE			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Remdesivir			S	Intravenous drip			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090949	DIRECT	Y	HO			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Nephropathy Toxic	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090950	DIRECT	Y	HO, OT			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Condition Aggravated; Renal Injury; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Acetaminophen			C				Not Reported	
	Cefepime			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Diphenhydramine			C				Not Reported	
	Metronidazole			C				Not Reported	

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Olanzapine	C	Not Reported
Tocilizumab	C	Not Reported
Vancomycin	C	Not Reported
Sennoside	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090951	DIRECT	Y				22 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Azithromycin 500mg In 250mg Ns			C				Not Reported
	Iodixanol 320mg/MI 100ml			C				Not Reported
	Acetaminophen 650mg Tab			C				Not Reported
	Aspirin 81mg Tab			C				Not Reported
	Benzonatate Capsule 100mg			C				Not Reported
	Tums 500mg			C				Not Reported
	Ceftriaxone 2g In Ns 100ml			C				Not Reported
	Mucinex Dm 30/600mg			C				Not Reported
	Doxycycline 100mg In 100ml Ns			C				Not Reported
	Enoxaparin 40mg Syringe			C				Not Reported
	Guaifenesin-Codeine 100-10mg/5ml			C				Not Reported
	Maraviroc 300mg			C				Not Reported
	Methylprednisolone 125mg			C				Not Reported
	Prednisone 40mg Tab			C				Not Reported
	Normal Saline 500ml			C				Not Reported
	Vitamin C 500mg			C				Not Reported
	Cholecalciferol 25mcg			C				Not Reported
	Zinc Sulfate Cap 220mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090952	DIRECT	Y	LT			77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Unevaluable Event	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir			S	Intravenous drip			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090953	DIRECT	Y				80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 200 Mg			C		Not Reported		
	Remdesivir 100 Mg			C		Not Reported		
	Albuterol			C		Not Reported		
	Apixaban			C		Not Reported		
	Ascorbic Acid			C		Not Reported		
	Atorvastatin			C		Not Reported		
	Budesonide			C		Not Reported		
	Cholecalciferol			C		Not Reported		
	Dexamethasone			C		Not Reported		
	Levofloxacin			C		Not Reported		
	Levothyroxine			C		Not Reported		
	Memantine			C		Not Reported		
	Metoprolol			C		Not Reported		
Pantoprazole			C	Not Reported				
Zinc			C	Not Reported				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090954	DIRECT	Y	HO, LT, OT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Intravenous bolus Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S		Not Reported		
	Rocuronium			C		Not Reported		
	Propofol			C		Not Reported		
	Potassium Phosphate			C		Not Reported		
	Miralax			C		Not Reported		
	Norepinephrine			C		Not Reported		
	Morphine			C		Not Reported		
	Butmetanide			C		Not Reported		

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Dexamethasone	C	Not Reported
Doxycycline	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090955	DIRECT	Y				61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Extravasation	Remdesivir			S				Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090956	DIRECT	Y	OT			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18090957	DIRECT	Y	DE			91 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18093125	DIRECT	Y	DE			80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Therapy Interrupted; Vascular	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Gilead

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Access Complication	Remdesivir 100mg	Y	S	Intravenous (not otherwise specified)	Gilead
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	17959115	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0474419		28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Diarrhoea; Leukocytosis; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Mg		Not Reported
	Plasma			C		291 MI		Not Reported
	Acetaminofen			C	Oral	975 Mg		Not Reported
	Acetaminofen			C	Oral	650 Unk		Not Reported
	Acetaminofen			C	Intravenous (not otherwise specified)	1000 Unk		Not Reported
	Simethicone			C	Oral	15 MI		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	180 Mcg		Not Reported
	Albuterol [Salbutamol]			C		2.5 Mg		Not Reported
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Budesonide			C		0.25 Mg		Not Reported
	Budesonide			C				Not Reported
	Captopril			C	Oral	6.25 Mg		Not Reported
	Captopril			C	Oral	12.5 Unk		Not Reported
Ceftriaxone			C	Intravenous (not otherwise specified)	1 G		Not Reported	
Enoxaparin			C	Subcutaneous	40 Mg		Not Reported	
Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported	

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Furosemide	C	otherwise specified)	Intravenous (not otherwise specified)	40 Mg	Not Reported
Furosemide	C	otherwise specified)	Intravenous (not otherwise specified)	20 Unk	Not Reported
Furosemide	C	otherwise specified)	Intravenous (not otherwise specified)	40 Unk	Not Reported
Melatonin	C		Oral	6 Mg	Not Reported
Morphine	C		Intravenous (not otherwise specified)	2 Mg	Not Reported
Ondasetron [Ondansetron]	C		Intravenous (not otherwise specified)	Unk	Not Reported
Ondasetron [Ondansetron]	C				Not Reported
Pneumococcal Vaccine	C		Intramuscular	0.5 MI	Not Reported
Potassium Chloride	C		Oral	40 Meq	Not Reported
Potassium Chloride	C		Oral	20 Unk	Not Reported
Potassium Chloride	C		Oral	40 Unk	Not Reported
Sodium Chloride	C		Intravenous (not otherwise specified)	3 MI	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	17970934	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0477763		85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Famotidine			C				Not Reported
	Heparin Axicur			C				Not Reported
	Insulin			C				Not Reported
	Cefepime			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Docusate			C				Not Reported

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Epinephrine	C	Not Reported
Hydromorphone	C	Not Reported
Methylprednisolone	C	Not Reported
Midazolam	C	Not Reported
Norepinephrine	C	Not Reported
Sennoside [Sennoside A+B]	C	Not Reported
Sucralfate	C	Not Reported
Vancomycin	C	Not Reported
Vasopressin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	17979287	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0478145		34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Product Preparation Error	Remdesivir			S	Intravenous drip	200 Mg/M2, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18021692	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0482369		35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Lisinopril			C				Not Reported
	Gabapentin			C				Not Reported
	Enoxaparin			C				Not Reported
	Dexamethasone			C				Not Reported
	Doxepin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18091971	DIRECT	Y	OT			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Dizziness	Remdesivir	Y	S	Intravenous (not otherwise specified)	Other Frequency:Once;	Not Reported
	Apixaban		C			Not Reported
	Guaifenesin		C			Not Reported
	Levothyroxine		C			Not Reported
	Metoprolol Succinate XI		C			Not Reported
	Pantoprazole		C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18092382	DIRECT	Y				38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18092386	DIRECT	Y	HO			62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Bilirubin Increased	Remdesivir			S	Intravenous drip			Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Cistatracurium			C				Not Reported
	Dexamethasone			C				Not Reported
	Fentanyl			C				Not Reported
	Gabapentin			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Propofol			C				Not Reported
	Vasopressin			C				Not Reported
	Nortriptyline			C				Not Reported

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30-Jul-2020	18092389	DIRECT	Y	DE			69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
	Diltiazem			C				Not Reported
	Furosemide			C				Not Reported
	Metoprolol			C				Not Reported
	Acetaminophen			C				Not Reported
	Dexamethasone			C				Not Reported
	Ketorolac			C				Not Reported
	Lorazepma			C				Not Reported
	Morphine			C				Not Reported
	Enoxaparin			C				Not Reported
	Docusate			C				Not Reported
	Famotidine			C				Not Reported
	Omeprazole			C				Not Reported
	Senna			C				Not Reported
	Dexamethasone			C				Not Reported
	Insulin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18093860	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486676		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Respiratory Distress	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Docusate			C	Oral	100 Mg, Bid		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Intravenous (not otherwise specified)	70 Mg, Bid		Not Reported
	Insulin			C		Sliding Scale		Not Reported
	Insulin Aspart			C	Subcutaneous	7 Iu, Tid With Meals		Not Reported
	Lantus			C	Subcutaneous	17 Iu, Qhs		Not Reported
	Ativan			C	Intravenous (not	1 Mg		Not Reported

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				otherwise specified)		
Losartan	C	Oral	25 Mg, Qd			Not Reported
Morphine	C	Intravenous (not otherwise specified)	1 Mg			Not Reported
Morphine	C	Intravenous (not otherwise specified)	4 Mg			Not Reported
Morphine	C	Intravenous (not otherwise specified)	Pca			Not Reported
Protonix [Pantoprazole Sodium Sesquihydrate]	C	Intravenous (not otherwise specified)	20 Mg, Qd			Not Reported
Senna Acutifolia	C	Oral	1 Tablet, Qhs			Not Reported
Thiamine	C	Intravenous (not otherwise specified)	100 Mg, Qd			Not Reported
Precedex	C		Titrated			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18094971	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477762		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Nervousness	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Atorvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lisinopril			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol Hfa			C				Not Reported
	Guaifenesin			C				Not Reported
	Ondansetron [Ondansetron Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported

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30-Jul-2020	18095728	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486976		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Plasma			C				Not Reported
	Dexamethasone			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Aspirin (E.C.)			C				Not Reported
	Atorvastatin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported
	Cholecalciferol			C				Not Reported
	Clopidogrel			C				Not Reported
	Cyanocobalamin			C				Not Reported
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported
	Meropenem			C				Not Reported
	Thiamine			C				Not Reported
	Zinc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096015	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487389		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096598	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486979		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Death; Hypoxia; Pneumonia Pseudomonal; Renal Impairment	Remdesivir	S	Intravenous (not otherwise specified)	Unk	Gilead
	Plasma	C			Not Reported
	Dexamethasone	C			Not Reported
	Amiodarone	C			Not Reported
	Amlodipine	C			Not Reported
	Aspirin (E.C.)	C			Not Reported
	Atorvastatin	C			Not Reported
	Cefepime	C			Not Reported
	Ceftolozane	C			Not Reported
	Tazobactam	C			Not Reported
	Clopidogrel	C			Not Reported
	Enoxaparin	C			Not Reported
	Ezetimibe	C			Not Reported
	Famotidine	C			Not Reported
	Meropenem	C			Not Reported
	Metoprolol	C			Not Reported
	Pravastatin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096871	DIRECT	Y	DE, DS, HO, LT, OT			38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Herniation; Brain Injury; Brain Oedema; Cardiac Arrest	Remdesivir			S	Intravenous bolus			Not Reported
	Remdesivir			S	Intravenous bolus			Not Reported
	Convalescent Plasma			C				Not Reported
	Tocilizumab			C				Not Reported
	Decadron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096880	DIRECT	Y	DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Hypoxia; Respiratory Acidosis	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported
	Dexamethasone 6 Mg Iv Once			C				Not Reported

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Daily			
Ascorbic Acid 1000 Mg Po Once	C		Not Reported
Daily			
Ceftriaxone 1 Gm Iv Once Daily	C		Not Reported
Azithromycin 500 Mg Iv Once	C		Not Reported
Daily			
Enoxaparin 70 Mg Sq Q12hrs	C		Not Reported
Famotidine 20 Mg Iv Q12hr	C		Not Reported
Insulin Glargine 10 Units Sq At	C		Not Reported
Hs			
Insulin Glargine 15 Units Sq Bid	C		Not Reported
Smz/Tmp Iv Q6hr	C		Not Reported
Zinc Sulfate 220 Mg Po Once	C		Not Reported
Daily			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096891	DIRECT	Y	OT			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096906	DIRECT	Y	DE			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Disease Complication	Remdesivir			S	Intravenous bolus			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096915	DIRECT	Y	DE			96 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ceftriaxone			C				Not Reported

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Flagyl	C	Not Reported
Albuterol	C	Not Reported
Lovenox	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096967	DIRECT	Y				81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Flushing; Oxygen Saturation Decreased	Veklury (Remdesivir)	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead
	Albuterol/Ipratropium			C				Not Reported
	Restasis			C				Not Reported
	Ibuprofen			C				Not Reported
	Pantoprazole			C				Not Reported
	Aspirin			C				Not Reported
	Fluticasone Propionate			C				Not Reported
	Miralax			C				Not Reported
	Simvastatin			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Labetalol			C				Not Reported
	Hydralazine			C				Not Reported
	Benzonatate			C				Not Reported
	Guaifenesin			C				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18096997	DIRECT	Y				59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Schedule Of Product Administration	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097007	DIRECT	Y	HO			72 YR	Male	USA

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Blood Creatinine Increased; Creatinine Renal Clearance Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097016	DIRECT	Y				61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Duplicate Therapy Error; Product Dispensing Error; Product Prescribing Error	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone			C			Not Reported	
	Zinc Sulfate			C			Not Reported	
	Azithromycin			C			Not Reported	
	Ascorbic Acid			C			Not Reported	
	Enoxaparin			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097027	DIRECT	Y	OT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Esmolol			C			Not Reported	
	Famotidine			C			Not Reported	
	Heparin			C			Not Reported	
	Furosemide			C			Not Reported	
	Meropenem			C			Not Reported	
	Micafungin			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097038	DIRECT	Y	OT			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased	Remdesivir	S	Intravenous (not otherwise specified)	Gilead
	Dexamethasone	C		Not Reported
	Zinc Sulfate	C		Not Reported
	Ascorbic Acid	C		Not Reported
	Aspirin	C		Not Reported
	Rosuvastatin	C		Not Reported
	Rocuronium	C		Not Reported
	Norepinephrine	C		Not Reported
	Fentanyl	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097047	DIRECT	Y	OT			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097065	DIRECT	Y	OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dexamethasone			C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenasin			C				Not Reported
	Hydrocodone-Acetaminophen			C				Not Reported
	Ondansetron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097076	DIRECT	Y	OT			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Bradycardia	Remdesivir	S	Intravenous drip	10 DAY	Not Reported
	Propofol	C			Not Reported
	Fentanyl	C			Not Reported
	Pantoprazole	C			Not Reported
	Levothyroxine	C			Not Reported
	Enoxaparin	C			Not Reported
	Dexamethasone	C			Not Reported
	Azithromycin	C			Not Reported
	Ceftriaxone	C			Not Reported
	Tocilizumab	C			Not Reported
	Piperacillin/Tazobactam	C			Not Reported
	Ipratropium	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097088	DIRECT	Y	OT			27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dystonia	Remdesivir			S				Not Reported
	Compazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097098	DIRECT	Y				65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intercepted Product Preparation Error; Product Preparation Issue	Remdesivir	Y		S	Intravenous drip			Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097531	DIRECT	Y	HO, RI, OT			80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Interrupted	Remdesivir 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir 100mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead

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	Ceftriaxone	C	otherwise specified)	Not Reported
	Dexamethasone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097822	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486167		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone			C	Oral	200 Mg		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Enoxaparin			C	Subcutaneous	100 Mg		Not Reported
	Famotidine			C	Intravenous (not otherwise specified)	20 Mg, Bid		Not Reported
	Lantus			C	Subcutaneous	Up To 20 lu		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097839	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0486577		82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Death; Drug Ineffective; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Q24h		Gilead
	Acetaminophen			C	Oral	1000 Mg, Q6h Prn		Not Reported
	Albuterol [Salbutamol]			C	Respiratory (inhalation)	2 Puffs, Q8h		Not Reported
	Alprazolam			C		0.25 Mg, Q6h Prn		Not Reported
	Amlodipine			C	Oral	5-10 Mg		Not Reported
	Ascorbic Acid			C	Oral	1000 Mg, Tid		Not Reported

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Atorvastatin	C	Oral	40 Mg, Qhs	Not Reported
Chlorhexidine	C	Oral	15 MI, Bid	Not Reported
Cholecalciferol	C	Oral	20000 Units	Not Reported
Clonidine	C	Oral	0.1-0.2 Mg	Not Reported
Dexamethasone	C	Intravenous (not otherwise specified)	6 Mg Q12-24hr	Not Reported
Diphenhydramine	C	Intravenous (not otherwise specified)	25 Mg Q6h Prn	Not Reported
Enoxaparin	C	Subcutaneous	30-90 Mg Q24h	Not Reported
Famotidine	C	Oral	20 Mg, Qd	Not Reported
Gabapentin	C	Oral	100 Mg, Tid	Not Reported
Hydralazine	C	Intravenous (not otherwise specified)	10 Mg Q 6 Hr Prn	Not Reported
Levofloxacin	C	Intravenous (not otherwise specified)	500 Mg Q 28 Hr	Not Reported
Lorazepam	C	Intravenous (not otherwise specified)	0.5 Mg Q4hr Prn	Not Reported
Mupirocin	C	Nasal	Unk, Bid	Not Reported
Ondansetron	C	Intravenous (not otherwise specified)	4 Mg Q 8 Hr Prn	Not Reported
Patiomer Sorbitex Calcium	C	Ophthalmic	8.4 G, Once	Not Reported
Sodium Bicarbonate	C	Oral	650-1300 Bid-Tid	Not Reported
Sodium Bicarbonate In Dextrose 5%	C	Intravenous (not otherwise specified)	Continuous	Not Reported
Sodium Bicarbonate In Dextrose 5%	C	Intravenous (not otherwise specified)	Unk Continuous	Not Reported
Sodium Polystyrene Sulfonate	C	Oral	15 G, Qd	Not Reported
Sucralfate	C	Oral	1 G, Q6h	Not Reported
Timolol Maleate 0.5%	C		1 Drop Both Eyes, Bid	Not Reported
Zinc Sulfate	C	Oral	220 Mg, Bid	Not Reported

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30-Jul-2020	18098576	DIRECT	Y	RI, OT			65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Platelet Count Decreased; Therapy Cessation	Remdesivir 100mg Injection	Y		S	Intravenous (not otherwise specified)			Gilead	
	Remdesivir 100mg Injection	Y		S				Gilead	
	Azithromycin Dexamethasone			C C				Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	17818827	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-GILEAD-2020-0468514		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Respiratory Distress	Remdesivir			S	Unknown	100 Mg		Gilead	
	Cyclobenzaprine			C		Unk	Not Reported		
	Aspirin Ec			C		Unk	Not Reported		
	Doxycycline			C		Unk	Not Reported		
	Pyridostigmine			C		Unk	Not Reported		
	Atorvastatin			C		Unk	Not Reported		
	Calcium Carbonate			C		Unk	Not Reported		
	Zinc			C		Unk	Not Reported		
	Ondansetron			C		Unk	Not Reported		
	Diphenhydramine			C		Unk	Not Reported		
	Amiodarone			C		Unk	Not Reported		
	Famotidine			C		Unk	Not Reported		
	Ceftriaxone			C		Unk	Not Reported		
	Acetaminophen			C		Unk	Not Reported		
Albuterol [Salbutamol]			C	Unk	Not Reported				

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Furosemide	C	Not Reported
Insulin Detemir	C	Not Reported
Lorazepam	C	Not Reported
Metoprolol	C	Not Reported
Potassium Chloride	C	Not Reported
Apixaban	C	Not Reported
Cefepime	C	Not Reported
Chlorhexidine	C	Not Reported
Dexmedetomidine	C	Not Reported
Fentanyl	C	Not Reported
Heparin	C	Not Reported
Insulin Aspart	C	Not Reported
Ketamine	C	Not Reported
Metronidazole	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	17856483	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469863		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	17881226	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470048		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Melatonin			C				Not Reported
	Levothyroxine			C				Not Reported
	Propofol			C				Not Reported
	Norepinephrine			C				Not Reported
	Insulin			C				Not Reported

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Insulin Lispro	C	Not Reported
Hydromorphone	C	Not Reported
Meropenem	C	Not Reported
Primasol	C	Not Reported
Linezolid	C	Not Reported
Famotidine	C	Not Reported
Heparin	C	Not Reported
Lisinopril	C	Not Reported
Diclofenac	C	Not Reported
Insulin Aspart	C	Not Reported
Insulin Glargine	C	Not Reported
Convalescent Plasma	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	17950432	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475638		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Unk		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Unk		Gilead
	Dopamine			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Insulin			C				Not Reported
	Metoprolol			C				Not Reported
	Norepinephrine			C				Not Reported
	Vecuronium			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	17952475	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0475664		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Heart Rate Increased; Maternal Exposure During Pregnancy	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

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31-Jul-2020	18013909	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0481352			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead	
	Propofol			S	Unknown			Not Reported	
	Fentanyl			C				Not Reported	
	Midazolam			C				Not Reported	
	Atropine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18021543	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482491		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	200/100mg, Qd		Gilead	
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg		Not Reported	
	Furosemide			C	Intravenous (not otherwise specified)	20 Mg		Not Reported	
	Pantoprazole			C	Oral	40 Mg		Not Reported	
	Valsartan			C	Oral	320 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18034091	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0483269		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Maternal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	

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Exposure During Pregnancy	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Once	Gilead
	Acetaminophen	C		Unk	Not Reported
	Dexamethasone	C		Unk	Not Reported

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31-Jul-2020	18038072	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0470345		85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Haemoglobin Decreased; Hypernatraemia; Melaena; Mental Status Changes; Ulcer Haemorrhage	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Diclofenac			C	Oral			Not Reported
	Finasteride			C	Oral			Not Reported
	Lisinopril			C	Oral			Not Reported
	Pantoprazole			C	Intravenous (not otherwise specified)			Not Reported
	Simvastatin			C	Oral			Not Reported
Tamsulosin			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18069578	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0485585		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Death; Multiple Organ Dysfunction Syndrome; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C				Not Reported
	Vitamin C Asc Acid			C				Not Reported
	Zinc			C				Not Reported

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Azithromycin	C	Not Reported
Ceftriaxone	C	Not Reported
Cisatracurium	C	Not Reported
Dexmedetomidine	C	Not Reported
Enoxaparin	C	Not Reported
Fentanyl	C	Not Reported
Gabapentin	C	Not Reported
Ketamine	C	Not Reported
Norepinephrine	C	Not Reported
Pantoprazole	C	Not Reported
Propofol	C	Not Reported
Rosuvastatin	C	Not Reported
Cholecalciferol	C	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Not Reported

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31-Jul-2020	18097139	DIRECT	Y				67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Mstt1041a			C				Not Reported	

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31-Jul-2020	18099278	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487565		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Plasma			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Ascorbic Acid			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Azithromycin			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Famotidine			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Smz-Tmp			C				Not Reported	

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Zinc Sulfate C Not Reported
Bicarbonate C Not Reported

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31-Jul-2020	18099507	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487050		23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Azithromycin			C		250 Mg		Not Reported
	Famotidine			C		20 Mg, Bid		Not Reported
	Ceftriaxone			C		1 G Q24h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18099542	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487536		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18099549	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487413		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead
	Fentanyl			C		Unk		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Rocuronium			C		Unk		Not Reported

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31-Jul-2020	18100023	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487474		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Covid-19; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Insulin Glargine			C		35 Iu, Bid		Not Reported	
	Pantoprazole			C		40 Mg, Qd		Not Reported	
	Gabapentin			C		300 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18100350	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487983		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S	Unknown	200 Mg, Qd		Gilead	
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18100399	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487417		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remdesivir			S	Intravenous bolus	200 Mg, Once		Gilead	
	Apixaban			C		5 Mg, Bid		Not Reported	
	Bupropion			C		50 Mg, Tid		Not Reported	
	Duloxetine			C		30 Mg, Qd		Not Reported	
	Aripiprazole +Pharma			C		5 Mg, Bid		Not Reported	
	Insulin Glargine			C		15 Units Hs		Not Reported	
	Levothyroxine			C		100 Mcg Qd		Not Reported	

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31-Jul-2020	18100690	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0487549		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Erythema; Lip Swelling	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	
	Enoxaparin			C	Subcutaneous	30 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18100843	EXPEDITED (15-DAY)		HO	US-GILEAD-2020-0487466		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead	
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18100879	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487538		12 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Death; Renal Impairment	Remdesivir			S	Unknown	200 Mg, Once		Gilead	
	Remdesivir			S	Unknown	100 Mg, Qd		Gilead	

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31-Jul-2020	18100913	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0487393		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Liver Function Test Increased	Remdesivir			S	Unknown	Unk		Gilead	
	Hydroxychloroquine			S	Oral	400 Mg, Bid		Not Reported	

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Albumin	C	Not Reported
Azithromycin	C	Not Reported
Ceftriaxone	C	Not Reported
Potassium Chloride	C	Not Reported
Propofol	C	Not Reported
Sodium Bicarbonate	C	Not Reported
Acetaminophen	C	Not Reported
Ascorbic Acid	C	Not Reported
Cholecalciferol	C	Not Reported
Dexamethasone	C	Not Reported
Docusate	C	Not Reported
Enoxaparin	C	Not Reported
Etomidate	C	Not Reported
Furosemide	C	Not Reported
Insulin	C	Not Reported
Ivermectin	C	Not Reported
Ondansetron	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18102972	DIRECT	Y	OT			55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;		Gilead
	Tocilizumab			C				Not Reported
	Azithromycin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18102974	DIRECT	Y	OT			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
White Blood Cell Count Decreased	Remdesivir			S				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103011	DIRECT	Y	OT			52 YR	Female	USA

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Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Dexamethasone			C		Not Reported		
	Bumetanide			C		Not Reported		
	Heparin			C		Not Reported		
	Guaifenesin			C		Not Reported		
	Tocilizumab			C		Not Reported		
	Insulin Nph			C		Not Reported		
	Cisatracurium			C		Not Reported		
	Dexmedetomidine			C		Not Reported		
	Fentanyl			C		Not Reported		
	Propofol			C		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103017	DIRECT	Y	DE			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C		Not Reported		
	Albumin			C		Not Reported		
	Cisatracurium			C		Not Reported		
	Epoprostenol			C		Not Reported		
	Fentanyl			C		Not Reported		
	Insulin Nph			C		Not Reported		
	Lactobacillus			C		Not Reported		
	Midazolam			C		Not Reported		
	Norepinephrine			C		Not Reported		
	Pantoprazole			C		Not Reported		
	Phenylephrine			C		Not Reported		
	Piperacillin/Tazobactam			C		Not Reported		
	Propofol			C		Not Reported		
	Sodium Polystyrene Sulfonate			C		Not Reported		
	Tocilizumab			C		Not Reported		
Vaopressin			C	Not Reported				

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31-Jul-2020	18103026	DIRECT	Y				69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Remdesivir			S	Intravenous drip	Other Frequency:X1, Then 100 Mg Qd;		Gilead	
	Solu-Medrol			C				Not Reported	

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31-Jul-2020	18103031	DIRECT	Y	OT			36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported	
	Acetaminophen			C				Not Reported	
	Atracurium			C				Not Reported	
	Epinephrine			C				Not Reported	
	Cefepime			C				Not Reported	
	Famotidine			C				Not Reported	
	Fentanyl			C				Not Reported	
	Heparin			C				Not Reported	
	Hydrocodone			C				Not Reported	
	Hydrocortisone			C				Not Reported	
	Labetalol			C				Not Reported	
	Humulin R			C				Not Reported	
	Duoneb			C				Not Reported	
	Midazolam			C				Not Reported	
	Levophed			C				Not Reported	
	Ondansetron			C				Not Reported	
	Promethazine			C				Not Reported	
	Vasopressin			C				Not Reported	
	Rocuronium			C				Not Reported	
	Propofol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103049	DIRECT	Y	DE			75 YR	Male	USA

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Death	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous drip			Gilead
	Ascorbic Acid			C				Not Reported
	Aspirin			C				Not Reported
	Dexamethasone			C				Not Reported
	Docusate			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxparin			C				Not Reported
	Famotidine			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin Glargine			C				Not Reported
	Insulin Lispro			C				Not Reported
	Ipratropium			C				Not Reported
	Metoprolol			C				Not Reported
	Multivitamin			C				Not Reported
	Ondansetron			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
Zinc Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103051	DIRECT	Y	OT			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia; Hypothermia; Oxygen Saturation Decreased	Remdesivir			S				Not Reported
	Insulin Isophane/Reg 70/30			C				Not Reported

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31-Jul-2020	18103066	DIRECT	Y	OT			38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Critical Illness; Liver Function Test Increased; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Azithromycin			C				Not Reported

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Ceftriaxone	C	Not Reported
Codeine-Guifenesin	C	Not Reported
Dexamethasone	C	Not Reported
Dexmedetomidine	C	Not Reported
Enoxaparin	C	Not Reported
Famotidine	C	Not Reported
Fentanyl	C	Not Reported
Furosemide	C	Not Reported
Linezolid	C	Not Reported
Midazolam	C	Not Reported
Multivitamin With Iron	C	Not Reported
Norepinephrine	C	Not Reported
Perfluten Lipid Microspheres	C	Not Reported
Polyethylene Glycol (Glycolax)	C	Not Reported
Potassium Chloride	C	Not Reported
Propofol	C	Not Reported
Rocuronium	C	Not Reported
Sennosides	C	Not Reported
Vancomycin	C	Not Reported

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31-Jul-2020	18103069	DIRECT	Y	OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreased; Hypotension; Urine Output Decreased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Doxycycline			C			Not Reported	
	Hydrocortisone			C			Not Reported	
	Piperacillin/Tazobactam			C			Not Reported	
	Quetiapine			C			Not Reported	
Midazolam			C			Not Reported		

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31-Jul-2020	18103071	DIRECT	Y	DE			49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Product Storage	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

Error	Dexamethasone	C	Not Reported
	Doxazosin	C	Not Reported
	Furosemide	C	Not Reported
	Isosorbide Dinitrate	C	Not Reported
	Losartan	C	Not Reported
	Metoprolol	C	Not Reported
	Aspirin	C	Not Reported
	Gabapentin	C	Not Reported
	Morphine	C	Not Reported
	Oxycodone-Acetaminophen	C	Not Reported
	Ropinirole	C	Not Reported
	Vecuronium	C	Not Reported
	Enoxaparin	C	Not Reported
	Ticagrelor	C	Not Reported
	Famotidine	C	Not Reported
	Atorvastatin	C	Not Reported
	Insulin	C	Not Reported
	Amitriptyline	C	Not Reported
	Duloxetine	C	Not Reported

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31-Jul-2020	18103075	DIRECT	N	OT			53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Temazepam			C				Not Reported
	Senna			C				Not Reported
	Ondansetron			C				Not Reported
	Nystatin			C				Not Reported
	Dexamethosone			C				Not Reported
	Enoxaparin			C				Not Reported
	Robitussin			C				Not Reported
	Insulin			C				Not Reported

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31-Jul-2020	18103076	DIRECT	N	OT			37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Transaminases Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead	
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead	
	Dilaudid			C				Not Reported	
	Tylenol			C				Not Reported	
	Norvasc			C				Not Reported	
	Albuterol			C				Not Reported	
	Zofran			C				Not Reported	

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31-Jul-2020	18103088	DIRECT	Y	OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remdesivir			S	Intravenous drip		5 DAY	Not Reported	
	Acetaminophen			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Citalopram			C				Not Reported	
	Clopidogrel			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Ondansetron			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103093	DIRECT	Y				52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hallucination, Auditory	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103095	DIRECT	Y				49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error; Product Dose Omission	Remdesivir			S	Intravenous bolus			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103097	DIRECT	Y	OT			53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103366	DIRECT	Y				69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Veklury (Remdesivir)			S	Intravenous (not otherwise specified)			Gilead	
	Albuterol Inhaler			C				Not Reported	
	Ascorbic Acid Iv			C				Not Reported	
	Aspirin Enteric Coated			C				Not Reported	
	Benzonatate			C				Not Reported	
	Budesonide Respule			C				Not Reported	
	Doxycycline Iv			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Heparin Subq			C				Not Reported	
	Insulin Regular			C				Not Reported	
	Insulin Glargine			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Propofol			C				Not Reported	
	Rocuronium			C				Not Reported	

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Ropinirole	C	Not Reported
Rosuvastatin	C	Not Reported
Albuterol/Ipratropium	C	Not Reported
Cefepime	C	Not Reported
Dexamethasone	C	Not Reported
Fentanyl Pca	C	Not Reported
Pantoprazole Iv	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18103897	DIRECT	N	DE			15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Blood Urea Increased; Cardiac Arrest; Disease Progression; Hypercapnia; Oxygen Saturation Decreased; Pulseless Electrical Activity; Pyrexia; Respiratory Failure; Urine Output Decreased	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Frequency: Once		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18104113	DIRECT	Y	DE			16 YR	Female	UMI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Blood Creatinine Increased; Blood Urea Increased; Cardiac Arrest; Condition Aggravated; Disease Progression; Drug Ineffective; Hypercapnia; Oxygen Saturation Decreased; Pulseless	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)			Not Reported
	Gilead Sciences			C	Intravenous (not otherwise specified)			Not Reported

Electrical Activity; Pyrexia;
Renal Impairment;
Respiratory Failure; Urine
Output Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18101474	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-255176		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Azithromycin			S	Unknown	Unk		Sun
Death; Drug Ineffective;	Hydroxychloroquine			S	Unknown	Unk		Ipca
Heparin-Induced Thrombocytopenia;	Ceftriaxone			S	Unknown	Unk		Not Reported
Hypotension; Platelet Count Decreased;	Bivalirudin			S	Unknown	0.15 Mg/Kg/H		Not Reported
Pulmonary Embolism;	Unfractionated Heparin			S	Unknown	5000 Unit, Bid		Not Reported
Tachycardia	Unfractionated Heparin			S		18 Units/Kg/H		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Cisatracurium			S	Unknown	Unk		Not Reported
	Remdesivir			S	Unknown	Unk		Not Reported
	Vasopressin			S	Unknown	Unk		Not Reported
	Norepinephrine			S	Unknown	Unk		Not Reported
	Nitric Oxide			S		Unk		Not Reported
	Tenecteplase			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103103	DIRECT		DE			53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103107	DIRECT		DE			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103111	DIRECT	Y	OT			66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Tocilizumab			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103116	DIRECT	Y	OT			25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetylcysteine			C				Not Reported
	Ascorbic Acid Iv			C				Not Reported
	Azithromycin 500 Mg Iv			C				Not Reported
	Dexamethasone 6 Mg Iv			C				Not Reported
	Zinc Sulfate 200 Mg Po Bid			C				Not Reported
	Enoxaparin 1 Mg/Kg Subq Bid			C				Not Reported
	Docusate 100 Mg Po Bid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103144	DIRECT	Y				57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Remdesivir			S	Intravenous drip		5 DAY	Gilead

Aminotransferase Increased; Disease Complication	Acetaminophen 650mg Tab	C	Not Reported
	Albuterol-Ipratropium 2.5-0.5mg/3ml Nebulizer Soln	C	Not Reported
	Aspirin 81mg Chew Tab	C	Not Reported
	Azithromycin 500mg In Ns 250ml	C	Not Reported
	Dexamethasone 10mg In 50ml Ns	C	Not Reported
	Dexmedetomidine 500mcg In 100ml Ns	C	Not Reported
	Lovenox 100mg Syringe	C	Not Reported
	Lovenox 40mg Syringe	C	Not Reported
	Epoprostenol 1.5mg In 60ml Ns Inh Solution	C	Not Reported
	Famotidine 20mg Inj	C	Not Reported
	Furosemide 20mg Inj	C	Not Reported
	Ketamine 1000mg In 100ml Ns	C	Not Reported
	Oxycodone Ir 5mg Tab	C	Not Reported
	Lorazepam 2mg Tab	C	Not Reported
	Melatonin 3mg Tab	C	Not Reported
	Solu-Medrol 40mg	C	Not Reported
	Miconazole 2% With Zinc Oxide Cream	C	Not Reported
	Midazolam 2mg Inj	C	Not Reported
	Midodrine 10mg Tab	C	Not Reported
	Levophed In D5w	C	Not Reported
	Rocuronium 100mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103151	DIRECT	Y				56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Remdesivir			S	Intravenous drip			Gilead
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Liver Function Test Increased	Acetaminophen 160mg/5ml Soln			C				Not Reported
	Atropine 0.5mg Inj			C				Not Reported
	Azithromycin			C				Not Reported
	Bumetanide 10mg In 100ml D5l			C				Not Reported
	Ceftriaxone 1gram In 100ml Ns			C				Not Reported
	Clonazepam 2mg Tab			C				Not Reported
	Desmopressin 1mcg Inj			C				Not Reported

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Dopamine 400mg/250ml	C	Not Reported
Enoxaparin 40mg Syr	C	Not Reported
Enoxaparin 50mg Syr	C	Not Reported
Veleti 1.5mg In 60ml Ns Inh Soln	C	Not Reported
Famotidine 20mg Inj	C	Not Reported
Furosemide 40mg Inj	C	Not Reported
Unfractionated Heparin	C	Not Reported
Hydromorphone Inj	C	Not Reported
Ketamine 1000mg/100ml Ns	C	Not Reported
Solumedrol	C	Not Reported
Metolazone 10mg Tab	C	Not Reported
Midodrine 20mg Tab	C	Not Reported
Levophed 8mg/100ml	C	Not Reported
Phenylephrine 100mg/250ml In Ns	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103159	DIRECT	Y				63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Function Abnormal	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen 1000mg Tab			C				Not Reported
	Proventil Hfa			C				Not Reported
	Ceftriaxone 1g In 100ml Ns			C				Not Reported
	Azithromycin 500mg In Ns 250ml			C				Not Reported
	Lovenox 70mg Syr			C				Not Reported
	Furosemide 40mg Inj			C				Not Reported
	Gauifenesin-Dextromethorphan 100mg/10mg/5ml			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Humulin R			C				Not Reported
	Solumedrol			C				Not Reported
	Spiriva 18mcg Cap			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103165	DIRECT	Y	HO			31 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Viral; Transaminases Increased	Remdesivir Iv			S	Intravenous (not otherwise specified)			Not Reported	
	Enoxaparin 40mg Sq			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103169	DIRECT		DE			87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103174	DIRECT		DE			90 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103179	DIRECT	Y	OT			27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead	
	Acetaminophen			C		Not Reported			
	Aspirin-Acetaminophen-Caffeine			C		Not Reported			
	Prochlorperazine			C		Not Reported			
	Azithromycin			C		Not Reported			
	Ceftriaxone			C		Not Reported			
	Bupropion			C		Not Reported			
	Ketorolac			C		Not Reported			
	Lorazepam			C		Not Reported			
	Nystatin Swish And Swallow			C		Not Reported			
	Benzonatate			C		Not Reported			
Ondansetron			C	Not Reported					

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103184	DIRECT		OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Interrupted	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103189	DIRECT	Y	DE			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Refusal Of Treatment By Patient	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103201	DIRECT	Y				61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Swelling	Remdesivir			S	Intravenous drip			Gilead
	Aspirin 81mg Chew Tab			C				Not Reported
	Benzonatate Cap 100mg			C				Not Reported
	Lovenox 40mg Syr			C				Not Reported
	Gabapentin 100mg Cap			C				Not Reported
	Lantus			C				Not Reported
	Humalog			C				Not Reported
	Ondansetron 4mg Inj			C				Not Reported
	Miralax			C				Not Reported
	Senna 8.6mg Tab			C				Not Reported
	Trazodone 50mg Tab			C				Not Reported
	Vitamin C 500mg Tab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103206	DIRECT	Y				46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Condition Aggravated; Dizziness; Hypoaesthesia; Therapy Interrupted	Remdesivir Acetaminophen 1000mg Tab Proventil Hfa Cetirizine 10mg Tab Enoxaparin 40mg Syr Enoxaparin 60mg Syr Famotidine 20mg Tab Furosemide Inj Lorazepam 0.25mg Tab Melatonin 3mg Tab Ondansetron 4mg Inj Klor-Con 50mg Cr Tab Saline Nasal Spray	S C C C C C C C C C C C C	Intravenous drip	Other Frequency:X1;	Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103213	DIRECT	Y				73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Glomerular Filtration Rate Decreased	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103220	DIRECT		DE			81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2020	18103226	DIRECT	Y	OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	17950546	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475646		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19	Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Unk		Gilead
	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Unk		Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	17950557	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0475632		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19	Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Unk		Gilead
	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Unk		Gilead
	Ceftriaxone				C				Not Reported
	Doxycycline				C				Not Reported
	Insulin				C				Not Reported
	Fentanyl				C				Not Reported
	Methylprednisolone				C				Not Reported
	Norepinephrine				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	17951557	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473011		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Amiodarone				C		Unk		Not Reported

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Apixaban	C	Oral	5mg Q12h	Not Reported
Diltiazem	C		Unk	Not Reported
Metoprolol	C	Oral	12.5 Mg Q12h	Not Reported
Pantoprazole	C	Oral	40 Mg, Qd	Not Reported
Tocilizumab	C		400 Mg, Once	Not Reported
Heparin	C	Intravenous (not otherwise specified)	1150-1300 Units/Hr	Not Reported
Adenosine	C	Intravenous (not otherwise specified)	6 Mg	Not Reported
Tylenol	C			Not Reported
Albuterol Hfa	C	Respiratory (inhalation)	180 Mcg Q6h	Not Reported
Ipratropium	C	Respiratory (inhalation)	34 Mcg	Not Reported
Ondansetron	C		4 Mg, Once	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18021106	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482495		40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cisatracurium			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Insulin			C				Not Reported
	Ketamine			C				Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Budesonide			C				Not Reported
	Carboxymethylcellulose			C	Ophthalmic	Unk		Not Reported
	Ipratropium Bromide And Albuterol Sulfate			C				Not Reported

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Norepinephrine	C					Not Reported
Propofol	C	Intravenous (not otherwise specified)	Unk			Not Reported
Gabapentin	C	Oral	Unk			Not Reported
Aztreonam	C	Intravenous (not otherwise specified)	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18044852	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0484004		20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Maternal Exposure During Pregnancy	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir Oxygen			S C				Gilead Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18045042	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0484008		80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Dexamethasone			C		Unk		Not Reported
	Plasma			C				Not Reported
	Oxygen			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported
	Epinephrine			C				Not Reported
	Phenylephrine			C				Not Reported
	Amiodarone			C				Not Reported

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03-Aug-2020	18052169	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482484		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Pyrexia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Cisatracurium			C		Unk		Not Reported
	Dexmedetomidine			C				Not Reported
	Enoxaparin			C	Subcutaneous	40 Mg		Not Reported
	Fentanyl			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Propofol			C		Intravenous (not otherwise specified)	Titrate	Not Reported
	Carboxymethylcellulose			C		Ophthalmic	Unk	Not Reported
	Norepinephrine			C			Unk	Not Reported
	Insulin Aspart			C		Subcutaneous	Sliding	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18103451	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0487735		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Cardiac Arrest; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Tocilizumab			C				Not Reported
	Cefepime			C				Not Reported
	Dexamethasone			C				Not Reported
	Diphenhydramine			C				Not Reported
	Metronidazole			C				Not Reported
	Olanzapine			C				Not Reported

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Vancomycin	C	Not Reported
Sennoside A	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18103742	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0487467		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Kidney Injury; Blood Creatinine Increased; Shock	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C	Unknown	Unk		Not Reported
	Amiodarone			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Azithromycin			C	Unknown	Unk		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Furosemide			C	Unknown	Unk		Not Reported
	Heparin			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Vasopressin			C	Unknown	Unk		Not Reported
	Potassium Chloride			C	Unknown	Unk		Not Reported
	Epinephrine			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18103755	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0487454			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Preparation Issue	Remdesivir			S	Unknown	Unk		Gilead	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104148	DIRECT	Y	DE			77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir Dexamethasone			S C	Intravenous bolus			Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104149	DIRECT	Y	DE			72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir Remdesivir			S C				Gilead Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104150	DIRECT	Y	LT			79 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Platelet Count Decreased	Remdesivir Dexamethasone Azithromycin 500 Mg Daily Lovenox 40 Mg Daily Gabpentin 300 Mg Tid			S C C C C	Intravenous drip			Gilead Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104151	DIRECT	Y	DE			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Remdesivir			S				Gilead	

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Remdesivir			C			Not Reported			
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03-Aug-2020	18104152	DIRECT	Y	HO			88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Chest Pain; Hepatomegaly; Liver Function Test Increased	Remdesivir			S	Intravenous drip			Gilead	
	Azithromycin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Doxycycline			C				Not Reported	
	Ascorbic Acid Iv			C				Not Reported	
	Acetaminophen Prn			C				Not Reported	
	Albuterol			C				Not Reported	
	Belladonna/Opium Suppository			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Montelukast			C				Not Reported	
	Piperacillin/Tazobactam			C				Not Reported	
	Prednisone			C				Not Reported	
	Dexamethasone			C				Not Reported	
	Diltiazem			C				Not Reported	
	Thiamine Iv			C				Not Reported	
	Zinc Sulfate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104153	DIRECT	Y	OT			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remdesivir			S	Intravenous drip			Gilead	
	Dexamethasone 6mg			C				Not Reported	
	Pantoprazole 40mg			C				Not Reported	
	Thiamine 100mg			C				Not Reported	
	Vancomycin 1500mg			C				Not Reported	
	Fentanyl			C				Not Reported	
	Heparin			C				Not Reported	
	Ketamine			C				Not Reported	
	Midazolam			C				Not Reported	
	Norepinephrine			C				Not Reported	
	Piperacillin/Tazobactam			C				Not Reported	

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03-Aug-2020	18104154	DIRECT	Y				32 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Ofirmev			C				Not Reported
	Pantoprazole			C				Not Reported
	Lantus			C				Not Reported
	Fish Oil			C				Not Reported
	Fenofibrate			C				Not Reported
	Humalog			C				Not Reported
	Primaxin			C				Not Reported
	Vancomycin			C				Not Reported
	Meropenem			C				Not Reported
	Doxycycline			C				Not Reported
	Benzonatate			C				Not Reported
	Tramadol			C				Not Reported
	Dexamethasone Iv			C				Not Reported
Iopamidol 76% Injection			C				Not Reported	
Lovenox			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104155	DIRECT	Y	DE			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S				Not Reported
	Remdesivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104156	DIRECT	Y	OT			76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Remdesivir Injection			S	Intravenous (not otherwise specified)			Not Reported
	Dexamethasone			C				Not Reported

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Cefepime	C	Not Reported
Vancomycin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104162	DIRECT	Y	HO			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Urea Abnormal; Glomerular Filtration Rate Abnormal	Remdesivir Remdesivir			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104269	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0488298		56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C				Not Reported
	Albumin			C				Not Reported
	Cisatracurium			C				Not Reported
	Epoprostenol			C				Not Reported
	Fentanyl			C				Not Reported
	Insulin Nph [Insulin Isophane Bovine]			C				Not Reported
	Lactobacillus			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Pantoprazole			C				Not Reported
	Phenylephrine			C				Not Reported
	Piperacillin / Tazobactam			C				Not Reported
	Propofol			C				Not Reported
	Sodium Polystyrene Sulfonate			C				Not Reported
	Tocilizumab			C				Not Reported
	Vasopressin			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104356	DIRECT	Y	HO			38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir				S	Intravenous drip			Gilead
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104603	DIRECT	Y	OT			79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
	Dexamethasone				C				Not Reported
	Aspirin				C				Not Reported
	Heparin				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18104604	DIRECT	Y				70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Remdesivir				S	Intravenous (not otherwise specified)			Gilead
	Vancomycin				C				Not Reported
	Phenylephrine				C				Not Reported
	Clopidogrel				C				Not Reported
	Dexamethasone				C				Not Reported
	Famotidine				C				Not Reported
	Albuerol				C				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18106190	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0486993		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Liver Function Test Increased	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once	Gilead
	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
	Albuterol [Salbutamol Sulfate]	C	Respiratory (inhalation)	Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Budesonide	C	Respiratory (inhalation)	Unk	Not Reported
	Fluticasone	C	Nasal	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Guaifenesin	C	Unknown	Unk	Not Reported
	Hydralazine	C	Unknown	Unk	Not Reported
	Lorazepam	C	Unknown	Unk	Not Reported
	Losartan	C	Unknown	Unk	Not Reported
	Melatonin	C	Unknown	Unk	Not Reported
	Zinc Sulfate	C	Unknown	Unk	Not Reported
	Ivermectin	C	Unknown	Unk	Not Reported
	Thiamine	C	Unknown	Unk	Not Reported
	Vancomycin	C	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Ascorbic Acid	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Azithromycin	C	Unknown	Unk	Not Reported
Cefepime	C	Unknown	Unk	Not Reported	
Famotidine	C	Unknown	Unk	Not Reported	
Heparin	C	Unknown	Unk	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18107384	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0488611		67 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Haemorrhage	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Doxycycline			C	Intravenous (not otherwise specified)			Not Reported
	Zosyn			C				Not Reported
	Iviglob-Ex			C		Unk		Not Reported
	Plasma			C		Unk		Not Reported
	Argatroban			C		Unk		Not Reported
	Argatroban			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18107532	EXPEDITED (15-DAY)		OT	US-GILEAD-2020- 0487812		79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Albuterol Hfa			C				Not Reported
	Apixaban			C				Not Reported
	Ascorbic			C				Not Reported
	Atorvastatin			C				Not Reported
	Budesonide			C				Not Reported
	Cholecalciferol			C				Not Reported
	Dexamethasone			C				Not Reported
	Levofloxacin			C				Not Reported
	Levothyroxine			C				Not Reported
	Memantine			C				Not Reported
	Metoprolol			C				Not Reported
	Pantoprazole			C				Not Reported
	Zinc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18107815	EXPEDITED (15-DAY)		DE, OT	US-SA-2020SA199688			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19; Disseminated Intravascular Coagulation; Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic Shock; Shock Haemorrhagic	Lovenox			S	Subcutaneous	40 Mg, Qd		Sanofi
	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Nph Insulin			C		Unk		Not Reported
	Insulin Human;Insulin Human Injection, Isophane			C		Unk		Not Reported
	Sodium Chloride			C		Unk		Not Reported
	Sitagliptin			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
Pantoprazole			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2020	17941111	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0473733		39 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Respiratory Failure	Remdesivir			S	Unknown	100 Mg, Qd		Gilead
	Aspirin [Acetylsalicylic Acid]			C	Oral	81 Mg, Qd		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Chlorhexidine			C	Oral	Unk		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	6 Mg, Qd		Not Reported
	Famotidine			C	Oral	20 Mg, Bid		Not Reported
	Furosemide			C	Intravenous (not otherwise specified)	20 Mg, Q8h		Not Reported
	Metoclopramide			C	Intravenous (not otherwise specified)	5 Mg, Q8h		Not Reported

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Mvi [Vitamins Nos]	C	otherwise specified)	Unk	Not Reported
Senna-S [Docusate Sodium;Sennoside A+B]	C	Oral	Unk, Bid	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	Unk	Not Reported
Artificial Tears [Hypromellose]	C		Unk	Not Reported
Dexmedetomidine	C	Intravenous (not otherwise specified)		Not Reported
Fentanyl	C	Intravenous (not otherwise specified)		Not Reported
Heparin	C	Intravenous (not otherwise specified)		Not Reported
Insulin	C	Intravenous (not otherwise specified)		Not Reported
Midazolam	C	Intravenous (not otherwise specified)		Not Reported
Oxygen	C			Not Reported
Cotrimoxazole	C		7 Doses	Not Reported
Tocilizumab	C			Not Reported
Plasma	C			Not Reported
Ativan	C			Not Reported
Precedex	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2020	17975539	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0477764		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remdesivir			S	Unknown	Unk		Gilead

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2020	18026839	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0482905		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Acute Kidney Injury; Acute Respiratory Failure;	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
Cardiac Arrest; Congestive	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
Cardiomyopathy; Covid-19; Ischaemic Hepatitis;	Fentanyl	C			Not Reported
Metabolic Acidosis;	Norepinephrine	C			Not Reported
Multiple Organ Dysfunction Syndrome;	Propofol	C			Not Reported
Renal Failure; Sepsis;	Vasopressin	C			Not Reported
Septic Shock	Albuterol Hfa	C			Not Reported
	Ascorbic	C			Not Reported
	Vitamin D3	C			Not Reported
	Doxycycline	C			Not Reported
	Enoxaparin	C			Not Reported
	Famotidine	C			Not Reported
	Novolog Mix	C			Not Reported
	Levemir	C			Not Reported
	Nitroglycerin Recip	C			Not Reported
	Zinc Sulfate	C			Not Reported
	Ceftriaxone	C			Not Reported
	Lovenox Hp	C			Not Reported
	Ivermectin	C			Not Reported
	Dexamethasone	C			Not Reported
	Vitamin C + Zinc	C			Not Reported
	Plasma	C		Unk	Not Reported