U.S. FOOD & DRUG ADMINISTRATION

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	REMDESIVIR			
Active Moiety:				
FDA Received Date:	From:	01-Feb-2020	To:	02-Jun-2020
MedDRA® Version* :	23.0			
Total Cases**:	446			
Number of Pages:	183			

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.

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

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).

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.

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-May-2020	17731692	NON-EXPEDITED		OT	US-SA-2020SA110743			Male	USA

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770498	DIRECT	Y	DE			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulseless Electrical Activity; Ventricular Fibrillation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770540	DIRECT	Y	OT			48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17770559	DIRECT	Y				79 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17770551	DIRECT	Y	OT			72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Acetaminophen			C				Not Reported
	Allopurinol			C				Not Reported
	Aspirin			C				Not Reported
	Digoxin			C				Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2020	17774804	DIRECT	Y	HO			61 YR	Male	USA

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

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

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

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

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

	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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17775263	DIRECT	Y					Unknown	USA

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17781018	DIRECT	Y	DE			69 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-May-2020	17781025	DIRECT	Y				41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Chest X-Ray Abnormal; Clinical Trial Participant; Oxygen Consumption Increased; Product Use In Unapproved Indication; White Blood Cell Count Increased	Remdesivir			S				Not Reported
	Fentanyl			C				Not Reported
	Hydralazine			C				Not Reported
	Piperacillin-Tazobactam			C				Not Reported
	Pantoprazole			C				Not Reported
	Enoxaparin			C				Not Reported
	Propofol			C				Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17790340	DIRECT	Y	OT			66 YR	Female	USA

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

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

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

Vecuronium	C	Not Reported

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

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

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

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

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

	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		Not Reported
	Tracrium	C	Unk	Not Reported
	Tracrium	C	Unk	Not Reported

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

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

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

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

			(Loading Dose);
	Apap 500 Mg Po Q6hr Prn Pain/Fever	C	Not Reported
	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 Anxiety	C	Not Reported
	Ondansetron 4 Mg Iv Push Q6hr Prn N/V	C	Not Reported
	Vancomycin 1.5 G Ivpb Q12hr	C	Not Reported
	Zinc Sulfate 220 Mg Po Daily	C	Not Reported

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17793631	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0466952		65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Pulseless Electrical Activity	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794224	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0467265		74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Cardio-Respiratory Arrest; Covid-19 Pneumonia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797263	DIRECT	Y	OT			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Poor Quality Product Administered; Product Storage Error	Remdesivir	Y		S	Intravenous (not otherwise specified)		6 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17797264	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	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
	Methylprednislone			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
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Gilead
	Convalescent Plasma For Covid-19			C				Not Reported
	Tocilizumab Or Placebo/Covacta Study			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797268	DIRECT	Y	OT			72 YR	Female	USA

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Hydroxychloroquine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17797292	DIRECT	Y	OT			70 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17798027	DIRECT	Y	RI			70 YR	Male	USA

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

Alanine Aminotransferase Increased	Remdesivir (Gs-5734)	Y		S	Intravenous (not otherwise specified)	Gilead
	Remdesivir (Gs-5734)	Y		S	Intravenous (not otherwise specified)	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-May-2020	17798044	DIRECT	Y	HO			60 DAY	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Coagulopathy; Organ Failure; Transaminases Increased	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17800831	EXPEDITED (15-DAY)		DE	US-GILEAD-2020-0467444		69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; General Physical Health Deterioration; Oxygen Saturation Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)		3 DAY	Gilead
	Cefepime 2g Iv Q12h			C				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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801746	DIRECT	Y	OT			84 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Hypotension; Respiratory Failure; Tachypnoea; Urine Output Decreased; White Blood Cell Disorder	Remdesivir			S				Gilead
	Vancomycin			C				Not Reported
	Furosemide			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801755	DIRECT	Y	OT			77 YR	Male	USA

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

Clinical Trial Participant; Liver Function Test Increased; Product Use In Unapproved Indication; Renal Replacement Therapy	Remdesivir		S	Intravenous drip	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801760	DIRECT	Y				53 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Differential White Blood Cell Count Abnormal; Leukopenia; Lymphocyte Percentage Increased; Neutrophil Percentage Decreased; Product Use In Unapproved Indication	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Ascorbic Acid 1500mg Po Bid			C				Not Reported
	Cholecalciferol 50mcg Po Q24h			C				Not Reported
	Zinc Capsule 50mg Po Q24h			C				Not Reported
	Magnesium Oxide 420mg Po Bid			C				Not Reported
	Insulin Glargine 12 Units Sc Qhs			C				Not Reported
	Insulin Aspart Sliding Scale Tid Ac			C				Not Reported
	Senna 17.2mg Po Daily			C				Not Reported
	Enoxaparin 30mg Sc Q12h			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17801796	DIRECT	Y	OT			70 YR	Male	USA

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Azotaemia; Continuous Haemodiafiltration; Glomerular Filtration Rate Decreased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Enoxaparin			C				Not Reported
	Famotidine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17802626	DIRECT	Y	DE			76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Covid-19; Dyspnoea; General Physical Health Deterioration; Hypotension; Liver Function Test Abnormal; Multiple Organ	Convalescent Plasma			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Not Reported
	Remdesivir			S				Not Reported
	Dapsone			C				Not Reported
	Linezolid			C				Not Reported
	Vancomycin			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported

Dysfunction Syndrome; Oxygen Saturation Decreased; Pneumonia Staphylococcal; Pyrexia; Renal Function Test Abnormal; Sars-Cov-2 Test Positive

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Continuous Haemodiafiltration; Inadequate Haemodialysis; Renal Impairment	Remdesivir			S	Intravenous drip		2 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17802638	DIRECT	Y	DE			60 YR	Female	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Renal Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Hydroxychloroquine Or Matching Placebo (Orchid Trial)			C				Not Reported
	Convalescent Plasma			C				Not Reported

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805184	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0466961		48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hepatic Function Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806590	DIRECT	Y	OT			59 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806639	DIRECT	Y	LT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
General Physical Health Deterioration; Haemodynamic Instability; Pneumothorax; Pulmonary Embolism; Sepsis; Shock	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17806644	DIRECT	Y	OT			45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Bisacodyl Suppository			C				Not Reported
	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/Ml Infusion			C				Not Reported

	Vancomycin			C						Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Furisemide 40mg			C				Not Reported
	Heparin			C				Not Reported

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Cardiac Arrest; Hypernatraemia; Metabolic Acidosis; Paralysis; Respiratory Acidosis; Respiratory Failure	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Dexmedetomide 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 Q12h			C				Not Reported
	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 1l At 150 Ml/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

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

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

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

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

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

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

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

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

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

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

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir		S	Intravenous (not otherwise specified)	Gilead

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17807091	DIRECT	Y	DE			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir (Euc) (Remdesivir (Eau))			S				Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807338	DIRECT	Y				8 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Product Formulation Administered; Product Use Issue	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807340	DIRECT					62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypoxia; Pneumomediastinum	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807341	DIRECT	Y	OT			54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir	Y		S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17807897	DIRECT	Y	OT			59 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810056	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2020-0467380		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatinine Increased; Oliguria	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 5 Mg/Ml Qd		Gilead
	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		Unk		Not Reported
	Epoprostenol			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Aspirin (E.C.)			C		Unk		Not Reported

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810957	DIRECT	Y	OT			74 YR	Female	USA

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

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

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17810988	DIRECT	Y				60 YR	Male	USA

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811012	DIRECT	Y	OT			35 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811020	DIRECT	Y	DE			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous bolus			Gilead
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Cefazolin			C				Not Reported
	Cisatricurium			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 Ii			C				Not Reported
	Hydromorphone			C				Not Reported
	Fentanyl			C				Not Reported
	Midazolam			C				Not Reported
	Norepinephrine			C				Not Reported
	Vasopressin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811029	DIRECT	Y	OT			72 YR	Female	USA

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

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

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

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

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

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

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

Therapy Cessation

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Zestorectic			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811063	DIRECT	Y				49 YR	Male	USA

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Haemofiltration; Liver Function Test Increased; Renal Impairment; Right Ventricular Dysfunction	Remdesivir Via Emergency Use Authorization			S	Intravenous drip			Not Reported
	Covid-19 Convalescent Plasma			C				Not Reported
	Tocilizumab 400 Mg Iv In 100 Ml Nacl			C				Not Reported
	Tocilizumab 400 Mg Iv In 100 Ml Nacl			C				Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811139	DIRECT	Y	HO, LT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Oxygen Saturation Decreased; Respiratory Distress	Remdesivir			S				Gilead
	Albuterol			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Aspirin Ec			C				Not Reported
	Doxycycline			C				Not Reported
	Atorvastatin			C				Not Reported
	Pyridostigmine			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Ceftriaxone			C				Not Reported
	Acetaminophen			C				Not Reported
	Zinc			C				Not Reported
	Ondansetron			C				Not Reported
	Diphenhydramine			C				Not Reported
	Amiodarone			C				Not Reported

	Famotidine			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811147	DIRECT	Y	DS, HO, LT			60 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Carotid Artery Occlusion; Ischaemic Stroke	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Acetaminophen			C				Not Reported
	Aspirin			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Furosemide			C				Not Reported
	Hydroxychloroquine Or Placebo			C				Not Reported
	Magnesium Sulfate			C				Not Reported
	Potassium Bicarbonate			C				Not Reported
	Enoxaparin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17811158	DIRECT	Y	DE			60 YR	Male	ALB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia; Oxygen Saturation Decreased	Remdesivir			S		Other Frequency:Loading Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17812033	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Rash; Tachycardia	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812217	DIRECT	Y	DE			71 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Failure; Hypertension; Hypotension; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812224	DIRECT	Y	DE			41 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Lung Disorder; Pulmonary Embolism; Sudden Death	Remdesivir			S	Intravenous bolus			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812243	DIRECT	Y	DE			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Sarilumab			C				Not Reported
	Apixaban			C				Not Reported
	Furosemide			C				Not Reported
	Polyetheylene 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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Finasteride			C				Not Reported
	Terazosin			C				Not Reported
	Pantoprazole			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Vancomcyin			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Supraventricular Tachycardia	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812599	DIRECT	Y				39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysphagia; Throat Irritation	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17813534	EXPEDITED (15-DAY)			US-GILEAD-2020-0467788		11 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Malfunction; Medication Error	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17815405	DIRECT	Y	OT			53 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17815427	DIRECT	Y				69 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Benztropine			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			C				Not Reported

Room: Zosyn)

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Deep Vein Thrombosis; Intentional Product Use Issue; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Unknown			Not Reported
	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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acute Kidney Injury; Blood Lactic Acid Increased; Cardio-Respiratory Arrest; Haemoglobin Decreased; Hypotension; White Blood Cell Count Increased	Remdesivir			S	Intravenous bolus			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17815906	DIRECT		DE, HO			69 YR	Female	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Heparin			C				Not Reported
	Hydrocortisone			C				Not Reported
	Norepinephrine			C				Not Reported
	Vancomycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816200	DIRECT	Y	DE			66 YR	Female	USA

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Cefepime			C				Not Reported
	Doxycycline			C				Not Reported
	Enoxaparin 40 Mg Bid			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19 Pneumonia;	Remdesivir			S				Not Reported

Disease Progression

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816208	DIRECT		HO			62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816211	DIRECT	Y				78 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Agitation; Anxiety; Hallucination, Visual; Intensive Care Unit Delirium	Remdesivir			S	Intravenous drip	Other Frequency:Once;		Gilead
	Lorazepam Iv 0.25 Mg			C				Not Reported
	Gabapentin 100 Mg			C				Not Reported
	Requip 1 Mg			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816477	DIRECT	Y	OT			75 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816490	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Transaminases Increased	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Desc;		Gilead

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Sars-Cov-2 Test Positive	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816556	DIRECT	Y	HO, OT			84 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816562	DIRECT	Y	OT			53 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17816575	DIRECT	Y	HO			43 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aspartate Aminotransferase Increased; Blood Creatinine Increased; Renal Impairment; Septic Shock	Remdesivir	Y		S	Intravenous drip			Gilead
	Furosemide 40 Mg Iv			C				Not Reported
	Norepinephrine			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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) Sliding Scale			C				Not Reported
	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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818496	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468321		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 A	C	Unk		Not Reported
	Levophed	C	Unk		Not Reported
	Dopamine	C	Unk		Not Reported
	Epinephrine Hydrochloride	C	Unk		Not Reported
	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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818529	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0468184		77 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818539	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468282		53 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818552	EXPEDITED (15-DAY)		DE, LT, OT	US-GILEAD-2020-0468312		72 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818827	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0468514		52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg		Gilead
	Convalescent Plasma			C				Not Reported
	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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818858	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0468531		34 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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				Not Reported
	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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17818878	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-GILEAD-2020-0468569		60 YR	Male	USA

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

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

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

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

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

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

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

Product Preparation Error	Remdesivir Injection	Y		S	Intravenous (not otherwise specified)					Gilead

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17822997	DIRECT	Y	OT			74 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17823220	DIRECT	Y	RI			60 YR	Male	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Hypoaesthesia; Pruritus	Remdesivir Eua	Y		S	Intravenous drip			Gilead
	Ceftriaxone (Rocephin) 1,000			C				Not Reported

Mg In 0.9 % Sodium Chloride (Ns) 50 Ml Ad			
Enoxaparin (Lovenox) (Conc: 40 Mg/ 0.4 Ml) Injection 40 Mg	C		Not Reported
Benzonatate (Tessalon Perles) Capsule 100 Mg	C		Not Reported
Dextromethorphan-Guaifenesin (Conc: 10-100 Mg/5 Ml) (Robitussin Dm) Sy	C		Not Reported
Ondansetron (Zofran) (Conc: 2 Mg/Ml) 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 (Ns) 50 Ml I	C		Not Reported
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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823000	DIRECT	Y	OT			85 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pain	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823003	DIRECT	Y	DE			74 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823009	DIRECT	Y	OT			39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise; Renal Impairment	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atracurium			C				Not Reported
	Midazolam			C				Not Reported
	Furosemide			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased	Remdesivir Injection			S	Intravenous drip			Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823020	DIRECT	Y	LT			64 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Hyperkalaemia	Remdesivir	Y		S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823021	DIRECT	Y	DE, DS			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Renal Failure	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Tocilizumab			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823024	DIRECT	Y				64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir (5 Mg/Ml Injection Concentrate)			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Ascorbic Acid 500 Mg Tab			C				Not Reported
	Azithromycin 500 Mg Ivpb			C				Not Reported
	Benzonatate 100 Mg Cap			C				Not Reported
	Ceftriaxone 1 Gm Ivpb			C				Not Reported
	Enoxaparin Inj			C				Not Reported
	Methylprednisolone 40 Mg Iv			C				Not Reported
	Zinc Sulfate 220 Mg Cap			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-May-2020	17823028	DIRECT	Y	OT			42 YR	Female	USA

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

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

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

	Fentanyl	C		Not Reported
	Versed	C		Not Reported
	Ketamine	C		Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Blood Creatine Increased; Dialysis; Gastrointestinal Haemorrhage; Glomerular Filtration Rate Decreased; Hepatic Failure; Hypovolaemic Shock; Liver Function Test Increased; Shock Haemorrhagic	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Aspirin			C				Not Reported
	Diltiazem			C				Not Reported
	Insulin Lispro			C				Not Reported
	Methylprednisolone			C				Not Reported
	Protonix			C				Not Reported
	Atarax			C				Not Reported
	Lovenox			C				Not Reported
	Ativan			C				Not Reported
	Ketamine			C				Not Reported
	Versed			C				Not Reported
	Ativan			C				Not Reported
	Fentanyl			C				Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Remdesivir			S				Gilead

Increased

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S				Not Reported
	Zosyn			C				Not Reported
	Doxycyline			C				Not Reported
	Ceftriaxone			C				Not Reported

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypopnoea; Infusion Related Reaction; Rash; Rash Pruritic; Respiratory Distress; Wheezing	Remdesivir			S				Not Reported
	Allopurinol 100 Mg Tablet			C				Not Reported
	Carvedilol 12.5 Mg Tablet			C				Not Reported
	Enoxaparin 40 Mg Subcutaneous			C				Not Reported
	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 Tablet			C				Not Reported
	Tamoxifen 20 Mg Tablets			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S				Not Reported
	Albuterol Inhaler			C				Not Reported
	Amlodipine 5 Mg Tablet			C				Not Reported
	Benzonatate 200mg Capsules			C				Not Reported
	Docusate 100 Mg Capsule			C				Not Reported
	Senna Tablets			C				Not Reported
	Enoxaparin 40 Mg Subcutaneous			C				Not Reported
	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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17792758	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2020191603		61 YR	Female	CHE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
Heparine [Heparin Sodium]	C	Unknown	Unk	Not Reported
Lexotanil	C	Unknown	Unk	Not Reported
Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C	Unknown	Unk	Not Reported
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
	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

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

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

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

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

Condition Aggravated; Diarrhoea; Dyspnoea	Remdesivir	Y	S	Intravenous (not otherwise specified)		Gilead

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

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

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Protonix			C				Not Reported
	Tiotropium			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Burning Sensation; Clinical Trial Participant; Condition Aggravated; Covid-19 Pneumonia; Product Use In Unapproved Indication; Respiratory Disorder	Remdesivir			S				Gilead

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Inflammatory Marker Increased;	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen Tab			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Benzonatate			C				Not Reported

Therapy Cessation	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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	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; Dose Calculation Error; Glomerular Filtration Rate Decreased; Incorrect Dose Administered By Product; Sepsis	Remdesivir			S	Intravenous drip			Gilead
	Ascorbic Acid Po			C				Not Reported
	Azithromycin Iv			C				Not Reported
	Ceftriaxone Iv			C				Not Reported
	Cholecalciferol			C				Not Reported
	Cimetidine Po			C				Not Reported
	Furosemide Ivp And Gtt			C				Not Reported
	Zinc Gluconate Po			C				Not Reported
	Cisatricurium			C				Not Reported
	Epoprostenol Inhaled			C				Not Reported
	Fentanyl Infusion Vent Sedation			C				Not Reported
	Propofol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824960	DIRECT	Y	HO			46 YR	Male	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Blood Urea	Remdesivir	Y		S	Intravenous (not otherwise specified)		5 DAY	Gilead

Increased; Dialysis	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
	Vitamin D 2000 Units	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824970	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 Iiv 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			C				Not Reported

Continuous Iv

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824973	DIRECT	Y	OT			41 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Chromaturia; Fatigue; Therapy Cessation	Remdesivir	Y		S				Not Reported
	Azithromycin			C				Not Reported
	Cefepime			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17824977	DIRECT	Y				55 YR	Male	USA

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

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

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

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

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

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

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

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

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

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

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

Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Remdesivir	Y	S	Intravenous bolus	Gilead
	Bisacodyl		C		Not Reported
	Lansoprazole		C		Not Reported
	Metoclopramide		C		Not Reported
	Polyethylene Glycol		C		Not Reported
	Sennosides-Docusate		C		Not Reported

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826572	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0467950		70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Ethacrynic Acid			C				Not Reported
	Metoprolol			C		Unk		Not Reported

	Tradipitant	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826584	EXPEDITED (15-DAY)			US-GILEAD-2020-0467774			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Storage Error	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17827902	DIRECT	Y	DS, HO, LT			67 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crystal Nephropathy; Hydronephrosis; Renal Tubular Necrosis; Respiratory Disorder; Urine Analysis Abnormal	Remdesivir			S	Intravenous drip			Gilead
	Acetominophen			C				Not Reported
	Duonebs			C				Not Reported
	Amiodarone 150mg Iv Bolus Once			C				Not Reported
	Azithromycin 500mg Iv Once			C				Not Reported
	Cefepime 2gm Iv			C				Not Reported
	Potassium Chloride 20meq Iv			C				Not Reported
	Tocilizumab 400mg Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17827908	DIRECT	Y	OT			59 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Condition Aggravated; Enteritis	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Atorvastatin			C				Not Reported
	Lovenox			C				Not Reported
	Imodium			C				Not Reported
	Losartan			C				Not Reported
	Pantoprazole			C				Not Reported
	Phosphorus			C				Not Reported
	Toradol			C				Not Reported

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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)			Gilead
	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
	Linozolid			C				Not Reported
	Meropenem			C				Not Reported
	Methylprednisolone			C				Not Reported
	Pantoprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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
Distraneurin /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

	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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17831684	EXPEDITED (15-DAY)		DE, HO, OT	US-GILEAD-2020-0468502		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Alanine	Remdesivir			S	Unknown	200 Mg		Gilead

Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased; Pneumonia Viral; Renal Failure

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833398	DIRECT	Y				41 YR	Male	USA

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Acute Respiratory Failure; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Creatinine Increased; Hypoxia; Shock; Viral Cardiomyopathy	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Amiodarone Infusion			C				Not Reported
	Ceftriaxone			C				Not Reported
	Dobutamine Infusion			C				Not Reported
	Doxycycline Iv			C				Not Reported
	Enoxaparin 40mg Q12			C				Not Reported
	Famotidine 20mg Iv Q12			C				Not Reported
	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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833420	DIRECT	Y	DE			64 YR	Male	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
27-May-2020	17833421	DIRECT	Y	OT			24 YR	Female	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Dexmedetomindine Additive			C				Not Reported
	Epinephrine			C				Not Reported
	Fentalnyl			C				Not Reported

	Vancomycin			C						Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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.			C				Not Reported

	Solution		
	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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833468	DIRECT	Y	OT			71 YR	Female	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased	Remdesivir			S	Intravenous (not			Gilead

		otherwise specified)	
	Tocilizumab	C	Not Reported
	Aztreonam	C	Not Reported
	Levaquin	C	Not Reported
	Pravastatin	C	Not Reported
	Sirolimus	C	Not Reported
	Prednisone	C	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pulmonary Embolism	Remdesivir			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833483	DIRECT	Y	DE			61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead
	Covid-19 Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833489	DIRECT	Y	DE			83 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Hepatic Failure; Diarrhoea; Malaise; Pyrexia	Remdesivir			S	Intravenous bolus			Gilead
	Acetaminophen			C				Not Reported
	Apixaban			C				Not Reported
	Ceftriaxone			C				Not Reported
	Chlorhexidine Oral Solution			C				Not Reported
	Enoxaparin			C				Not Reported
	Furosemide			C				Not Reported
	Gabapentin			C				Not Reported
	Insulin (Lispro, Regular)			C				Not Reported

	Lactated Ringers	C	Not Reported
	Latanoprost Drops	C	Not Reported
	Magnesium Sulfate	C	Not Reported
	Metoprolol Tartrate	C	Not Reported
	Metronidazole	C	Not Reported
	Modafinil	C	Not Reported
	Mometasone/Formoterol	C	Not Reported
	Montelukast	C	Not Reported
	Morphine	C	Not Reported
	Potassium Chloride	C	Not Reported
	Sertraline	C	Not Reported
	Sodium Chloride 0.9% Infusion	C	Not Reported
	Vancomycin	C	Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833505	DIRECT	Y	OT			56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Distension; General Physical Health Deterioration; Haemoglobin Decreased; Intestinal Dilatation; Intestinal Ischaemia; Lactic Acidosis; Neutrophil Count Decreased; Platelet Count Decreased; Septic Shock; Supraventricular Tachycardia; Tissue Infiltration	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Amiodarone			C				Not Reported
	Albumin			C				Not Reported
	Cyanocobalamin			C				Not Reported
	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
	Epineprhrine 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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833533	DIRECT	Y				64 YR	Male	USA

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Benztropine			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, Zinc Sulfate, & Zosyn	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833630	DIRECT	Y				66 YR	Male	USA

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Pulseless Electrical	Remdesivir			S	Intravenous (not otherwise specified)		1 DAY	Gilead

Activity; Transaminases Increased	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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833647	DIRECT	Y				42 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833652	DIRECT	Y	HO, OT			80 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Torsemide			C				Not Reported
	Cardizem			C				Not Reported
	Lipitor			C				Not Reported
	Protonix			C				Not Reported
	Metoprolol Xl			C				Not Reported

	Prednisone			C					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833668	DIRECT	Y				40 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833677	DIRECT	Y	DE			77 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Dyspnoea; Hypoxia; Lethargy; Respiratory Disorder	Remdesivir			S				Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833720	DIRECT	Y				57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Extravasation	Remdesivir	Y		S	Intravenous drip	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833738	DIRECT	Y				1 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Product Formulation Administered; Product Dispensing Error; Product Use Issue; Therapy Interrupted	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833753	DIRECT		DE			80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir			S				Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17833766	DIRECT		OT			62 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17839011	DIRECT	Y					Unknown	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17812574	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2020198894			Male	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Multiple Organ Dysfunction Syndrome	Spironolactone			S	Oral	50 Mg, Bid (100mg Per Day)		Pfizer
	Furosemide			S	Intravenous (not otherwise specified)	40 Mg, Bid (80 Mg Per Day)		Not Reported
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
	Atorvastatin			C		Unk		Not Reported

Ipratropium	C			Not Reported
Azithromycin	C		Unk	Not Reported
Co-Amoxiclav [Amoxicillin;Clavulanate Potassium]	C		Unk	Not Reported
Lansoprazole	C		Unk	Not Reported
Paracetamol	C		Unk	Not Reported
Midazolam	C		Unk	Not Reported
Metoclopramide	C		Unk	Not Reported
Morphine	C		Unk	Not Reported
Salbutamol	C		Unk	Not Reported
Noradrenaline [Norepinephrine]	C		Unk	Not Reported
Rocuronium	C		Unk	Not Reported
Piperacilin/Tazobactam	C		Unk	Not Reported
Erythromycin	C		Unk	Not Reported
Heparin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17833859	DIRECT	Y	OT			78 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disturbance In Attention; Lethargy; Oxygen Saturation Decreased; Palpitations; Tremor; Ventricular Tachycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once (Loading Dose;		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834192	DIRECT	Y	OT			92 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury;	Remdesivir			S				Gilead
Alanine Aminotransferase	Remdesivir			C				Not Reported

Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Rate Decreased

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Allopurinal			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Lorazepam			C				Not Reported
	Furosemide			C				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Therapy Interrupted	Remdesivir	Y		S	Intravenous bolus			Gilead
	Atorvastatin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834597	DIRECT	Y	DE			38 YR	Female	USA

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

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

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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834646	DIRECT	Y	OT			70 YR	Male	USA

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834887	DIRECT	Y	DE			66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Palliative Care; Product Use In Unapproved Indication; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834892	DIRECT	Y	OT			56 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clinical Trial Participant; Dysphagia; Headache; Product Use In Unapproved Indication	Remdesivir			S				Not Reported
	Convalescent Plasma			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834894	DIRECT	Y	OT			74 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication	Remdesivir			S				Not Reported
	Amlodipine			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834895	DIRECT	Y	OT			73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatic Enzyme Increased; Therapy Cessation	Remdesivir			S	Intravenous drip			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834911	DIRECT	Y				54 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous bolus			Gilead
	Valproic Acid			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834946	DIRECT	Y	OT			65 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 Ml			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
	Tocilzumab	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834965	DIRECT	Y	OT			49 YR	Male	USA

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Therapy Interrupted	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	17834979	DIRECT	Y				84 YR	Female	USA

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835865	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468246		70 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Aspartate Aminotransferase Abnormal	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Atorvastatin			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835872	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468272		46 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Levetiracetam			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835873	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468468		75 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Acetaminophen			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported
	Apixaban			C		Unk		Not Reported
	Doxazosin			C		Unk		Not Reported
	Hydralazine			C		Unk		Not Reported
	Lorazepam			C		Unk		Not Reported
	Combivent Respimat			C		Unk		Not Reported
	Ascorbic Acid			C		Unk		Not Reported
	Cholecalciferol			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Zinc Sulfate			C		Unk		Not Reported
	Tylenol			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835874	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468237		23 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835876	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468482		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Abnormal; Blood Alkaline Phosphatase Increased; Hypotension	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Atorvastatin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Desvenlafaxine			C		Unk		Not Reported
	Epoetin Alfa			C		Unk		Not Reported
	Famotidine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported
	Hydrocortisone Sodium Succinate			C		Unk		Not Reported
	Insulin Glargine			C		Unk		Not Reported

	Insulin Lispro	C	Unk	Not Reported
	Methadone	C	Unk	Not Reported
	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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17835882	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468290		67 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837784	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468230		60 YR	Male	USA

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

Acute Kidney Injury; Medication Error; Product Use Issue	Remdesivir		S	Unknown	Unk	Gilead

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17837798	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468927		76 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Vancomycin	C	Unk	Not Reported
	Vasopressin	C	Unk	Not Reported

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

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

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

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

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

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

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
	Cetriaxone			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
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

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

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

Acute Kidney Injury; Haemodialysis	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	17838962	DIRECT	Y				73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Famotidine			C				Not Reported
	Prazosin			C				Not Reported
	Tamsulosin			C				Not Reported

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Glomerular Filtration Rate Decreased	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	17838988	DIRECT	Y	OT			49 YR	Male	USA

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

Glomerular Filtration Rate Decreased

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

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

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
White Blood Cell Count Decreased	Remdesivir	Y		S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Allopurinol			C				Not Reported
	Amiodarone			C				Not Reported
	Aspirin			C				Not Reported
	Atorvastatin			C				Not Reported
	Cardidopa-Levodapa			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

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

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

Ventricular Fibrillation	Remdesivir		S	Intravenous drip	Other Frequency:Once;		Gilead

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17839552	DIRECT	Y	HO, RI, OT			94 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Thrombocytopenia	Remdesivir 100mg/20ml			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	17839768	DIRECT	Y				32 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased	Remdesivir	Y		S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839763	DIRECT	Y				76 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ventricular Tachycardia	Remdesivir Injection			S	Intravenous bolus	Other Frequency:200mg X1;		Gilead
	Amlodipine			C				Not Reported
	Enoxaparin			C				Not Reported
	Metoprolol Xl			C				Not Reported
	Prazosin			C				Not Reported
	Probenecid			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839790	DIRECT	Y	DE			81 YR	Female	USA

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

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

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

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase	Remdesivir			S	Intravenous drip			Not Reported

Increased; Therapy Cessation	Acetaminophen		C	Not Reported
	Azithromycin		C	Not Reported
	Ceftriaxone		C	Not Reported
	Enoxaparin		C	Not Reported
	Vancomycin		C	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Hyperhidrosis; Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Continuous Haemodiafiltration; Creatinine Renal Clearance Decreased; Endotracheal Intubation; Renal Impairment; Therapy Cessation	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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

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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; C-Reactive Protein Increased; Fibrin D Dimer Increased; Glomerular Filtration Rate Decreased; Haematuria; Interleukin Level Increased; Seizure	Remdesivir			S	Intravenous bolus			Gilead
	Acetylcysteine 20% Oral Solution			C				Not Reported
	Aztreonam			C				Not Reported
	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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hypoxia; Respiratory Failure; Severe Acute Respiratory Syndrome	Remdesivir 100mg/20 Ml			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
	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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Distributive Shock; Drug Ineffective	Remdesivir 100mg/20 Ml 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

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine	Remdesivir			S	Intravenous (not			Gilead

Increased					otherwise specified)					
	Furosemide Iv			C						Not Reported
	Furosemide Po			C						Not Reported

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17841756	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0468849		68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Failure; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	Unk		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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842534	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468511		54 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir			S	Unknown	Unk		Gilead

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17842544	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468274		34 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Blood Pressure Increased; Body Temperature Abnormal; Erythema; Heart Rate Increased; Hyperhidrosis; Nausea; Oxygen Saturation Decreased; Respiratory Rate Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 Xl			C				Not Reported
	Omeprazole			C				Not Reported
	Polyethylene Glycol			C				Not Reported
	Spironolactone			C				Not Reported
	Tamsulosin			C				Not Reported
	Metoprol Tartrate			C				Not Reported
	Zosyn			C				Not Reported

	Saline			C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844976	DIRECT	Y	HO			27 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844978	DIRECT	Y	OT			61 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrial Fibrillation; Heart Rate Irregular	Remdesivir			S	Intravenous (not otherwise specified)			Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844983	DIRECT	Y				47 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Hyperhidrosis; Hypotension	Remdesivir	Y		S	Parenteral			Gilead
	Lovenox			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17844998	DIRECT	Y	HO			77 YR	Female	USA

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

Acute Kidney Injury	Remdesivir		S	Intravenous drip	Gilead

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

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

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

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

	Rocuronium	C	Not Reported
	Vancomycin	C	Not Reported

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

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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 Clnical 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 Dextrose 5%			C				Not Reported
	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

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

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

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

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

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

	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

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 Doses			C				Not Reported
	Actemra 400mg X1			C				Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acidosis; Acidosis; Acute Kidney Injury; Blood Creatinine Increased; Blood Pressure Systolic Decreased; Bronchitis; Hypotension; Multiple Organ Dysfunction Syndrome; Oliguria; Pneumonia; Renal Impairment; Respiratory Failure; Sepsis	Remdesivir			S	Intravenous drip			Gilead
	Remdesivir			S	Intravenous drip			Gilead
	Convalescent Plasma			C				Not Reported
	Azithromycin			C				Not Reported
	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

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845070	DIRECT	Y	DE, HO, LT			68 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Acetominopohen			C				Not Reported
	Amlopidine			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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845071	DIRECT	Y	HO			73 YR	Female	USA

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

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

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

Bradycardia	Remdesivir	Y		S	Intravenous bolus	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845081	DIRECT	Y	OT			69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity; Laryngeal Oedema; Periorbital Swelling; Peripheral Swelling; Peripheral Swelling	Remdesivir	Y		S	Intravenous bolus			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845085	DIRECT	Y	OT			69 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845113	DIRECT	Y	OT			57 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Related Reaction; Nausea	Remdesivir			S	Intravenous (not otherwise specified)		7 DAY	Gilead
	Remdesivir			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845123	DIRECT	Y	OT			55 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845128	DIRECT					48 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intercepted Product Preparation Error; Product Preparation Error	Remdesivir			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17845130	DIRECT	Y	HO, OT			70 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bradycardia	Remdesivir	Y		S	Intravenous (not otherwise specified)			Gilead
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lisinopril			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17846348	DIRECT		HO				Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Infusion Site Pain	Remdesivir (Eua)			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2020	17846639	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469017		82 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Hypoxia	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gilead
	Famotidine			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17845136	DIRECT	Y				63 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Chronic Kidney Disease	Remdesivir (Eua)	Y		S	Intravenous (not otherwise specified)			Gilead
	Remdesivir (Eua)			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2020	17845140	DIRECT	Y				57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Haemorrhage; Thrombocytopenia	Remdesivir			S	Intravenous drip			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17844495	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468824		26 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Liver Function Test Increased; Oxygen Consumption Decreased; Renal Impairment	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)	Unk		Gilead
	Covalescent Plasma			C		Unk		Not Reported
	Tocilizumab			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846453	DIRECT	Y				61 YR	Male	USA

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846476	DIRECT	Y				39 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Acetominophen			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846480	DIRECT	Y				51 YR	Male	USA

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

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

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

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846712	DIRECT	N	DE			68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Remdesivir 5mg/Ml Concentrated Solution	Y		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Other Dose:200mg/40ml; Frequency: 1 Dose Or Amount: 100/Mg/20ml Frequency: 2		Gilead
	Convalescent Plasma 213 Ml			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847828	EXPEDITED (15-DAY)			US-GILEAD-2020-0468846		67 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Product Administration Error; Product Storage Error	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847986	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469172		92 YR	Female	USA

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

Acute Kidney Injury; Death	Remdesivir	S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848017	EXPEDITED (15-DAY)		LT, OT	US-GILEAD-2020-0469288		79 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848022	EXPEDITED (15-DAY)		HO, LT, OT	US-GILEAD-2020-0469201		48 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848028	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469174		76 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848032	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468530		57 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bilirubin Conjugated Increased	Remdesivir			S	Unknown	Unk		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848037	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468536		55 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypotension; Infusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd		Gilead

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848039	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469173		82 YR	Female	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848043	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469167		61 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Respiratory Arrest	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		Gilead
	Convalescent Plasma			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848044	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020-0469503		45 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Creatinine Increased; Cardiac Arrest; Glomerular Filtration Rate Decreased; Liver Function Test 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
	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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17848077	EXPEDITED (15-DAY)		OT	US-GILEAD-2020-0468738		71 YR	Male	USA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17794570	EXPEDITED (15-DAY)		DE, HO, LT, OT	NL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-037224		66 YR	Male	NLD

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17852138	EXPEDITED (15-DAY)		DE, HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000437			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 Al			C		Unk		Not Reported
	Ciprofloxacin			C		Unk		Not Reported
	Tazobactam			C		Unk		Not Reported
	Solupred /00016217/			C		Unk		Not Reported
	Bisoce			C		Unk		Not Reported