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

Selection Criteria:

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

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

^{*. &}quot;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.

^{**. &}quot;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.



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

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

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



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Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products.
Product	Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Comp.	Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.
отс	Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Mfr	The manufacturer of the product, as indicated in the report.
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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcome	Mfr Control	503B Facilit	ty <u>Age</u>	Sex Country
01-May-2020	1773169	2 NON-EXPEDITED			ОТ	US-SA-2020S/	A110743		Male USA
Preferred Term	<u> </u>	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr
Anaemia; Aspartate	L	ovenox			S	Subcutaneous	100 Mg, Bid		Sanofi
Aminotransferase Increased; Blood Calcii Decreased; Blood	um F	Remdesivir			S	Intravenous (not otherwise specified)	Unk		Not Reported
Potassium Decreased;	E	Eliquis			С	Unknown	Unk		Not Reported
Gastrointestinal Haemorrhage	Δ	Acetaminophen			С	Unknown	Unk		Not Reported
riaemorriage	Α	Ascorbic Acid			С	Unknown	Unk		Not Reported
	Α	Atorvastatin			С	Unknown	Unk		Not Reported
		Dexmedetomidine			С	Unknown	Unk		Not Reported
	Α	Apixaban			С	Unknown	Unk		Not Reported
	Α	Aspirin [Acetylsalicylic Acid]			С	Unknown	Unk		Not Reported
	Α	Azithromycin			С	Unknown	Unk		Not Reported
		Oocusate Sodium			С	Unknown	Unk		Not Reported
	F	Fluticasone Furoate; Vilanterol			С	Unknown	Unk		Not Reported
	G	Sabapentin			С	Unknown	Unk		Not Reported
	F	Hydrocodone			С	Unknown	Unk		Not Reported
	lı	nsulin Aspart			С	Unknown	Unk		Not Reported
	L	antus			С	Unknown	Unk		Not Reported
	L	oratadine			С	Unknown	Unk		Not Reported
	F	Polyethylene Glycol			С	Unknown	Unk		Not Reported
	F	Prednisone			С	Unknown	Unk		Not Reported
	S	Sertraline			С	Unknown	Unk		Not Reported
	A	nula Helenium Root;Senna Alexandrina Leaf			С		Unk		Not Reported
	C	Quetiapine			С		Unk		Not Reported
	F	Propofol			С		Unk		Not Reported



	Panto	prazole			С		Unk				Not Reported
	Multiv	vitaminum			С		Unk				Not Reported
	Hydro	omorphone			С		Unk				Not Reported
	Enox	aparin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Contro	ol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
08-May-2020	17770443	DIRECT	Υ	ОТ	-				55 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Chills; Hyperhidrosis; Hypotension; Infusion Related Reaction; Infu Site Reaction; Nausea Vomiting	ısion	desivir	Y		S	Intravenous drip			30 MIN		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Contro	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2020	17770487	DIRECT	Υ	ОТ	-				62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia; Disease Progression; Hypertension; Oxyger Saturation Decreased	1	desivir	Y		S	Intravenous drip					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17770490	DIRECT	Υ	ОТ	-				62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Endotracheal Intubation	Enox: Famo	desivir aparin utidine ylprednisolone			S C C C						Not Reported Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-May-2020	17770498	DIRECT	Υ	DI	E			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Cardiac Arrest; Pulsele Electrical Activity; Ventricular Fibrillation	ess Remo	desivir	Y		S	Intravenous (not otherwise specified)		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-May-2020	17770540	DIRECT	Υ	0	Т			48 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	ŗ
Blood Creatinine Increased; Liver Funct Test Increased; Thera Cessation	ion	desivir	Y		S	Intravenous (not otherwise specified)		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-May-2020	17770559	DIRECT	Υ					79 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	ŗ
Aspartate Aminotransferase Increased	Remo	desivir			S	Intravenous (not otherwise specified)		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17770551	DIRECT	Υ	0	Т			72 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	ŗ
Chills; Clinical Trial		desivir			S	Intravenous drip	Other Frequency:Once;		Gi	lead
Participant; Product Us Unapproved Indication		in			C C C				No No	ot Reported ot Reported ot Reported ot Reported

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		otidine oprolol Succinate farin			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774804	DIRECT	Υ	F	Ю			61 YR	Male	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted	Ren	ndesivir	Υ		S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774838	DIRECT	Υ	С	ÞΕ			74 YR	Male	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Cardio-Respiratory Ard Dialysis; Pneumonia	lio-Respiratory Arrest;		Y		S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774848	DIRECT	Υ	F	Ю			69 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B	Blood Rem	ndesivir			S	Intravenous drip				Gilead
Creatinine Increased; Oliguria		comycin assium Chloride			C C	·				Not Reported Not Reported
	Etomidate				С					Not Reported
					C					Not Reported
	Suc	cinylcholine tanyl			C C					Not Reported Not Reported
	Suc Fen Nalo	cinylcholine tanyl oxone			C C					Not Reported Not Reported
	Suc Fen Nalo Pipe	cinylcholine tanyl oxone eracillin/Tazobactam			C C C					Not Reported Not Reported Not Reported
	Suc Fen Nalo Pipe Nore	cinylcholine tanyl oxone eracillin/Tazobactam epinephrine			C C C C					Not Reported Not Reported Not Reported Not Reported
	Suc Fen Nald Pipe Nord Inha	cinylcholine tanyl oxone eracillin/Tazobactam			C C C					Not Reported Not Reported Not Reported

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	G In P S Iv H E H	sacodyl Suppository abapentin sulin Lispro ropofol enna Furosemide 40 Mg X 1 ydroxychloroquine Or Placebo noxaparin eparin etolazone 10 Mg	o		000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774850	DIRECT	Υ	(ТС			61 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Covid-19 Pneumonia; Haemodynamic Instab Hypotension; Renal Tubular Necrosis; Respiratory Failure; Weight Decreased	oility; C V: D D Fr H In N Q	emdesivir efepime ancomycin azepam ocusate entanyl urosemide eparin 7,500 Units Sq sulin Lispro orepinephrine antoprazole uetiapine ropofol			8 00000000000	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774851	DIRECT	Υ	I	НО			54 YR	Female	e USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Renal Impairment	nt Remdesivir		Υ		S	Intravenous drip		2 DAY		Gilead



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-May-2020	17775263	DIRECT	Υ						Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Incorrect Dose Administered; Product		Remdesivir			S	Intravenous (not otherwise specified))		G	ilead
Label Confusion	Remo	lesivir	S			Intravenous (not otherwise specified)		G	ilead	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-May-2020	17776492	DIRECT	Υ					76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Clinical Trial Participaı Thrombocytopenia	Aspiri Amloo Chole Torse Enoxa Levot	dipine calciferol			s c c c c c c				N N N N	lot Reported lot Reported lot Reported lot Reported lot Reported lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-May-2020	17781018	DIRECT	Υ		DE			69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Cardio-Respiratory Art Clinical Trial Participat Product Use In Unapproved Indicatior	nt;	lesivir			S	Intravenous bolus	Other Frequency:Once;		G	ilead
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
	17781025	DIRECT	Υ					41 YR	Male	USA



Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		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 Fentanyl Hydralazine Piperacillin-Tazobactam Pantoprazole Enoxaparin Propofol			800000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020 1778	34372 DIRECT	Υ	0	Γ			70 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participant; Diarrhoea; Nausea; Product Use In Unapproved Indication; Vomiting	Remdesivir Acetaminophen Amlodipine Ascorbic Acid Finasteride Gabapentin Guaifenesin/Codeine Heparin Lisinopril Ondansetron Pantoprazole Propranolol Saline Nasal Spray Zinc Sulfate Combivent Respimat			\mathfrak{s} occoocoocoooo	Intravenous drip	Other Frequency:Once;			Gilead Not Reported
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020 1779	00333 DIRECT	Υ					71 YR	Female	e USA
Preferred Term	Product	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain; Chills; Clinical Trial Participant;	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead

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

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
14-May-2020	17790340	DIRECT	Υ		ОТ			66 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Clinical Tria Participant; Product Us Unapproved Indication Therapy Interrupted	al se In	desivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020	17790341	DIRECT	Υ		ОТ			63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine		desivir			S	Intravenous drip	Other Frequency:Once;			Gilead
Increased; Product Lat Confusion; Product	^{bel} Furos	semide			S	Intravenous bolus				Not Reported
Preparation Error	Calcii Docu Epop Etomi Fenta Gaba Loraz Mara Methy Midaz Norep	rostenol Inhalation idate anyl pentin tepam viroc ylprednisolone zolam binephrine			0000000000000					Not Reported

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						Dotalica Ite	port			
		Vecuronium			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Healt</u>	n Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020	177911	32 DIRECT	Υ		DE			61 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
		Remdesivir			S	Intravenous (not otherwise specified)	1			Gilead
Clinical Trial Participant; Product Use In Unapproved Indication		Ascorbic Acid 500mg Atorvastatin 20mg Tab Azithromycin 500mg Iv Ceftriaxone 1gm Iv Daily Cholecalciferol 4,000 Units Daily Doxycycline 100mg Iv Q12h Enoxaparin 40mg Daily Furosemide 20mg Once Hydroxychloroquine 400mg Irbesartan 75mg Daily Potassium 20meq Once Zinc Sulfate 440mg Daily Acetaminophen 650mg Q4h Prn Dexmedetomidine Infusion Heparin Infusion Insulin Lispro			0000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Healt</u>	n Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	177920	90 EXPEDITED (15-DA	Y)		ОТ	CH-SA-2020SA	A124099	61 YR	Female	CHE
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dermatitis Exfoliative Generalised; Eosinoph		Ceftriaxone Clarithromycin			S S		Unk			Not Reported Not Reported
Rash Erythematous		Azithromycin			S		Unk			Not Reported
		Amlodipine (Salt Not Specified	l)		S		5 Mg			Not Reported
	Oxazepam				S		Unk			Not Reported
		Lasix			S		Unk			Sanofi

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



		Dexdor					С						Not Reported
									Unk				•
		Sintenyl					С		Unk				Not Reported
		Sintenyl					С		Unk				Not Reported
		Dormicu					С		Unk				Not Reported
		Dormicu					С		Unk				Not Reported
		Dormicu					С		Unk				Not Reported
		Noradre					С		Unk				Not Reported
		Noradre	naline				С		Unk				Not Reported
		Noradre	naline				С		Unk				Not Reported
		Propofo	I				С		Unk				Not Reported
		Propofo	ļ				С		Unk				Not Reported
		Propofo	I				С		Unk				Not Reported
		Propofo	I				С		Unk				Not Reported
		Rocuror	nium				С		Unk				Not Reported
		Tracriun Tracriun					C C		Unk				Not Reported Not Reported
		Tracriun					С		Unk				Not Reported
FDA Received Date	Case #		Case Type		Health	<u>Prof</u>	Outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	1779212	26	DIRECT		Υ		DE				57 YR	Male	USA
Preferred Term		<u>Produc</u>	<u>t</u>	<u>(</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		Mfr
Death		Remdes	sivir				S	Intravenous bolus					Gilead
			scent Plasma				С	milavenous bolus					Not Reported
FDA Received Date	Case #		Case Type		Health	Prof	Outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	1779212	28	DIRECT		Υ		ОТ				59 YR	Female	e USA
Preferred Term		<u>Produc</u>	<u>t</u>	<u>(</u>	Comp.	OTC	Role	<u>Route</u>	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>		Mfr
Chills; Hypotension; Infusion Related Reac		Remdes	sivir				S	Intravenous drip	Other	Frequency:X1			Gilead

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							(Loading Dose);			
		pap 500 Mg Po Q6hr Prn ain/Fever			С		(Loading Dose),			Not Reported
		scorbic Acid 1500 Mg Po Da	ily		С					Not Reported
		efepime 1 G lvpb Q12hr	,		С					Not Reported
		-Thyroxine 175 Mcg Po Daily			С					Not Reported
		orazepam 0.5 Mg Po Tid Prn nxiety			С					Not Reported
		ndansetron 4 Mg Iv Push Q6 rn N/V	Shr		С					Not Reported
		ancomycin 1.5 G lvpb Q12hr inc Sulfate 220 Mg Po Daily			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17792132	2 DIRECT	Υ	D	E			70 YR	Male	USA
<u>Preferred Term</u>	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Refusal Of Treatment	By R	emdesivir			S	Intravenous bolus	Other Frequency:Once			Gilead
Relative	•	onvalescent Plasma			С	initiavenous bolus	Other Frequency. Once,			Not Reported
										·
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17792142	2 DIRECT	Υ	Н	0			67 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury	R	emdesivir	Y		S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17792175	5 DIRECT	Υ	Н	0			73 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury; Dialysis	R	emdesivir	Υ		S	Intravenous (not otherwise specified))			Gilead



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

							•			
FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17794224	EXPEDITED (15-DAY)		DE	, OT	US-GILEAD-2 0467265	020-	74 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u> :	<u>fr</u>
Acute Respiratory Dist Syndrome; Cardio- Respiratory Arrest; Co 19 Pneumonia		desivir			S	Intravenous (not otherwise specified	100 Mg, Qd)		G	iilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17797263	DIRECT	Υ	ОТ	-			66 YR	Female	USA
Preferred Term	<u>Prod</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Poor Quality Product Administered; Product Storage Error		desivir	Υ		S	Intravenous (not otherwise specified)	6 DAY	G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17797264	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acidosis; Blood Creati		desivir			S	Intravenous drip			G	ilead
Increased; Fluid Overle	Lacto Aspiri Fenta Dexto Propo Hepa Famo	bacillus in anyl Continuous Drip ometomedine ofol irin Subcutaneous otidine ylpredinosolone			0000000000				N N N N N	lot Reported
	Humu Vene	ulin Nph			CCC				N N	ot Reported ot Reported ot Reported



	Refre	sh			С				Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17797623	DIRECT	Υ	0	Т			66 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Blood Creatinine Increased; Hypotensio	Remo n	esivir			S	Intravenous drip			Gile	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17797878	DIRECT	Υ	0	Т			71 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Hypotension	Remo	esivir			S				Gile	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797266	DIRECT	Υ	0	Т			46 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Seizure	Remo	esivir			S	Intravenous bolus			Gile	ead
	Ascor	bic Acid			С				Not	Reported
		astatin			С					Reported
	Enoxa				С					Reported
	Famo Insulii				C C					Reported Reported
	Melat				C					: Reported
		rlprednislone			С					Reported
	Zinc				С				Not	Reported
	Fenta				С					Reported
	Norep	inephrine			С				Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797267	DIRECT	Υ	0	Т			41 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	

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Alanine Aminotransfera Increased; Aspartate Aminotransferase		Remdesivir Convalescent Plasma For 0	Covid-			S C					Gilead Not Reported
Increased		Tocilizumab Or Placebo/Co Study	vacta			С					Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	1779726	DIRECT		Υ		ОТ			72 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Coronary Artery Stenosis; Depressed Level Of Consciousness;		Remdesivir Remdesivir Convalescent Plasma For 0 19	Covid-			s s C	Intravenous bolus Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead Gilead Not Reported
Hemiparesis; Mental Status Changes; Rena Ischaemia	ıl								-		
FDA Received Date	Case #	Case Type		<u>Health</u>		Outcomes	Mfr Control i	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	1779726	9 DIRECT		Y		ОТ			57 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Function Test		Remdesivir				S	Intravenous drip				Gilead
Abnormal		Cefepime Vancomycin				C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	1779727	70 DIRECT		Υ					46 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Liver Functi Test Increased; Therap Interrupted	ion oy	Remdesivir Benzonatate Ceftriaxone Clonazepam Doxycycline				8 C C C					Not Reported Not Reported Not Reported Not Reported Not Reported

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						Dotalloa 110	port			
	Furo Meth Ome Ropi Topi	kaparin semide nylprednisolone eprazole nirole ramate asidone			0000000				1 1 1	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797271	DIRECT	Υ					70 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer Increased	rase Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797281	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Prod	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Liver Function Test Increased; Therapy Interrupted	Rem	desivir	Y		S	Intravenous drip	Other Frequency:Once;		(Bilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797285	DIRECT	Υ					52 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blood Pressure Systol Increased; Hypertensi	on:	desivir			S	Intravenous drip	Other Frequency:Once;			Gilead
Therapy Change	Acet Digo	aminophen xin			C C					lot Reported lot Reported
	Enox	kaparin			С				N	lot Reported
		semide			С					lot Reported lot Reported
	Hydr Losa	alazine Irtan			C C C					lot Reported
	Meth	nylprednisolone							N	lot Reported
	Nebi	volol			С				N	lot Reported

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	Hydro	xychloroquine			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797292	DIRECT	Υ	(TC			70 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Protein Tot	Remd al	esivir			S	Intravenous drip	Other Frequency:Once, Then 100mg;			Gilead
Increased; Renal Tubu Necrosis; Sepsis	нераг	in/Enoxaparin Itaneous			С		, , , , , , , , , , , , , , , , , , ,			Not Reported
	Aspirii Insulir Aceta	n 81 Mg n Lispro minophen nsetron			CCCC					Not Reported Not Reported Not Reported Not Reported
	Tociliz	nyroxine 150 Mcg tumab 400 Mg rynic Acid trolol			C C C					Not Reported Not Reported Not Reported Not Reported
	Tradip	oitant thobenzamide 200 Mg			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17798027	DIRECT	Υ	F	રા			70 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Remd	esivir (Gs-5734)	Υ		S	Intravenous (not otherwise specified)				Gilead
	Remd	esivir (Gs-5734)	Υ		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17798044	DIRECT	Υ	H	Ю			60 DAY	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>

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Cardiac Failure; Coagulopathy; Organ	Remo	esivir			S	Intravenous (not otherwise specified)				Gilead
Failure; Transaminases Increased	S Remo	esivir	Y		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17801712	DIRECT	Υ	0	Т			32 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Transamina Increased		lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17798196	DIRECT	Υ	0	Т			23 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Liver Function Test Increase		esivir 200 Mg			S	Intravenous (not otherwise specified)				Gilead
Therapy Cessation		minophen			C					Not Reported
		omethorphan			С					Not Reported
	Benzo Enoxa	onatate			C C					Not Reported Not Reported
	Aspiri				C					Not Reported
	Ibupro				Č					Not Reported
					С					Not Reported
	Vitam				С					Not Reported
	Zinc S	Sulfate								
	Zinc S Hydro	xychloroquine			С					Not Reported
	Zinc S Hydro Predr	xychloroquine isone			C C					Not Reported Not Reported
	Zinc S Hydro Predr	xychloroquine isone erol Hfa			C C					Not Reported
FDA Received Date	Zinc S Hydro Predr	xychloroquine isone	<u>Health</u>	Prof O	C C C	Mfr Control #	503B Facility	Age 23 YR	<u>Sex</u>	Not Reported Not Reported

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							, p = 1.			
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Liver Function Test Increase		desivir 200 Mg			S	Intravenous (not otherwise specified)				Gilead
Therapy Cessation	Aceta Dextr Benzo Enoxo Aspiri Ibupro Vitam Zinc S Hydro Predr	ofen			00000000000	outerwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801700	DIRECT	Υ	C	T			53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Abnormal	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801703	DIRECT	Υ					60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Incorrect Dose Administered	Remo	desivir			S					Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801706	DIRECT	Υ	0	DE, LT			77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; General Physical Heal		desivir	Υ		S	Intravenous (not		3 DAY		Gilead

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Deterioration; Oxygen							otherwise specified)				
Saturation Decreased		Ascorbi	ne 2g Iv Q12h c Acid 1500mg Iv Q6h e 200mg Iv Q12h			C C					Not Reported Not Reported Not Reported
			cline 100mg Po Bid			Č					Not Reported
			rednisolone 60mg lv			Č					Not Reported
		Q12h Pantopr	azole 20mg Po Q24h ne 100mg Po Q24h			C C					Not Reported Not Reported
			rednisolone 60mg lv			C					Not Reported
		Tamsul	osin 0.4mg Po Q24h			С					Not Reported
			psule 50mg Po Q24h			С					Not Reported
			ium Inh 2 Puffs Po Q6h			C					Not Reported
		Enoxap	arin 30mg Sc Q12h			С					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	178017	710	DIRECT	Υ		ОТ			43 YR	Female	USA
Preferred Term		Produc	t	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Coronavirus Test Posit	tive;	Remdes	sivir			S	Intravenous drip				Not Reported
Vomiting		Enoxap	arin			С					Not Reported
		Insulin A				С					Not Reported
			Glargine			С					Not Reported
		Ondans				С					Not Reported
		Oxycod				C					Not Reported
		Ceftriax	roperazine			C C					Not Reported Not Reported
		Doxycy				C					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	178017	711	DIRECT	Υ		ОТ			70 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	ото	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase	Remdes	sivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Aminotransferase Increased; Therapy		Atorvas	tatin			С	, in the same of				Not Reported

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Cessation	Prop	ofol			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801746	DIRECT	Υ	(ОТ			84 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased; Hypotension; Respirat Failure; Tachypnoea; Urine Output Decrease White Blood Cell Disor	Vano ory Furo ed;	desivir comycin semide			S C C					Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801755	DIRECT	Υ	(ОТ			77 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participar Liver Function Test Increased; Product Us Unapproved Indication Renal Replacement Therapy	e In	desivir			S	Intravenous drip				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801760	DIRECT	Υ					53 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participar Differential White Bloo	,	desivir			S	Intravenous (not otherwise specified)				Gilead
Cell Count Abnormal; Leukopenia; Lymphoc; Percentage Increased; Neutrophil Percentage Decreased; Product U: In Unapproved Indicati	yte Chol Zinc Mag se Insul	orbic Acid 1500mg Po Bid ecalciferol 50mcg Po Q24h Capsule 50mg Po Q24h nesium Oxide 420mg Po Bid lin Glargine 12 Units Sc Qhs lin Aspart Sliding Scale Tid			C C C C C	. ,				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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		Ac Senna 17.2mg Po Da Enoxaparin 30mg Sc				C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type		Health I	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	178017	96 DIRECT		Υ	C	T			70 YR	Male	USA
Preferred Term		Product	<u>C</u>	omp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; Clinical Trial Participan	nt;	Remdesivir				S	Intravenous (not otherwise specified)			(Gilead
Product Use In Unapproved Indication	;	Hydroxychloroquine (Or Matching			С	ourormoo opoomoa)			1	Not Reported
Renal Impairment		Convalescent Plasma	ì			С				1	Not Reported
FDA Received Date	Case #	Case Type		<u>Health I</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	178018	01 DIRECT		Υ	C	T			55 YR	Female	USA
Preferred Term		Product	<u>c</u>	omp.	<u>otc</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury;		Remdesivir Injection	(For Use			S	Intravenous drip			(Gilead
Hypovolaemia; Renal Tubular Necrosis		Under Eua) Remdesivir Injection Under Eua)	(For Use			S	Intravenous drip			(Gilead
		Vancomycin 2g Iv Q1 Vancomycin 1g Iv Q1 Vancomycin 1g Iv X Enoxaparin Famotidine Pregabalin	2			000000				1 1 1	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type		Health I	Prof C	outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	178018	05 DIRECT		Υ	C	T			80 YR	Female	USA
<u>Preferred Term</u>		Product	<u>C</u>	omp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Renal Impairment		Remdesivir				S	Intravenous bolus	Other Frequency:200mg X 1 100mg X4;	ζ.	(Gilead
		Cefepime				С		- - · · · g - · · ·,		1	Not Reported

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							1				
		/lprednisolone			С					Not Reported	
		omycin			С					Not Reported	
		xychloroquine			C C C					Not Reported	
		emide			C					Not Reported	
	Carve				C					Not Reported	
	Docus				C					Not Reported	
	Folic				C					Not Reported	
	Neuro				C C C					Not Reported Not Reported	
	Clopic	prazole			C					Not Reported	
	Mvi	prazole			C					Not Reported	
		rin Drip			C					Not Reported	
FDA Received Date	•	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	Age	Sex	Country	
						ini control	<u> </u>				
18-May-2020	17801809	DIRECT	Υ	Н	0			72 YR	Male	USA	
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr	
Acute Kidney Injury	Remo	lesivir			S	Intravenous bolus				Gilead	
	Aspiri	n			С					Not Reported	
	Azithr	omycin			С					Not Reported	
	Enoxa				C C					Not Reported	
		cortisone			С					Not Reported	
		xychloroquine			C					Not Reported	
		n Glargine			C					Not Reported	
		n Lispro			C C C					Not Reported	
		acillin-Tazobactam								Not Reported	
		thylene Glycol 3350			С					Not Reported	
	vanco	omycin			С					Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country	
18-May-2020	17801815	DIRECT	Υ	0	Т			67 YR	Femal	e USA	
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr	
Dysphagia; Swelling;		lesivir	Υ		S					Not Reported	
Throat Irritation	Amlor				С					Not Reported	
		erol Hfa			C					Not Reported	
	Lisino				C					Not Reported	
	Nysta	tin Oral Susp			С					Not Reported	



						Detailed it	eport			
	Sitag Zinc Vitam Vitam Aspiri Metfo Methy Dipric Empa	oprazole liptin nin D nin C in ormin ylprednisolone damole agliflozin n Lispro			0000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801819	DIRECT	Υ	Н	0			75 YR	Female	USA
<u>Preferred Term</u>	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Abdominal Pain; Discomfort; Infusion Related Reaction; Nausea; Vomiting	Albute Atorv Enoxe Hydro Lisino Panto Tiotro Norco Tussi Onda	pprazole ppium 5 5			8 0000000000	Intravenous drip	Other Frequency:Once;	20 MIN	 	Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801824	DIRECT	Y	0	Т			46 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Seizure	Remo	desivir			S	Intravenous drip			(Gilead
	Tocili Zinc	zumab			C C					Not Reported Not Reported

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		.,				Detailed Ke	port			
	N N L A	Quetiapine Methylprednisolone Melatonin evetiracetam torvastatin scorbic Acid			00000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	1780182	9 DIRECT	Υ	H	0			55 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration F	Rate R	temdesivir			S	Intravenous bolus				Gilead
Decreased; Hypoxia	C E	eftriaxone oxycycline noxaparin lethylprednisolone			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	1780188	5 DIRECT	Υ	0	Т			34 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Anxiety; Blood Pressul Increased; Body Temperature Increased; Heart Rate Increased; Hyperhidrosis; Nause Oxygen Saturation Decreased; Respirato Rate Increased	ed; ; a;	temdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	1780189	2 DIRECT	Υ	0	Т			38 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfe	rase R	temdesivir	Υ		S	Intravenous drip				Gilead
Increased	C	Eeftriaxone			С					Not Reported

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		. C. di					-			let Demente d
	Famo Hepa	otidine			C C					lot Reported lot Reported
	Insuli				C					lot Reported
		zolam			C					lot Reported
		pinephrine			C					lot Reported
		romycin			C C					lot Reported
		zumab			Č					lot Reported
		omycin			С					lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801899	DIRECT	Υ					52 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Administration	Remo	desivir			S	Intravenous bolus			G	Bilead
Error; Product Dose Omission		zumab 760mg			С					lot Reported
Officiality	Conv	alescent Serum			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801905	DIRECT	Υ	Н	0			15 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Hypotension	Remo	desivir	Υ		S	Intravenous bolus	Other Frequency:Once;		G	Bilead
	Remo	desivir	Υ		S	Intravenous bolus			G	Gilead
	Cosy	ntropin			С				N	lot Reported
	Cefe				C					lot Reported
	Melat									lot Reported
		ocortisone Sodium			С				N	lot Reported
	Succi				0					lat Danasta d
		aptopurine romycin			C C					lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801912	DIRECT	Υ	L ⁻	Γ			73 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>

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A-ataamia, Cantinggan		Remdesivir		Υ		S	Intravenous bolus				Gilead
Azotaemia; Continuou: Haemodiafiltration; Glomerular Filtration R Decreased		Enoxaparin Famotidine				C C					Not Reported Not Reported
FDA Received Date	Case #	Case 1	<u>ype</u>	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	1780262	26 DIREC	Т	Υ		DE			76 YR	Male	USA
Preferred Term]	Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Covid-19; Dyspnoea; General Physical Health		Convalescent Pl	asma			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Not Reported
Deterioration;		Remdesivir Dapsone				S C					Not Reported Not Reported
Hypotension; Liver Function Test Abnorma	ا ا	Linezolid Vancomycin				C C					Not Reported Not Reported
Multiple Organ Dysfunction Syndrome Oxygen Saturation Decreased; Pneumoni); 	Piperacillin/Tazo	bactam			Ċ					Not Reported
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2	ia;										
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2 Test Positive	ia;	Case 1	<u>ype</u>	<u>Health</u>	Prof	Outcomes	Mfr Control #	± 503B Facility	Age	<u>Sex</u>	Country
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2 Test Positive FDA Received Date	ia;			Health Y		<u>Outcomes</u> LT	Mfr Control #	# 503B Facility	Age 55 YR	Sex Male	<u>Country</u> USA
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2 Test Positive FDA Received Date 19-May-2020 Preferred Term	Case #					LT	Mfr Control a	503B Facility Dosage Text			_
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2 Test Positive FDA Received Date 19-May-2020	Case # 1780261	14 DIREC		Υ		LT		•	55 YR		USA
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2 Test Positive FDA Received Date 19-May-2020 Preferred Term Alanine Aminotransferal	Case # 1780261 ase	14 DIREC	Т	Y Comp. Y	ОТС	LT Role	Route	Dosage Text	55 YR <u>Duration</u>		USA Mfr
Staphylococcal; Pyrexi Renal Function Test Abnormal; Sars-Cov-2 Test Positive FDA Received Date 19-May-2020 Preferred Term Alanine Aminotransferal	Case # 1780261 ase	Product Remdesivir Case 1	T <u>ype</u>	Y Comp. Y	OTC	LT Role S	Route Intravenous drip	Dosage Text	55 YR Duration 5 DAY	Male	USA Mfr Gilead



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

2	Case # Case Type	Health Prof Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	Hydromorphone	С					Not Reported
	Vancomycin	С					Not Reported
	Senna	С					Not Reported
	Neutra-Phos	C					Not Reported
	Potassium Chloride	C					Not Reported
	Polyethylene Glycol 3350	C					Not Reported
	Oxycodone	C					Not Reported
	Multivitamin	C					Not Reported
	Metoclopramide	C					Not Reported
	Meropenem	C					Not Reported
	Lorazepam	C					Not Reported
	Lansoprazole	C					Not Reported
	Lactobacillus Acidophilus	C					Not Reported
	Insulin Lispro	C					Not Reported
	Insulin Glargine	C					Not Reported
	Furosemide	C					Not Reported
	Enoxaparin	C					Not Reported
	Docusate	C					Not Reported
-	Carvediloi	C					Not Reported
	atory Amioaipine	C					Not Reported
	ania Amiodarone	C					Not Reported
ea	000	_	intravenous bolus				
C	Remdesivir	S	Intravenous bolus				Gilead

FDA Received Date DIRECT DE 70 YR USA 17802944 19-May-2020 Male **Preferred Term Dosage Text Product** Comp. **OTC Role Route Duration** <u>Mfr</u> S Oxygen Saturation Remdesivir Gilead Intravenous (not

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Decreased; Renal Fail	lure					otherwise specified)				
	P	lydroxychloroquine Or Matching Placebo (Orchid Trial)			С	. ,				Not Reported
	C	Convalescent Plasma			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	1780295	2 DIRECT	Υ		DE			53 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Pulseless Electrical Activity	F	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	C A E F	eviteracetam Oxcarbazepine Imlodipine Enoxaparin Famotidine Insulin Lispro			00000	, ,				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	1780515	4 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0466529	20-	71 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Chills; Hypotension; Nausea	R	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	1780517	9 EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0467261	20-	61 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTO	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased	lood R	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead



							•			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806590	DIRECT	Υ	0	Т			59 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Blood Creatinine	Rem	desivir	Υ		S	Intravenous drip				Gilead
Increased	Atrac Carv Fam Hepa Lido Mida Mult Acet Atrac Fent Mida	caine Patch Izolam vitamin aminophen curium			00000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806639	DIRECT	Υ	Lī	Г			60 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
General Physical Heal Deterioration; Haemodynamic Instab Pneumothorax; Pulmo Embolism; Sepsis; Sho	oility; onary	desivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806644	DIRECT	Υ	0	Т			45 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransfer Increased		desivir codyl Suppository	Υ		s C	Intravenous bolus				Gilead Not Reported

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	Bume	tanide 1mg Inj			С						Not Reported
		axone 2g Inj			С						Not Reported
		nexidine 0.12% Swish			С						Not Reported
	Enoxa	parin 100mg			С						Not Reported
		nyl 100mcg/Hr			С						Not Reported
	Ipratro	ppium-Albuterol Neb			С						Not Reported
		ed Ringer Infusion			С						Not Reported
	Potas: Bolus	sium Phosphate 15mmol			С						Not Reported
	Propfo	ol Infusion 40mcg/Kg/Min			С						Not Reported
		onium 10m/MI Infusion			С						Not Reported
	Vanco	omycin			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806653	DIRECT	Υ	Ľ	Т				29 YR	Female	USA
Preferred Term						5 . 4.	D	Food	Duration		<u>Mfr</u>
	Produ petal Remd		Comp.	OTC	Role S	Route	Dosage 1	<u>rext</u>	<u>Duration</u>		
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instab Respiratory Failure	oetal Remd		Comp.	<u>oic</u>	Role S	Route	Dosage	<u>Text</u>	<u> Durution</u>		Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instab	petal Remd					Route Mfr Control		503B Facility	Age		
Caesarean Section; Fo Heart Rate Abnormal; Haemodynamic Instab Respiratory Failure	petal Remd	esivir			S						Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instab Respiratory Failure	cetal Remd	esivir Case Type DIRECT	Health	Prof O	S			503B Facility	Age	<u>Sex</u> Female	Not Reported Country
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term	cetal Remd bility; Case # 17806658	esivir Case Type DIRECT	<u>Health</u> Y	Prof O	S utcomes T Role	Mfr Control	#	503B Facility	Age 55 YR	Sex Female	Not Reported Country USA
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine	cetal Remd bility; Case # 17806658 Produ	Case Type DIRECT uct esivir Eua	<u>Health</u> Y	Prof O	S utcomes T Role S	Mfr Control	#	503B Facility	Age 55 YR	Sex Female	Country USA Wifr Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition	cetal Remd bility; Case # 17806658 Produ Remd Amloc	Case Type DIRECT uct esivir Eua dipine 5mg	<u>Health</u> Y	Prof O	S utcomes T Role S C	Mfr Control	#	503B Facility	Age 55 YR	Sex Female	Country USA Mfr Not Reported Not Reported Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition Aggravated;	cetal Remd collity; Case # 17806658 Produ Remd Amloc Ascori	Case Type DIRECT Ict esivir Eua dipine 5mg bic Acid 1000mg	<u>Health</u> Y	Prof O	S utcomes T Role S C C C	Mfr Control	# :	503B Facility	Age 55 YR	Sex Female	Country USA Mfr Not Reported Not Reported Not Reported Not Reported Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition Aggravated;	cetal Remd collity; Case # 17806658 Produ Remd Amloc Ascorl Ceftria	Case Type DIRECT LCT esivir Eua dipine 5mg bic Acid 1000mg axone 1g	<u>Health</u> Y	Prof O	S utcomes T Role S C C C C	Mfr Control	# :	503B Facility	Age 55 YR	Sex Female	Country USA Mfr Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition Aggravated;	cetal Remd collity; Case # 17806658 Produ Remd Amloc Ascort Ceftria Doxyo	Case Type DIRECT Let esivir Eua dipine 5mg bic Acid 1000mg axone 1g cycline 100mg	<u>Health</u> Y	Prof O	S Utcomes T Role S C C C C C	Mfr Control	# :	503B Facility	Age 55 YR	Sex Female	Country USA Mfr Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition	cetal Remd collity; Case # 17806658 Produ Remd Amloc Ascorl Ceftria Doxyo Furise	Case Type DIRECT LCT esivir Eua dipine 5mg bic Acid 1000mg axone 1g cycline 100mg emide 40mg	<u>Health</u> Y	Prof O	S utcomes T Role S C C C C	Mfr Control	# :	503B Facility	Age 55 YR	Sex Female	Country USA Mfr Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition Aggravated;	cetal Remd collity; Case # 17806658 Produ Remd Amloc Ascort Ceftria Doxyo	Case Type DIRECT LCT esivir Eua dipine 5mg bic Acid 1000mg axone 1g cycline 100mg emide 40mg	Health Y Comp.	Prof O	S Utcomes T Role S C C C C C C	Mfr Control	# Dosage 1	503B Facility	Age 55 YR	Sex Female	Country USA Mfr Not Reported
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instable Respiratory Failure FDA Received Date 19-May-2020 Preferred Term Blood Creatinine Increased; Condition Aggravated; Haemodialysis	Case # 17806658 Produ Remd Amloc Ascorl Ceftria Doxyo Furise Hepar	Case Type DIRECT uct esivir Eua dipine 5mg bic Acid 1000mg axone 1g cycline 100mg emide 40mg in	Health Y Comp.	Prof O	S utcomes T Role S C C C C C C C C C C C C C C C C C C	Mfr Control Route	# Dosage 1	503B Facility Text	Age 55 YR Duration	Sex Female	Country USA Wifr Not Reported



<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>N</u>	<u>lfr</u>
Atrial Fibrillation; Bloo	d Remo	lesivir			S	Intravenous drip			(Gilead
Creatinine Increased; Body Temperature		minophen			С					Not Reported
Increased; Infusion	Amlo				С					Not Reported
Related Reaction	Apixa				С					Not Reported
Trolated Treaction	Doxa				C					Not Reported
	•	ılazine			С					Not Reported
	Loraz				С					Not Reported
		pivent Respimat			С					Not Reported
		bic Acid			C C					Not Reported
		calciferol hyroxine			C					Not Reported
		nyroxine Sulfate			C					Not Reported Not Reported
										•
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806699	DIRECT	Υ	С	T			72 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; A Respiratory Distress		lesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		(Gilead
Syndrome; Septic Sho	^{OCK} Norep	pinephrine			С				1	Not Reported
	Cisatr	acurium			С				1	Not Reported
	Fenta				С					Not Reported
	Propo				С					Not Reported
	Midaz	rolam			С				1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806709	DIRECT	Y	R	I			54 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Bradycardia	Remo	lesivir			S	Intravenous drip			(Gilead
	·			Drof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	Case #	Case Type	Health	Proi U	<u>utcomes</u>	MIT CONTROL II	<u> </u>	<u>Age</u>	OUX	<u>country</u>

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Note: If the field is blank, there is no data.

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Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Fluid	Remdesivir			S	Intravenous bolus				Gilead
Overload; Hypoxia;	Acetaminophen			С					Not Reported
Respiratory Disorder;	Bensonatate			Č					Not Reported
Shock	Cefepime			Č					Not Reported
	Chlorhexidine			Č					Not Reported
	Cisatracurium			Č					Not Reported
	Dexmedetomidine			Č					Not Reported
	Normosol-R			Č					Not Reported
	Enoxaparin			Č					Not Reported
	Epinephrine			Č					Not Reported
	Fentanyl			C					Not Reported
	Heparin			C					Not Reported
	Hydroxychloroquine			C					Not Reported
	lopamidol			C					Not Reported
	Lactated Ringers			C					Not Reported
				C					
	Lorazepam			С					Not Reported
	Magnesium Sulfate			С					Not Reported
	Melatonin			С					Not Reported
	Metaclopramide			С					Not Reported
	Metoprolol Tartrate			С					Not Reported
	Morphine			С					Not Reported
	Norepinephrine			С					Not Reported
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020 1780	06725 DIRECT	Υ	С	E, OT			72 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney	Remdesivir			S	Intravenous (not				Gilead
njury; Cardiac Arrest;				-	otherwise specified)			
Hypernatraemia;	Dexmedetomide Drip			С					Not Reported
Metabolic Acidosis;	Enoxaparin 100 Mg Subq Q12h			Č					Not Reported
Paralysis; Respiratory	Insulin			Č					Not Reported
Acidosis; Respiratory	Methylprednisolone 60 Mg Iv			Č					Not Reported
Failure	Q12h			J					Hot Roportou
	Lorazepam 2 Mg Iv Q4h Prn			С					Not Reported
	Levophed Infusion			C					Not Reported
	Methylprednisolone 40 Mg Iv			C					Not Reported
	wellypreunsolone 40 wg W			U					Not Keported



								10 0 0 0			
		Q12h									
			e Infusion			С					Not Reported
			ine Infusion			C					Not Reported
			hrine Infusion			С					Not Reported
			enol For Inhalation			С					Not Reported
		At 150 M	Bicarb 150 Meq/Swi 1I I/Hr			С					Not Reported
		Vancomy	vcin			С					Not Reported
			in/Tazobactam			С					Not Reported
			ow Intensity Infusion			C C					Not Reported
		Amiodard				С					Not Reported
			e Infusion			С					Not Reported
		Morphine				C					Not Reported
			um Infusion			C					Not Reported
		locilizum	nab 800 Mg Iv X1 Dose			С					Not Reported
FDA Received Date	Case #	1	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	178067	'29	DIRECT	Υ		DE			92 YR	Male	USA
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Death		Remdesi	vir			S	Intravenous bolus	Other Frequency:Once;			Gilead
		Convales	scent Plasma			С					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	178067	' 34	DIRECT	Υ		DE			96 YR	Female	e USA
,											
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Electrocardiogram Abnormal; Renal Failu	ıre;	Remdesi	vir Eua			S	Intravenous (not otherwise specified)				Gilead
Respiratory Failure		Ascorbic	Acid 500 Mg			С	'				Not Reported
		Cefepime				Č					Not Reported
			iferol 50,000 Units			Ċ					Not Reported
			rphone 0.2 Mg Iv			C					Not Reported
			ednisolone 40 Mg			Ċ					Not Reported
		Injection	ŭ								•
			zole 40 Mg Tablet			С					Not Reported
		Senna 17				С					Not Reported
		Sodium (Chloride 0.9% Neb			С					Not Reported

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Zinc Sulfate 220 Mg Mirtazapine 7.5 Mg Morphine 4 Mg/Ml Injection Torsemide 20 Mg Norepinephrine 8 Mg / 250 Ml Vancomycin FDA Received Date 19-May-2020 17806736 DIRECT		Prof Ou	·	Mfr Control	# 503B Facility	Age 54 YR	 	Not Reported Country USA
,	·							
<u>Preferred Term</u> <u>Product</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Arrhythmia; Clinical Trial Participant; Product Use In Unapproved Indication; Pulseless Electrical Activity; Tachycardia Activity; Tachycardia Activity; Tachycardia Activity; Tachycardia Activity; Tachycardia Aspirin Vasopressin Cefepime Cholecalciferol Diphenhydramine Docusate Doxycycline Enoxaparin Fentanyl Robitussin Dm Insulin Lispro Tocilizumab Melatonin Methylprednisolone Midazolam Montelukast Pantoprazole Vancomycin Norepinephrine	Y		%00000000000000000000					Not Reported
FDA Received Date	Health	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020 17806739 DIRECT	Υ	0	Г			46 YR	Female	USA
Preferred Term Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>



S Cholelithiasis; Clinical Trial Remdesivir Gilead Intravenous (not Other Frequency:Once; Participant; Product Use In otherwise specified) Unapproved Indication; Sepsis; Shock; Transaminases Increased **Health Prof** Outcomes FDA Received Date Case # **Case Type** Mfr Control # 503B Facility Sex Country Age 19-May-2020 17806745 DIRECT Υ OT 40 YR Female USA **Preferred Term OTC** Mfr **Product** Role **Dosage Text** Comp. Route Duration S Alanine Aminotransferase Remdesivir Gilead Intravenous (not Increased: Aspartate otherwise specified) Aminotransferase Increased FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Age Sex Country DIRECT OT USA 19-May-2020 17806790 49 YR Female **Preferred Term Product OTC** Role Route **Dosage Text Duration** Mfr Comp. **Blood Alkaline** Remdesivir S Gilead Intravenous (not Other Frequency:Once; Phosphatase Increased: otherwise specified) Blood Pressure С Atorvastatin Not Reported Decreased: Body Č Ceftriaxone Not Reported Temperature Increased С Desvenlafaxine Not Reported **Epoetin Alfa** С Not Reported С Famotidine Not Reported С Heparin Not Reported С Hydrocortisone Sodium Not Reported Succinate Insulin Glargine С Not Reported С Insulin Lispro Not Reported С Methadone Not Reported С Not Reported Metoprolol С Potassium Chloride Not Reported С Not Reported Pregabalin С Azithromycin Not Reported С Hydroxychloroquine Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	178070	DIRECT	Υ		DE			70 YR	Male	USA
Preferred Term		Product	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Death		Remdesivir (Eua) (Remdesivir (Eua))			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	178075	DIRECT	Υ		RI			79 YR	Female	USA
Preferred Term		Product	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation; Blood Creatinine Increased; Blood Pressure Systol Increased; Glomerular Filtration Rate Decrea Increased Bronchial Secretion; Oxygen Saturation Decreased; Po2 Decreased	lic r sed; ;	Remdesivir 100 Mg/20 MI Iv (Eua Drug) Cefepime Apap Ca/Vit D Magnesium Sulfate Quetiapine Morphine Pravastatin Ezetimibe Fluoxetine Memantine Rivaroxaban Docusate Famotidine Calcitonin			8 00000000000000	Intravenous (not otherwise specified	d)			Not Reported
		Kcl			С					Not Reported
FDA Received Date	Case #	Case Type		Prof	Outcomes	Mfr Control	# 503B Facility		<u>Sex</u>	Country
19-May-2020	178076	32 DIRECT	Y		DE			77 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death		Remdesivir (Euc) (Remdesivir (Eua))			S					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17807338	DIRECT	Υ					8 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Incorrect Product Formulation Administe Product Use Issue		desivir			S				Ν	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17807340	DIRECT						62 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Hypoxia; Pneumomediastinum	Rem	desivir			S				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17807341	DIRECT	Υ	0	Γ			54 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Rem	desivir	Y		S				C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17807897	DIRECT	Υ	0	Γ			59 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	M	<u>fr</u>
Aspartate Aminotransferase		desivir 200mg	Υ		S	Intravenous (not otherwise specified)			C	Gilead
Increased; Transamina Increased	ases Rem	desivir 100mg	Υ		S	Intravenous (not otherwise specified)			C	Gilead
	Rem	desivir 100mg	Υ		S				C	Gilead

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	Remd	esivir 100mg	Υ		S					Gilead
		morphone			С					Not Reported
	Acetai	minophen			С					Not Reported
	Zofran	1			С					Not Reported
	Vitd3				C C					Not Reported
	Titrala	ıc			С					Not Reported
	Seroq				С					Not Reported
	Calciu	m Gluconate			С				1	Not Reported
	Lasix				C C C				1	Not Reported
	Loven	ox			С				1	Not Reported
	Mirala				С					Not Reported
	Benad	lryl			С				1	Not Reported
	Levop	hed			С				1	Not Reported
	Magne	esium Sulfate			С				1	Not Reported
	Potas	sium Chloride			С				1	Not Reported
	Clozai	ril			C C C				1	Not Reported
	Propo	fol			С				1	Not Reported
	Amida	ite			C C C				1	Not Reported
	Quello	ein			С				1	Not Reported
	Fantai	nyl			С				1	Not Reported
	Verse	d			С					Not Reported
	Humu	lin			C C				1	Not Reported
	Huma	log			С				1	Not Reported
	Ancef	_			С				1	Not Reported
	Protor	nix			С				1	Not Reported
	Flagyl				С				1	Not Reported
	Rocep	phin			С				1	Not Reported
	Vanco	omycin			00000					Not Reported
	Zenpe	ep .			С				١	Not Reported
	Prilose				С					Not Reported
	Potass	sium Bicarbonate			С				1	Not Reported
	Zemui	ron			С				١	Not Reported
	Conva	alescent Plasm			С				١	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810951	DIRECT	Υ					58 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Vomiting	Remd	esivir	Υ		S	Intravenous drip		5 DAY	(Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810957	DIRECT	Υ	0	Т			74 YR	Female	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Burning Sensation	Re	emdesivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	Age	<u>Sex</u>	Country
20-May-2020	17810962	DIRECT	Υ	0	Т			69 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Kidney Injury; Bl Creatinine Increased;	lood Re	emdesivir Iv	Υ		S	Intravenous drip				Gilead
Blood Urea Increased	Me Ci: No Pr Fe Va Va Ce Er Pa To Di: Me As Ins	sulin Aspart Sliding Scale etoprolol Injection satracurium Injection opportunition opp			0000000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810969	DIRECT	Υ	0	Т			57 YR	Male	USA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Alanine Aminotransfer Increased; Blood Biliru Increased		desivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810975	DIRECT	Υ	Н	IO, OT			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>VIfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration F Decreased	Remo	desivir desivir			S C					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810977	DIRECT	Υ	C	T			21 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>VIfr</u>
Haemofiltration	Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Stat Dose;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810978	DIRECT	Υ					77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>VIfr</u>
Blood Creatine Increas	sed; Remo	desivir			S	Intravenous drip				Gilead
Haemofiltration		zumab			Ç	·				Not Reported
	Linez	olid aparin			C C					Not Reported Not Reported
	Vitam				C					Not Reported
	Thian	nine			С					Not Reported
	Pepci	id			С					Not Reported
	Zinc Prece	odov			C C					Not Reported Not Reported
	Prece	euex			U					пот керопеа

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	F F	Fentanyl Propofol Rocuronium Cisatracurium			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	1781098	8 DIRECT	Υ					60 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Impairment; Ren Injury	nal F	Remdesivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	1781099	4 DIRECT	Υ	0	Т			55 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypotension; Infusion Related Reaction	F	Remdesivir	Υ		S	Intravenous (not otherwise specified)	1			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	1781101	2 DIRECT	Υ	0	Т			35 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Renal	F	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Impairment; Respirato Failure	, , , , , , , , , , , , , , , , , , ,	Amlodipine 10 Mg Daily Ascorbic Acid 500 Mg Po Bid Aspirin 81 Mg Po Daily Ceftriaxone 1g Iv Daily Dextrose 5% Iv, 100 MI/Hr Diphenhydramine 25 Mg Iv X 1 Doxycycline 100 Mg Po Bid Doxycycline Suspension 100 Mg Po Bid Enoxaparin 40 Mg Sq Bid	g		00000000	,				Not Reported
		Famotidine 20 Mg Bid			C					Not Reported

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		nyl Iv Infusion emide Iv 20 Mg X1 Then Bid			C C						Not Reported Not Reported
	Hydral Regula Insulin Insulin Ketam Methyl Montel Ondan	azine 10 Mg Iv Q4h Prn ar Insulin Infusion Glargine Lispro ine Infusion prednisolone Iv lukast			00000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811020	DIRECT	Υ	DE	-				72 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		Mfr
Acute Kidney Injury	Remde	esivir			S	Intravenous bolus					Gilead
	Hydrox Insulin Insulin Lansop Propof Rocurd Sodiur Vanco Vecurd Angiot Hydror Fentar Midazd	omycin colin curium n cortisone kychloroquine Glargine Lispro brazole fol conium n Bicarbonate mycin braium ensin li morphone nyl blam nephrine			000000000000000000000000000000000000000						Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811029	DIRECT	Υ	C	T			72 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Alanine Aminotransfera Increased; Aspartate	ase Rem	desivir Injection			S	Intravenous (not otherwise specified))		G	ilead
Aminotransferase Increased	Azith Benz Enox Guait Potas Mela Nebiv Valsa	/olol			0000000000				N N N N N N	ot Reported
FDA Received Date		Case Type	Health	Prof C	Outcomes	Mfr Control	# 503B Facility	Age	Sex	Country
20-May-2020	17811036	DIRECT	Υ					66 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Acute Respiratory Failu Blood Creatinine Increased	ure; Remo	desivir	Y		S	Intravenous (not otherwise specified))		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811043	DIRECT	Υ	C)T			56 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Glomerular Filtration R	tate Remo	desivir			S	Intravenous bolus			G	ilead
Decreased; Therapy Interrupted	Cefe _l Enox Insuli	dipine pime aparin n Aspart n Detemir			0000				N N N	ot Reported ot Reported ot Reported ot Reported ot Reported



		Duo-Ne Linezoli Morphir Pantopi Acetam Fentany Midazol	d ne razole inophen /l			000000					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	178110	50	DIRECT	Υ	DE				76 YR	Male	USA
Preferred Term		<u>Produc</u>	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
General Physical Heal Deterioration; Respirat Failure; Septic Shock; Therapy Cessation	tory	Remde	sivir	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	178110	56	DIRECT	Υ	07	Γ			71 YR	Male	AFG
Preferred Term		<u>Produc</u>	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Platelet Count Decrea	sed	Remde	sivir	Υ		S	Intravenous drip				Gilead
		Zinc 22 Allopuri Azithror Benzon Ceftriaz Dipyrida Enoxap Insulin (Insulin I Zestore Merope	C 1000mg 0 nol 300mg mycin atate cone 1gm amole arin Glargine Lispro ctic nem orednisolone			00000000000000					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811063	3 DIRECT	Υ					49 YR	Male	USA
Preferred Term	<u>P</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera	ase R	Remdesivir	Υ		S	Intravenous drip			C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811080	0 DIRECT	Υ		DE			70 YR	Female	USA
Preferred Term	<u>P</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Ventricular Fibrillation	ABC2CEFNIrCPPRS	Remdesivir Albumin 5% 25g Aumetanide 1mg Q12h Calcium 500mg With Vit D 5mcg Daily Ceftriaxone 2g lv Daily Chrosemide 20mg Once Aurosemide 20mg Once Aurosemide 20mg Once Aurosemide 20mg Q12h Cantoprazole 40mg Q12h Cropofol Infusion 25mcg/Kg/Min Cryllium 58.6% Packet Albavirin 600mg Q8h Certraline 150mg Daily Critamin D 2000 Units Daily	Y		% 000 0000 000000	Intravenous bolus				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811088	8 DIRECT	Υ		ОТ			27 YR	Female	USA
Preferred Term	<u>P</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate		Remdesivir Via Emergency Use authorization			S	Intravenous drip			N	Not Reported



17811136

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Aminotransferase Increased; Blood Alkal Phosphatase Increase Haemofiltration; Liver Function Test Increase Renal Impairment; Rig Ventricular Dysfunction	d; ed; ht	Covid-19 Convalescent Plasn Tocilizumab 400 Mg Iv In 100 Nacl Tocilizumab 400 Mg Iv In 100 Nacl	MI		C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	178110	92 DIRECT	Υ	Н	O, LT, OT			34 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blister; Erythema; Ras Macular	h	Remdesivir Acetaminophen Morphine Vancomycin Potassium Chloride Tocilizumab Or Placebo Furosemide Famotidine Enoxaparin Ceftriaxone Albuterol			%0000000000					Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country

Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Eye Movement Disorder;	Remdesivir			S	Intravenous drip			Gilead
Hypoxia; Lung Infiltration; Miosis; Pyrexia;	Acetaminophen 650mg Po Q4h Prn			С	·			Not Reported
Respiratory Distress;	Azithromycin 500mg Po Daily			С				Not Reported
Tachycardia; Unresponsive To Stimuli;	Enoxaparin 40mg Subq Daily			С				Not Reported
Unresponsive To Stimuli	Famotidine 20mg Po Daily			С				Not Reported
Onlesponsive 10 Sumuli	Ondansetron 4mg Iv Q6h Prn			С				Not Reported

DS, HO, LT, OT

Υ

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DIRECT

Note: If the field is blank, there is no data.

USA

42 YR

Male



	Case Type	Health	<u>Prof</u> O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
1781113		Y		O, LT			53 YR	Female	USA
<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
y A A D F C C A Z C	Albuterol Cyclobenzaprine Aspirin Ec Doxycycline Atorvastatin Cyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Cinc Dodansetron Diphenhydramine Amiodarone			%0000000000000					Gilead Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
1781114	7 DIRECT	Υ	D	S, HO, LT			60 YR	Male	USA
<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
on; F	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
<i>A</i> C F H N F	spirin szithromycin Ceftriaxone urosemide łydroxychloroquine Or Place łagnesium Sulfate	ebo		000000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	E F F C C A A Z C C A A E F F C C A A A A A A A A A A A A A A A A	Remdesivir ry Albuterol Cyclobenzaprine Aspirin Ec Doxycycline Atorvastatin Pyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Zinc Ondansetron Diphenhydramine Amiodarone Famotidine Case # Case Type 17811147 DIRECT Product on; Remdesivir Acetaminophen Aspirin Azithromycin Ceftriaxone Furosemide	Remdesivir ry Albuterol Cyclobenzaprine Aspirin Ec Doxycycline Atorvastatin Pyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Zinc Ondansetron Diphenhydramine Amiodarone Famotidine Case # Case Type Health 17811147 DIRECT Product On; Remdesivir Acetaminophen Aspirin Azithromycin Ceftriaxone Furosemide Hydroxychloroquine Or Placebo Magnesium Sulfate	Remdesivir Albuterol Cyclobenzaprine Aspirin Ec Doxycycline Atorvastatin Pyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Zinc Ondansetron Diphenhydramine Amiodarone Famotidine Case # Case Type Health Prof O 17811147 DIRECT Y D Product On; Remdesivir Acetaminophen Aspirin Azithromycin Ceftriaxone Furosemide Hydroxychloroquine Or Placebo Magnesium Sulfate	Remdesivir Albuterol Cyclobenzaprine Aspirin Ec Doxycycline Atorvastatin Pyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Amiodarone Famotidine Product Case # Case Type Product Comp. OTC Role CC CC CC CC CC CAC CC CC CC CC CC CC C	Remdesivir y Albuterol Cyclobenzaprine Aspirin Ec Doxycycline C Atorvastatin Pyridostigmine Calcium Carbonate Ceftriaxone Acetaminophen Tinc Amiodarone Famotidine Case # Case Type Product Product Comp. OTC Comp. OTC Role Route Route Route Route Route Route Route Route Route Route Route Route Route	Product Comp. OTC Role Route Dosage Text Remdesivir S S Cycloben-zaprine C Cycloben-zaprine C Cycloben-zaprine C C Cycloben-zaprine C C C C C C C C C C C C C C C C C C C	Product Comp. OTC Role Route Dosage Text Duration Remdesivir Albuterol C C C Cyclobenzaprine C C C C Cyclobenzaprine C C C Cyclobenzaprine C C C C C C Cyclobenzaprine C C C C C C C C C C C C C C C C C C C	Product Comp. OTC Role Route Dosage Text Duration



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811158	DIRECT	Υ	D	E			60 YR	Male	ALB
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Oxygen Saturation Decreased	Remo	desivir			S		Other Frequency:Loading Dose;		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17812033	DIRECT	Υ					63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Hypotension; Rash; Tachycardia	Remo (Eua)	desivir (Eua) (Remdesivir)			S	Intravenous (not otherwise specified)			No	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812217	DIRECT	Υ	D	E			71 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Hepatic Failure; Hypertension; Hypotension; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased	Remo	desivir			S	Intravenous (not otherwise specified)		1 DAY	Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812224	DIRECT	Υ	D	E			41 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Condition Aggravated; Lung Disorder; Pulmor Embolism; Sudden De	nary _{Romo}	desivir desivir			S C	Intravenous bolus				lead ot Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812243	DIRECT	Υ	D	Е			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	lesivir	Y		S	Intravenous (not otherwise specified)				Gilead
	Sarilumab Apixaban Furosemide Polyetheylene Glycol Sennosides Bisacodyl Zinc Sulfate Ascorbic Acid Hydralazine Ferrous Sulfate Docusate Metoprolol Ropinorole Tamsulosin Carbidopa/Levodopa Losartan Paroxetine Finasteride Pantoprazole				0000000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812244	DIRECT	Υ	D	E			79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
	Levet Enoxa	nine Pca iracetam aparin ocobalamin Acid			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported

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						Detailed Ke	eport			
	Aspiri	osin prazole	C C C C C C Mealth Prof Outcomes Mfr							Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812245	DIRECT	Υ	07	Γ			50 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Chills; Hypotension	Remo	desivir			S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812248	DIRECT	Υ					67 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Poor Quality Product Administered; Product Storage Error	Remo	lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812559	DIRECT	Υ	07	Γ			64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Hyperhidrosis;	Remo	lesivir			S	Intravenous bolus				Gilead
Hypotension; Vomiting	Aspiri Prece Diltiaz Docus Dulox Enoxa Ferro	edex zem sate eetine aparin us Sulfate emide			0000000000					Not Reported

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							P • • • • • • • • • • • • • • • • • • •			
	Lantu: Insulir Lactol Loraz: Magn Methy	n Lispro pacillus epam esium Oxide rlprednisolone sium Chloride uel			00000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812562	DIRECT	Υ	C	DΤ			70 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasa	ation Remd	esivir			S	Intravenous drip				Gilead
	Remd	esivir			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812592	DIRECT	Υ					69 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Acten	n ohed net did olprednisolone			00000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Supraventricular Tachycardia	Remd	esivir			S				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812599	DIRECT	Υ					39 YR	Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Dysphagia; Throat Irritation	Remd	esivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17813534	EXPEDITED (15-DAY)				US-GILEAD-20 0467788	020-	11 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M1</u>	<u>ir</u>
Device Malfunction; Medication Error	Remd	esivir			S	Intravenous (not otherwise specified	Unk)		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17815405	DIRECT	Y	0	Т			53 YR	Female	USA
<u>Preferred Term</u>	<u>Produ</u>	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Hepatic Enzyme Increased	Remd	esivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17815427	DIRECT	Υ					69 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Body Temperature Increased; Condition	Remd	esivir			S	Intravenous (not otherwise specified	Other Frequency:X1) Then100mg Q24h;	5 DAY	N	ot Reported
Aggravated	Acetar Amlod	minophen lipine			C C	· .	-			ot Reported ot Reported

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	Anix	caban			С						Not Reported
		irin (Enteric Coated) 81 Mg			Č						Not Reported
		y vastatin			С						Not Reported
		ztropine			Č						Not Reported
		vedilol			C						Not Reported
	Diva	alproex			C C C						Not Reported
	Fam	notidine									Not Reported
	Gua	ifenesin + Codeine Prn			C C C						Not Reported
		nsulosin			С						Not Reported
		ılin Glargine									Not Reported
		ılin, Regular (Sliding Scale)			С						Not Reported
		tropium And Albuterol Alation			С						Not Reported
		atadine			С						Not Reported
		hylprednisolone Sodium cinate			С						Not Reported
	Mor	ntelukast			С						Not Reported
		phine, Intravenous (Prn)			С						Not Reported
		tinib			С						Not Reported
		toprazole			С						Not Reported
		etiapine (And I Ran Out Of om: Zosyn)			С						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17815613	DIRECT	Υ	RI					61 YR	Female	e USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		Mfr
Blood Creatinine Increased; Dialysis		ndesivir ndesivir			S C						Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17763474	EXPEDITED (15-DAY)		Н)	US-ROCHE-25	594510		47 YR	Male	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase Acte	emra			S	Intravenous (not otherwise specified))				Not Reported
Aminotransferase	Ren	ndesivir			S	Unknown					Not Reported



Increased; Deep Vein	Hydi	roxychloroquine			S	Unknown			١	Not Reported
Thrombosis; Intentional Product Use Issue; Off	Hydi	roxychloroquine			S	Unknown			١	Not Reported
Label Use	Oxyg Love Zosy Tyle Vand Zithr Calc Pota Chol	eramide enox [Enoxaparin Sodium] /n			0000000000000				P P P P P P P	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020 1	7815622	DIRECT	Υ		DE			67 YR	Female	USA
Preferred Term	Pro	duct	Comp.	ото	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest		ndesivir Injection			S	Intravenous (not otherwise specified)			(Gilead
Pulseless Electrical	Cefe	epime			С				١	Not Reported
Activity; Respiratory Failure		romycin			С					Not Reported
railure		azem			С					Not Reported
	Eno	xaparin			С					Not Reported
		zepam			С					Not Reported
		nesium Sulfate			С					Not Reported
		oprolol Tartrate			С					Not Reported
		ssium Chloride			C					Not Reported
	Sodi Solu	um Chloride 0.9% lv tion			С				١	Not Reported
		ralazine			С				١	Not Reported
		phine			Č					Not Reported
		uronium			Ċ					Not Reported
		ephrine Drip			Ċ					Not Reported
		nylephrine Drip			C					Not Reported
		oofol Drip			C					Not Reported
		um Bicarbonate Drip			С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17815629	DIRECT	Υ		ОТ			77 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Bl Creatinine Increased; Dialysis		desivir Injection			S	Intravenous (not otherwise specified)				Gilead
Jiaiysis	Duor Pant Sodi	aparin neb oprazole um Chloride 0.9% Iv			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
	Solut Prop				С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17815634	DIRECT	Υ		ОТ			78 YR	Female	USA
Preferred Term	Prod	luct	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Disseminated ntravascular Coagulat General Physical Heal	ion;	desivir Injection			S	Intravenous (not otherwise specified)				Gilead
Deterioration;	Aspii	rin vastatin			C C					Not Reported Not Reported
Hypotension; Hypothermia; Infusion	Cefe Enox	pime :aparin			C C					Not Reported Not Reported
Related Reaction	Duor Panto Valad Aceta	neb oprazole cyclovir aminophen			00000					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Prop	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Not Reported Country
22-May-2020	17815658	DIRECT	Y		DE	MIN CONTROL W	ooo raomty	59 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney	, Rem	desivir			S	Intravenous bolus				Gilead

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

FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	315906	DIRECT			E, HO			69 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> 1</u>	<u>Mfr</u>
Famotidir Aspirin C Gabapen Insulin Lis Fentanyl Propofol Lasix Enoxapan Heparin Metolazo Etomidate Succinylo		one inephrine d Epoprostenol idine n Chewable eentin Lispro nyl iol parin in izone date			%00000000000000					Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020 178	316199	DIRECT	Υ					44 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Incorrect Dose Administered; Product Dispensing Error	Remde	esivir rol Nebulizer	Y		S C	Intravenous (not otherwise specified)				Gilead Not Reported
	Carved Cefepi Furose	dilol me			CCC					Not Reported Not Reported Not Reported

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						Detailed Re	eport			
	Nore	arin rocortisone epinephrine comycin			C C C				1 1	Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816200	DIRECT	Υ	DE	į			66 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alka Phosphatase Increase Blood Prolactin Increa Cardiac Failure Congestive; Lung Disorder; Oxygen Saturation Decreased	Use lline ed; ised;	ndesivir Under Emergency Authorization (Eua			S	Intravenous (not otherwise specified))	4 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816201	DIRECT	Υ	DE				80 YR	Female	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Dialysis; Metabolic Acidosis; Pneumonia Viral		ndesivir Under Emergency Authorization (Eua)			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	(Gilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	itcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816202	DIRECT	Υ	ТО	-			67 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Liver Function Test Increased	Rem	ndesivir	Υ		S	Intravenous (not			(Gilead

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Enox: Case # 17816203	oime cycline aparin 40 Mg Bid Case Type DIRECT	·	Prof O	C C C	otherwise specified)				Not Reported Not Reported
Doxyo Enoxo Case # 17816203	cycline aparin 40 Mg Bid <u>Case Type</u>	·	Prof O	С					
17816203		·	Prof O						Not Reported
	DIRECT			<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Prod		Υ	0	Т			68 YR	Male	USA
<u>1 100</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Doxy	cycline			S C C				1	Not Reported Not Reported Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17816204	DIRECT	Υ	Н	0			82 YR	Male	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Remo	desivir			S				1	Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17816205	DIRECT	Υ	0	Т			56 YR	Female	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Remo	desivir	Υ		S	Intravenous bolus			(Gilead
Aceta Albute Apixa Dexm Baclo Cefep Ceftri Doxye	eminophen-Hydrocodone erol-Ipratropium ban nedetomidine fen oime axone cycline			0000000000				1 1 1 1 1	Not Reported
1	Remo Doxyo Zosyr 7816204 Prod Remo Remo Aceta Albuto Apixa Dexm Baclo Cefep Ceftri Doxyo Midaz	Doxycycline Zosyn Case # Case Type 7816204 DIRECT Product Remdesivir Case # Case Type	Remdesivir Eua Doxycycline Zosyn Case # Case Type Health 7816204 DIRECT Y Product Comp. Remdesivir Case # Case Type Health 7816205 DIRECT Y Product Comp. Remdesivir Acetaminophen Acetaminophen Acetaminophen-Hydrocodone Albuterol-Ipratropium Apixaban Dexmedetomidine Baclofen Cefepime Ceftriaxone Doxycycline Midazolam	Remdesivir Eua Doxycycline Zosyn Case # Case Type Health Prof O 7816204 DIRECT Y He Product Comp. OTC Remdesivir Case # Case Type Health Prof O 7816205 DIRECT Y O Product Comp. OTC Remdesivir Y O Acetaminophen Acetaminophen Acetaminophen-Hydrocodone Albuterol-Ipratropium Apixaban Dexmedetomidine Baclofen Cefepime Ceftriaxone Doxycycline Midazolam	Remdesivir Eua Doxycycline Zosyn Case # Case Type Product Remdesivir Remde	Remdesivir Eua Doxycycline Zosyn Case # Case Type Health Prof T816204 DIRECT Y HO Product Remdesivir Remdesivir S Case # Case Type Health Prof Outcomes Remdesivir S Case # Case Type Health Prof Outcomes Mfr Control # T816205 DIRECT Y OT Product Comp. OTC Role Route Remdesivir Y OT Remdesivir Y S Intravenous bolus C C C C C C C C C C C C C C C C C C	Remdesivir Eua Doxycycline Zosyn Case # Case Type Health Prof Product Remdesivir Remdesivir Comp. OTC Role Route Dosage Text Remdesivir S Case # Case Type Health Prof Outcomes Remdesivir Remdesivir Remdesivir Comp. OTC Role Route Dosage Text S Case # Case Type Health Prof OT Product Comp. OTC Role Route Dosage Text Intravenous bolus Acetaminophen Acetaminophen-Hydrocodone Albuterol-lipratropium Acetaminophen-Hydrocodone Albuterol-lipratropium Albuterol-lipratropium Acetaminophen-Hydrocodone Albuterol-lipratropium Acetaminophen-Hydrocodone Albuterol-lipratropium Acetaminophen-Hydrocodone Albuterol-lipratropium C C Apixaban Dexmedetomidine Baclofen C Cefepime C C Cefepime C C Ceftriaxone Doxycycline Midazolam C C	Remdesivir Eua Doxycycline Zosyn Case # Case Type Health Prof V HO 82 YR Product Comp. OTC Role Route Dosage Text Duration Remdesivir S Case # Case Type Health Prof V OT 56 YR Product Comp. OTC Role Route Dosage Text Duration Remdesivir S Case # Case Type Health Prof V OT 56 YR Product Comp. OTC Role Route Dosage Text Duration Remdesivir Age 7816205 DIRECT Y OT 56 YR Product Comp. OTC Role Route Dosage Text Duration Intravenous bolus Acetaminophen Acetaminophen-Hydrocodone Albuterol-Ipratropium Apixaban C C Dexmedetomidine Baclofen C Cefepime C Cefepime C Ceftriaxone Doxycycline C C Midazolam C C Midazolam C C Midazolam C C Midazolam C C	Remdesivir Eua Doxycycline Zosyn C C C C C C C C C C C C C

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	Flucc Folic Furos Hepa Mero Tocili Vanc	semide ırin penem izumab omycin pinephrine			000000000		Not Reported			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816206	DIRECT	Υ	LT	, OT			66 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation	Remo	desivir			S	Intravenous (not otherwise specified	Other Frequency:Once Once Load;	5 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816207	DIRECT	Υ	DE	≣			75 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated: Covid-19	; Remo	desivir			S	Intravenous (not otherwise specified)			Gilead
	Albut Chole Zinc Asco Aceta Rispe Mirta Trazo Rispe Rosu Rivar Folic	prolol erol 2 Mg/5ml Syrup ecalciferol Sulfate rbic Acid aminophen eridone zipine odone eridone ivastatin roxaban Acid oprazole			00000000000000					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816208	DIRECT		H	O			62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Hypotension	Remo	desivir			S				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816211	DIRECT	Υ					78 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Agitation; Anxiety;	Remo	desivir			S	Intravenous drip	Other Frequency:Once;		(Gilead
Hallucination, Visual; Intensive Care Unit Delirium	Gaba	epam Iv 0.25 Mg pentin 100 Mg ip 1 Mg			C C C				1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816477	DIRECT	Υ	0	Т			75 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Transaminases Increa	ased Remo	desivir Injection			S	Intravenous (not otherwise specified)	Other F		C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816490	DIRECT	Υ	0	Т			59 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Transaminases Increa	ased Remo	desivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Desc;		(Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>M</u>	<u>lfr</u>
Liver Function Test Increased; Sars-Cov-2 Test Positive		desivir	Y		S	Intravenous drip	Other Frequency:Once;		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816556	DIRECT	Υ		HO, OT			84 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Blood Creatinine Increased; Covid-19	Remo	desivir	Υ		S	Intravenous (not otherwise specified)		C	Gilead
	Diltia: Enox Furos Insuli Meto _l Panto	aparin semide n prolol pprazole sepam			000000000				P P P P	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816562	DIRECT	Υ		ОТ			53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	l <u>fr</u>
Transaminases Increa	sed Remo	desivir	Υ		S	Intravenous (not otherwise specified)		C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816575	DIRECT	Y		НО			43 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Aspartate Aminotransferase Increased; Blood		desivir semide 40 Mg Iv	Υ		S C	Intravenous drip				Gilead Not Reported

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Creatinine Increased; Renal Impairment; Sep Shock		repinephrine			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816997	DIRECT	Υ		НО			65 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Acute Kidney Injury; Bl Creatinine Increased;		ndesivir Solution For ection			S	Intravenous (not otherwise specified)				Gilead
Haemodialysis	De: Ace	oxaparin kmedetomidine etaminophen otine Patch			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17817002	DIRECT	Υ		ОТ			69 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participan		ndesivir Under Emergency e Authorization (Eua).			S	Intravenous (not otherwise specified)				Gilead
Product Use In Jnapproved Indication Renal Replacement	i; Ins	ntanyl Infusion ulin Regular (Humulin R) ling Scale			C C					Not Reported Not Reported
Therapy; Respiratory Failure; Shock	Pro End Fur Ins No	ing Scale pofol Infusion oxaparin (Lovenox) osemide ulin Glargine repinephrine (Levophed) sopressin			00000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17817004	DIRECT	Υ		ОТ			39 YR	Female	USA



S Clinical Trial Participant; Remdesivir Gilead Intravenous (not Hepatic Enzyme otherwise specified) Increased: Product Use In Unapproved Indication FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Country <u>Age</u> US-GILEAD-2020-DE 22-May-2020 17818831 **EXPEDITED (15-DAY)** 96 YR Female USA 0468218 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr Covid-19 Remdesivir S Gilead Unknown 200 Mg, Once Remdesivir S Gilead Unknown 100 Mg, Qd FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Age Sex Country Υ RΙ DIRECT 56 YR Male USA 22-May-2020 17819757 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr Acute Kidney Injury; Remdesivir (Eua) 100mg Vial Υ S Gilead Intravenous (not Clinical Trial Participant; otherwise specified) Product Use In Remdesivir (Eua) 100 Mgvial Υ S Gilead Intravenous (not Every 24 Hr Unapproved Indication: otherwise specified) Renal Replacement С Norepinephrine Not Reported Therapy С Not Reported Acetaminophen Ċ Albumin Not Reported CCC Azithromycin Not Reported Bumetanide Not Reported Ceftriaxone Not Reported C Clonazepam Not Reported Desmopressin Not Reported C Not Reported Docusate Dopamine Not Reported CCCCNot Reported Enoxaparin **Epoprostenol** Not Reported Famotidine Not Reported Not Reported Fentanyl Ċ Furosemide Not Reported Heparin Not Reported

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Hydromorphone

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Not Reported



	Insul Mido Pher Prop Rocu	drine nylephrine			000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17822985	DIRECT	Υ	ОТ	-			61 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation	Rem	desivir			S	Intravenous drip				Gilead
	Fenta Mida Aceta Enox	epinephrine anyl Izolam aminophen Kaparin otidine			00000	·				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17822988	DIRECT	Υ					44 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Preparation E	rror Rem	desivir Injection	Υ		S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17822990	DIRECT	Υ	ТО	-			35 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;	rase Rem	desivir			S	Intravenous (not otherwise specified))			Gilead

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Therapy Cessation										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17822997	DIRECT	Υ		ОТ			74 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Continuous Haemodiafiltration;	R	emdesivir			S	Intravenous bolus	Other Frequency:Once, Then;			Gilead
Respiratory Failure; Thrombosis In Device;	;	emdesivir			S	Intravenous (not otherwise specified)				Gilead
Urine Output Decrease	C	onvalescent Plasma ocilizumab Or Placebo Trial			C C	otherwise specifical				Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17823220	DIRECT	Υ		RI			60 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney Injury	y R	emdesivir (Eua) 100 Mg Vial	Υ		S	Intravenous (not otherwise specified)				Gilead
	R	emdesivir (Eua) 100 Mg Vial	Υ		S	Intravenous (not otherwise specified)				Gilead
		lbumin			С	. ,				Not Reported
		lbuterol			C					Not Reported
		umetanide			С					Not Reported
	_	affeine Citrate hlorothiazide			C C					Not Reported Not Reported
		noxaparin			Ċ					Not Reported
		amotidine			Č					Not Reported
		urosemide			Č					Not Reported
	G	abapentin			C					Not Reported
		sulin Glargine			С					Not Reported
		sulin Lispro			C					Not Reported
		sulin Regular			С					Not Reported
		actulose			С					Not Reported
		agnesium Sulfate			С					Not Reported
		ethylprednisolone etolazone			C C					Not Reported Not Reported
	IVI	CIUIAZUITE			U					Not Reported

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ADIVIT	ADMINISTRATION						Detailed R	eport			
		Midazo	lam			С					Not Reported
		Midodri	ne			C C					Not Reported
		Oxycod	lone			С					Not Reported
			illin/Tazobactam			C C					Not Reported
		Potassi	um Chloride			С					Not Reported
		Quetian	pine			С					Not Reported
		Rocuro	nium			C C C					Not Reported
		Vancon	nycin			С					Not Reported
		Dexme	detomidine			С					Not Reported
		Epopro	stenol			С					Not Reported
		Heparir	1			С					Not Reported
		Hydron	norphone			C C C					Not Reported
		Ketamii	ne			С					Not Reported
			nephrine			C C					Not Reported
		Propofo	ol			С					Not Reported
		Vasopr				С					Not Reported
		Acetam	inophen			С					Not Reported
		Fentan	/l			С					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	178229	98	DIRECT	Y					50 YR	Female	USA
Preferred Term		Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Cough; Hypoaesthesia	;	Remde	sivir Eua	Υ		S	Intravenous drip				Gilead
Pruritus			cone (Rocephin) 1,000			С					Not Reported
		Mg In 0 (Ns) 50	.9 % Sodium Chloride MI Ad								
		Ènóxap	arin (Lovenox) (Conc: 40			С					Not Reported
			MI) Injection 40 Mg atate (Tessalon Perles)			С					Not Reported
			e 100 Mg			O					Not reported
			nethorphan-Guaifenesin			С					Not Reported
			10-100 Mg/5 MI)								
			ssin Dm) Sy								
			setron (Zofran) (Conc: 2			С					Not Reported
			Injection 4 Mg								
			ylene Glycol 3350			С					Not Reported
			() Packet 17 G			_					
			hazine (Phenergan) 6.25			С					Not Reported
		Mg In 0	.9 % Sodium Chloride								



	(8.6-5 Table Simva Mg	60 MI I osides-Docusate Sodium 0 Mg/Tab) (Senna Plus) t 2 Table astatin (Zocor) Tablet 40 adol (Ultram) Tablet 50 Mg			с с с					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	17823000	DIRECT	Υ		ОТ			85 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Erythema; Pain	Remd	lesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	17823003	DIRECT	Υ		DE			74 YR	Male	USA
<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Hospice Care	Remd	lesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
23-May-2020	17823009	DIRECT	Υ		ОТ			39 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Malaise; Renal Impairr	ment Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
	Atracı Midaz Furos				C C C	. ,				Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
I BAT RECOGNED Bute										

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

Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mf	<u>r</u>
Blood Creatinine	F	emdesivir Injection			S	Intravenous drip			G	ilead
ncreased	F	temdesivir			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	1782302	D DIRECT	Υ	Ľ	Т			64 YR	Male	USA
Preferred Term	Ē	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Blood Creatinine Increased; Hyperkalae		temdesivir	Y		S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	1782302	1 DIRECT	Υ	D	E, DS			68 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Renal Failure	F	temdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	ilead
	Т	ocilizumab			С	,			No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	1782302	4 DIRECT	Υ					64 YR	Female	USA
Preferred Term	Ē	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Alanine Aminotransfera Increased; Aspartate		Lemdesivir (5 Mg/MI Injection Concentrate)	ı		S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	ilead
Aminotransferase Increased		scorbic Acid 500 Mg Tab			C					ot Reported
moreaseu		zithromycin 500 Mg Ivpb enzonatate 100 Mg Cap			C C					ot Reported ot Reported
		Seftriaxone 1 Gm lypb			C					ot Reported ot Reported
		noxaparin Inj			Č					ot Reported
	N	Methylprednisolone 40 Mg Iv			С				No	ot Reported
	Z	inc Sulfate 220 Mg Cap			С				No	ot Reported



FDA Received Date Ca	se #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020 178	823028	DIRECT	Υ	01	Γ			42 YR	Femal	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatine Increased; Nephropathy Toxic	Remd	esivir	Υ		S	Intravenous bolus	Other Frequency:X1;			Gilead
FDA Received Date Ca	se #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020 178	823098	DIRECT	Υ	LT				66 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatine Increased; Dialysis; Gastrointestinal	Remd	esivir			S	Intravenous (not otherwise specified)			Gilead
Haemorrhage; Glomerular Filtration Rate Decreased;					С					Not Reported
Hepatic Failure;		em Lispro			C C					Not Reported Not Reported
Hyperkalaemia; Hypovolaemic Shock;	Methy	/lprednisolone			С					Not Reported
Metabolic Acidosis; Renal	Protor				C C					Not Reported
Failure; Shock	Atara: Loven				C					Not Reported Not Reported
Haemorrhagic	Ativar				С					Not Reported
	Fenta				С					Not Reported
	Verse Ketan				C C					Not Reported Not Reported
FDA Received Date Ca	se #	Case Type	Health	Prof Ou		Mfr Control	# 503B Facility	Age	Sex	Country
						MIII COILLIOI	# <u>503B Facility</u>			•
23-May-2020 178	823103	DIRECT	Y	LT				66 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blood Creatine Increased;	Remd	esivir			S	Intravenous (not otherwise specified)			Gilead
Dialysis; Gastrointestinal Haemorrhage; Glomerular	Aspiri				С					Not Reported
Filtration Rate Decreased:	Dilliaz				С					Not Reported
Hepatic Failure;	insuiir	n Lispro			C C					Not Reported
·	iviethy	Iprednisolone			U					Not Reported

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Liver Function Test Increased: Shock Lovenox C C Not Report Not Re											
24-May-2020 17823031 DIRECT Y	Liver Function Test Increased; Shock	Ata Lo Ati Ke Ve Ati	arax venox van tamine rsed van			00000					Not Reported
Preferred Term	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Blood Creatinine Remdesivir Y S Intravenous (not otherwise specified) Silend	24-May-2020	17823031	DIRECT	Υ					62 YR	Male	USA
Increased Plavix C	Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
24-May-2020 17823035 DIRECT Y 31 YR Male USA	Increased; Liver Funct	tion Pla Lo Fe Hy Hu Le On Pro Hu Ati Ve So Ve Ke So Tyl Me Nit	avix venox ntanyl dralazine imalog vophed neprazole opofol imulin van rsed dium Bicarbonate curonium ppra lumedrol lenol elatonin roglycerin	Y		000000000000000000					Not Reported
	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr	24-May-2020	17823035	DIRECT	Y					31 YR	Male	USA
	Preferred Term	Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



Hepatic Enzyme Increased	Eua F	Remdesivir	Y		S	Intravenous (not otherwise specified)				Not Reported
	Lover	nox			С	•					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823037	DIRECT	Υ	(ОТ				64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Vomiting		lesivir Iesivir			S C	Intravenous drip					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823040	DIRECT	Υ	(ОТ				79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir			S	Intravenous bolus					Gilead
	Fenta Hepa Hydro Insulii Lactu Levot Norep Panto Propo Queti Senna	astatin nyl rin poortisone n Regular lose hyroxine pinephrine prazole apine			000000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823060	DIRECT	Υ	(ОТ				81 YR	Female	USA
<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>

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Hypotension	Remo	desivir			S	Intravenous drip	Other Frequency:Once Then 100 Mgx4;	30 MIN		Gilead
	Diltia: Hydra	orolol 5 Mg zem Er 30 Mg alazine 25 Mg rtan 100 Mg			C C C		G .			Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823067	DIRECT	Υ	D	E			86 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Respiratory Disorder	Conv	alescent Plasma			S	Intravenous (not otherwise specified)	Other Frequency:2 Units Given Once;			Versiti Blood Centers
		desivir (Eua) zumab			S S					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823073	DIRECT	Υ	Н	0			68 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		Mfr
Blood Creatinine Increased	Remo	desivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823078	DIRECT	Υ	D	E			68 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
	Fenta Methy Insuli	ylprednisolone n Glargine			C C C	,				Not Reported Not Reported Not Reported Not Reported
	Insuli Insuli	n Lispro n Regular			C C					Not Reported Not Reported

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						201404	P • • • • • • • • • • • • • • • • • • •			
	Dap Lab Duc Ator Bup Cef Cisa Dex	comycin tomycin etalol neb Nebulizer vastatin ropion epime atracurium medetomidine xaparin			000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823118	DIRECT	Υ	0	Γ			54 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Ren	ndesivir			S	Intravenous bolus				Gilead
	Nord Van Pipe Proj Seli Sen	azolam epinephrine comycin eracillin/Tazobactam pofol nexor na codone			000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823125	DIRECT	Y	0	Γ			71 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Lactic Acid Decreased; Renal Inju Respiratory Rate	ıry; Apix	ndesivir Injection caban 5 Mg			s C	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead Not Reported
Increased; Septic Sho Tachypnoea; Urinary	Asp	irin 81 Mg			C C					Not Reported
Casts		llin Lispro Sliding Scale epinephrine Infusion			C					Not Reported Not Reported
		opressin Infusion			Č					Not Reported

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						Dotalioa 110	PO. 1				
		Cisatracurium Infusion Propofol Infusion Fentanyl Infusion Tocilizumab 400 Mg Unfractionated Intravenous Heparin Piperacillin/Tazobactam 4.5 Grams Q6h Vancomycin 1250 Mg Q12h Tradipitant/Placebo			00000 0 00						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	178209	EXPEDITED (15-DAY)			DE, OT	US-SA-2020SA	130868			Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Disseminated		Lovenox			S	Subcutaneous	40 Mg	, Qd			Sanofi
Intravascular Coagulat Intra-Abdominal Haemorrhage;	ion;	Remdesivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
Retroperitoneal		Ascorbic Acid			С		Unk				Not Reported
Haemorrhage; Septic Shock; Shock		Fenofibrate			С		Unk				Not Reported
Haemorrhagic		Heparin			С		Unk				Not Reported
		Methylprednisolone			С		Unk				Not Reported
		Nph Insulin			С		Unk				Not Reported
		Insulin Human;Insulin Human Injection, Isophane			С		Unk				Not Reported
		Sodium Chloride			С		Unk				Not Reported
		Sitagliptin			С		Unk				Not Reported
		Midazolam			С		Unk				Not Reported
		Pantoprazole			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control :	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	178231	DIRECT	Υ		ОТ				32 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>



Hepatic Enzyme Increased		desivir	Y		s C	Intravenous drip				ilead ot Reported
EDA Passivad Data		erol Hfa 90mcg/Puff	Llaalth	Drof O		Mfr Control	# FOOD Facility	Ago		
FDA Received Date	Case #	Case Type			<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	17823162	DIRECT	Y	0	Т			56 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Acute Kidney Injury	Zosyı Doxy	desivir n cyline axone			S C C C				N N	ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	17823167	DIRECT	Υ	0	Т			72 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Bradycardia	Remo	desivir			S	Intravenous drip			G	ilead
	Propo	oxychloroquine ofol omorphone			C C C	·			N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	17823171	DIRECT	Υ					59 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Infusion Site Extravasa	ation Remo	desivir	Y		S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	17823177	DIRECT	Υ	0	Т			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Burning Sensation	Remo	desivir	Υ		S	Intravenous (not otherwise specified)		G	ilead

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	7823181 DIRECT Product Remdesivir	Health Y Comp.	Prof O	<u>utcomes</u> T	Mfr Control #	503B Facility	Age 75 YR	<u>Sex</u> Female	<u>Country</u> USA
Preferred Term Hypopnoea; Infusion Related Reaction; Rash;	Product			Т			75 YR	Female	USA
Hypopnoea; Infusion Related Reaction; Rash;		Comp.	отс						
Related Reaction; Rash;	Remdesivir		<u> </u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Distress; Wheezing	Enoxaparin 40 Mg Subcutaneous Famotidine 20mg Tablets Insulin Glargine Subcutaneous Insulin Lispro Subcutaneous Multivitamin Oral Tablet Polyethylene Glycol 17 G Packe Senna-Docusate 8.6 Mg-50 Mg Tablet	t		\$ C C C C C C C C C C C C C C C C C C C				Not Not Not Not Not Not Not	Reported
EDA Described Date - O	Tamoxifen 20 Mg Tablets		D (0	С			•		Reported
FDA Received Date Ca	ase # Case Type	Health	Prot O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020 17	7823188 DIRECT	Υ					60 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Albuterol Inhaler Amlodipine 5 Mg Tablet Benzonatate 200mg Capsules Docusate 100 Mg Capsule Senna Tablets Enoxaparin 40 Mg Subcutaneous Famotidine 20mg Tablets Insulin Glargine Insulin Lispro Subcutaneous Levothyroxine 50mcg Tablet			80000000000				Not Not Not Not Not Not Not Not	Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	17823195	5 DIRECT	Υ	i	DE			68 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Anxiety; Encephalopat Hypoxia; Respiratory Distress; Respiratory	thy; R	emdesivir			S	Intravenous (not otherwise specified)			Gilead
Failure; Unresponsive Stimuli	IO In A C A P Lo G S Lo A	osyn asulin Lispro & Insulin Glargine Ibuterol ombivent mlodipine recedex ovenox abapentin eebri evothyroxine tivan opressor ulera ercocet			00000000000000					Not Reported
FDA Received Date		Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	Age	Sex	Country
25-May-2020	17823212	2 DIRECT	Υ	(DT			73 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Glomerular Filtration R Decreased; Renal mpairment	Rate R	emdesivir			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	17823217	7 DIRECT	Υ					89 YR	Female	USA
referred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Administration Site Extravasation	R	emdesivir			S	Intravenous drip		5 DAY		Gilead

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FDA Received Date	Case #	1	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Co	ontrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	177927	758	EXPEDITED (15-DAY)			ОТ	CH-PFI 202019	IZER INC- 91603		61 YR	Female	CHE
Preferred Term		Product	<u>t</u>	Comp.	OTO	Role Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Dermatitis Exfoliative		Nexium				S	Unknown	Unk			ι	Jnknown
Generalised; Eosinoph Rash Erythematous	nilia;	Nexium				S	Unknown	Unk			ι	Jnknown
		Temesta	a (Lorazepam)			S	Unknown	Unk			F	Pfizer
		Zithroma	ax			S	Unknown	Unk			F	Pfizer
		Amlodip	ine Besilate			S	Unknown	Unk			F	Pfizer
		Haldol				S	Unknown	Unk			1	Not Reported
		Quetiapi	ine			S	Unknown	Unk			1	Not Reported
		Lasix [F	urosemide Sodium]			S	Unknown	Unk			1	Not Reported
		Lasix [F	urosemide Sodium]			S	Unknown	Unk			1	Not Reported
		Lasix [F	urosemide Sodium]			S	Unknown	Unk			1	Not Reported
		Ceftriaxo	one			S	Unknown	Unk			1	Not Reported
		Clarithro	omycine			S	Unknown	Unk			1	Not Reported
		Remdes	sivir			S	Unknown	Unk			1	Not Reported
		Anxiolit				S	Unknown	Unk			1	Not Reported
		Clexane				S	Unknown	40 Mg			1	Not Reported
		Clexane				S	Unknown	40 Mg			1	Not Reported
		Dafalgar	n			S	Unknown	Unk			1	Not Reported
		Dafalgar	n			S	Unknown	Unk			1	Not Reported
		Solu-Me	edrol			С	Unknown	Unk			1	Not Reported
		Diamox	[Acetazolamide]			С	Unknown	Unk			1	Not Reported
		Diamox	[Acetazolamide]			С	Unknown	Unk			1	Not Reported
		Diamox	[Acetazolamide]			С	Unknown	Unk			1	Not Reported
		Distrane	eurin [Clomethiazole]			С	Unknown	Unk			1	Not Reported
		Novorap	pid			С	Unknown	Unk			1	Not Reported
		Ipramol				С	Unknown	Unk			1	Not Reported

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



Age Duration Age	N N N N Sex Unknown	fr Not Reported Not Reported
<u>Duration</u>	N N N Sex Unknown Mt	Not Reported Not Reported Not Reported Not Reported Country DEU Ifr Not Reported Not Reported
<u>Duration</u>	Sex Unknown Mt	Not Reported Not Reported Not Reported Country DEU Ifr Not Reported Not Reported
<u>Duration</u>	Sex Unknown Mt	Not Reported Not Reported Country DEU Ifr Not Reported Not Reported
<u>Duration</u>	Sex Unknown Mt	Country DEU Ifr Not Reported Not Reported
<u>Duration</u>	Sex Unknown Mt N	Country DEU fr Not Reported Not Reported
<u>Duration</u>	Unknown <u>M</u> t N N	DEU fr Not Reported Not Reported
	<u>M</u> 1 N N	fr Not Reported Not Reported
	N N	Not Reported Not Reported
Age	N	Not Reported
Age		•
Age	Cov	_
	<u>Sex</u>	Country
76 YR	Male	USA
<u>Duration</u>	<u>M</u> 1	<u>fr</u>
	G	Gilead
<u>Age</u>	<u>Sex</u>	Country
71 YR	Female	USA
<u>Duration</u>	<u>M</u> 1	<u>fr</u>
	N	Not Reported
<u>Age</u>	<u>Sex</u>	Country
43 YR	Male	USA
	Age 71 YR Duration	Duration M Age Sex 71 YR Female Duration M Age Sex

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							- PO. 1			
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	M	<u>fr</u>
Liver Function Test Increased	Ren	ndesivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824009	DIRECT	Υ		ОТ			73 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate	ase Ren	ndesivir	Υ		S	Intravenous (not otherwise specifie	d)		G	ilead
Aminotransferase Increased	Milri	odarone 360 Mg/200 MI none 20 Mg/100 MI epinephrine			C C		-,		N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824025	DIRECT	Υ		DE			73 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Acute Respiratory Dist Syndrome; Pneumonia Renal Failure		ndesivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824060	DIRECT	Υ		DE			76 YR	Female	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Cardio-Respiratory Arr	rest Ren	ndesivir			S	Intravenous (not otherwise specifie	Other Frequency:Total;		G	ilead
		epime			С	-				ot Reported
		xaparin			C C					ot Reported
		notidine tanyl			C					ot Reported ot Reported
	Hep				C					ot Reported
		ilin Lispro			Č					ot Reported
		hocarbamol			Č				N	

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						Dotalioa Itt	<u> </u>				
	Midaz Norej Prega Propo Vanc	oinephrine abalin			000000					1 1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824081	DIRECT	Υ						38 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Heart Rate Decreased	Remo	desivir			S	Intravenous (not otherwise specified)			(Gilead
	Asco Cefta Enox Insuli Methy Panto	ınyl			0000000000					 	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824084	DIRECT	Υ						59 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Bradycardia	Remo	desivir			S	Intravenous (not otherwise specified)		5 DAY	(Gilead
	Atorv Citalo Enox Famo	lcysteine astatin pram aparin stidine			00000					1 1 1	Not Reported Not Reported Not Reported Not Reported Not Reported
	Gaba	pentin			U					l	Not Reported

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	Proto Tiotro	nix opium			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824086	DIRECT	Υ		OT			69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased	Albut Famo Senn Docu Insuli Epop Aspri Aceta Nore Hepa Meth Midoo Ampi Meto Ketar Hydro Cisat Furos Potas Aceta	n Lispro rostenol n aminophen binephrine rin Drip ylprednisone drine cillin Sulbactam lazone mine Drip bmorphone Drip racurium Drip semide			% 0000000000000000000000000000000000000	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824087	DIRECT	Υ		HO, OT			80 YR	Femal	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Burning Sensation; Clinical Trial Participal Condition Aggravated;	nt;	desivir			S					Gilead



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

FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824088	DIRECT	Υ					85 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participar Decreased Appetite; Product Use In Unapproved Indication	(Eua)	lesivir (Eua) (Remdesivir)			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824089	DIRECT	Υ		DE			82 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Clinica Trial Participant; Produ		lesivir	Y		S	Intravenous (not otherwise specified)				Gilead
Use In Unapproved Indication	Mirala Loraz Ceftria Dilaud Guiaf Aspiri Aceta Mylar	aparin IX epam axone did enesin			00000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824090	DIRECT	Υ		ОТ			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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

Clinical Trial Participant; Ischaemic Stroke; Product Use In Unapproved Indication; Vertebral Artery Remdesivir Y S Intravenous drip

Gilead

Indication; Vertebral A Occlusion	rtery									
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824149	DIRECT	Υ	F	RI			68 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	ŗ
Acute Kidney Injury; A Kidney Injury; Clinical Participant; Product U Unapproved Indication	Trial (Eua)) se In	sivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)			No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824205	DIRECT	Υ					67 YR	Female	USA

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



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824219	DIRECT	Υ	H	O, OT			43 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Dyspnoea	Remo	desivir	Υ		S	Intravenous bolus	Other Frequency:One Time;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824509	DIRECT	Υ	Н	O, OT			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Pneumonia; Sepsis	Remo (Eua)	desivir (Eua) (Remdesivir)			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824895	DIRECT	Υ	0	Т			62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Impairment; Therapy Cessation	Aceta Albun Ascor Bume Chlor Enoxa Fenta Hepa Lidoc Metro Norep Panto Vecui	bic Acid stanide othiazide aparin anyl rin aine Patch onidazole oprazole	Y		» 0000000000000000	Intravenous bolus				Gilead Not Reported

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Blood Creatinine Increased; Therapy Cessation Remdesivir Eua Y S Intravenous bolus Gilead Increased; Therapy Cessation C C Increased; Therapy C Chlorhexidine 0.12% Solution C C Increased; Therapy C C Intravenous bolus C C C Intravenous bolus C C C Intravenous bolus C C C C C C C C C C C C C C C C C C C	FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B F	acility Age	<u>Sex</u>	Country
Remdesivir Eua Y S Intravenous bolus Gilead	26-May-2020	17824899	DIRECT	Υ		НО			62 YR	Female	e USA
Cessation Creased; Therapy Chlorhexidine 0.12% Solution Envaparin C C Envaparin C C C C C C C C C C C C C C C C C C C	Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duratio	<u>n</u>	<u>Mfr</u>
Lorazepam Norepinephrine C C C Norepinephrine C C S Norepinephrine C C C Norepinephrine C C C S 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 Anninotransferase Increased; Inflammatory Marker Increased; Therapy Cessation Enoxagarin Famolidine Iv Metoprolol Iv Potassium & Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Tab Vancomycin Iv C C S Sodium Phosphates Packet Potassium Chloride Ta	Blood Creatinine Increased; Therapy Cessation	Ch En Far He Ipra Mu Ro Sei	lorhexidine 0.12% Solution oxaparin motidine parin atropium-Albuterol ltivitamin curonium nnosides-Docusate	Y		00000000	Intravenous bolus				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspartate Aminotransferase Increased; Inflammatory Marker Increased; Therapy Cessation	FDA Received Date 26-May-2020	No	repinephrine <u>Case Type</u>		Prof	C Outcomes	Mfr Control #	<u>503B F</u>			Not Reported Country
Acetaminophen Tab C Azithromycin Iv Ceftriaxone Iv Ceftriaxone Iv Benzonatate Enoxaparin Famotidine Iv C Ceftriaxone Iv C C Not Reported	Preferred Term	Pro	oduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duratio</u>	<u>n</u>	<u>Mfr</u>
	Increased; Aspartate Aminotransferase	Aco Azi Per Ber End Far Me Pot Pho Pot	etaminophen Tab thromycin Iv ftriaxone Iv nzonatate oxaparin motidine Iv toprolol Iv nassium & Sodium osphates Packet nassium Chloride Tab			00000000 0	Intravenous bolus				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
26-May-2020 17824932 DIRECT Y OT 69 YR Female USA											
	FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B F	acility Age	<u>Sex</u>	Country

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Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>M</u> 1	<u>fr</u>
Hepatic Enzyme	Ren	ndesivir	Υ		S	Intravenous bolus			G	ilead
Increased	Asp Ator Ceft Dipl Dox Enc Etor Fen Lev Nor Pota Proj	taminophen irin vastatin triaxone nenhydramine ycycline xaparin midate tanyl othyroxine epinephrine assium Chloride pofol cinylcholine			0000000000000				N N N N N N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824939	DIRECT	Υ	DI	≣			39 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Hepatic Enzyme Increased	Ren	ndesivir	Υ		S	Intravenous (not otherwise specified)		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824944	DIRECT	Υ	DI	≣			76 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Cardiac Arrest; Dyspno Emphysema; Interstitia		ndesivir	Υ		S	Intravenous (not otherwise specified)		G	ilead
Lung Disease; Respira Failure; Tachycardia	atory End Albu Bro And Las	xaparin uterol vana ro Ellipta ix dnisone			C C C C C	ss.mos specimou	,		N N N N	ot Reported ot Reported ot Reported ot Reported ot Reported ot Reported

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						Detailed Re	port			
		Insulin Protonix Atorvastatin Metformin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	1782495	50 DIRECT	Υ	0	Т			46 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	I	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	,	Voriconazole Iv			С					Not Reported
		Enoxaparin			C					Not Reported
		Fluconazole			С					Not Reported
		Fluticasone Nasal Spray			C C					Not Reported
		Insulin Lispro Levothyroxine			C					Not Reported Not Reported
		Senna			C					Not Reported
		Ascorbic Acid			C C C					Not Reported
		Zinc Sulfate			С					Not Reported
		Sodium Chloride 0.9% W/ 20 Meq Kcl			С					Not Reported
		Acetaminophen			С					Not Reported
		Benzonatate			С					Not Reported
		lopamidol Ondansetron			C					Not Reported Not Reported
		Promethazine W/ Codeine			C					Not Reported
		Vancomycin			C					Not Reported
		Piperacillin-Tazobactam			Č					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	1782495	56 DIRECT	Υ	0	Т			72 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B	lood	Remdesivir			S	Intravenous drip				Gilead
Creatinine Increased; Dose Calculation Erro	r;	Ascorbic Acid Po Azithromycin Iv			C					Not Reported Not Reported
Glomerular Filtration F		Ceftriaxone Iv			С					Not Reported

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						Detailed No	port			
Decreased; Incorrect I Administered By Prod Sepsis	uct; Cimet Furos Zinc (Cisati Epopi	calciferol cidine Po emide Ivp And Gtt Gluconate Po ricurium rostenol Inhaled nyl Infusion Vent Sedation	n		00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824960	DIRECT	Υ	Н	0			46 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	Remo	lesivir	Υ		S	Intravenous (not otherwise specified))	2 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824966	DIRECT	Υ	L ⁻	Г, ОТ			79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Blood Urea	Remo	lesivir	Y		S	Intravenous (not otherwise specified))	5 DAY		Gilead
Increased; Dialysis	Cefep Azithr Fenta Midaz Propo Albun Famo Aspiri Furos Enoxa Insulii Cisati Meroj	zumab pime pomycin nyl Continuous Infusion colam Infusion pfol Infusion nin 25 Gm Infusion tidine 20 Mg Po n 81 Mg emide 40 Mg Iv aparin 40 Mg Sq n Infusion racurium Infusion penem astatin 20 Mg			000000000000000					Not Reported



	Vitan	nin D 2000 Units			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824970	DIRECT	Υ		ОТ			56 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Daily After 200mg;			Gilead
	Atorv Ceftri	rbic Acid Po 1000mg Bid astatin 10mg Po Daily axone 1gm liv Daily			C C C	,	J.			Not Reported Not Reported Not Reported
	Enox Famo Insuli	dogrel 75mg Po Daily aparin 90mg Sq Q12hrs utidine 20mg Iv Daily n Lispro Sq Sliding Scale			C C C					Not Reported Not Reported Not Reported Not Reported
	Meth Q12h				C					Not Reported Not Reported
	Norce Fenta	220mg Oral Bid 5 5/325mg Po Q6hrs Prn anyl Variable Rate nuous Iv			C C					Not Reported Not Reported Not Reported
	Nore Conti Propo	pinephrine Variable Rate nuous Iv ofol Variable Rate			C C					Not Reported Not Reported
FDA Received Date	Case #	nuous Iv Case Type	Hoalth	Brof	Outcomes	Mfr Control #	503B Facility	Λαο	Sov	Country
26-May-2020	17824973	DIRECT	Y		OT	MIT COULTOL #	SUSB FACILITY	Age 41 YR	<u>Sex</u> Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Asthenia; Chromaturia Fatigue; Therapy Cessation		desivir romycin oime	Y		S C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824977	DIRECT	Υ					55 YR	Male	USA

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Rash; Rash Maculo- Papular	Remo	lesivir			S	Intravenous (not otherwise specified)				Not Reported
	Stribil Prezis Lover Solun	sta nox			C C C	. ,				Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824979	DIRECT	Υ		DE			52 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	lesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Remo	lesivir	Y		S	Intravenous (not otherwise specified)				Gilead
		omycin 250mg Iv sium Chloride Er 40meq			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824984	DIRECT	Υ		ОТ			51 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme	Remo	lesivir			S	Intravenous drip				Gilead
Increased; Therapy Interrupted	Aceta Aspiri Enoxa	zumab minophen 325 Mg n 81mg Ec aparin 40mg Sc Bid prazole 40mg Po Qday			C C C C	•				Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824989	DIRECT	Υ		DE			85 YR	Male	USA
Preferred Term	Prod	uet	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Arrhythmia; Creatinine Renal Clearance Decreased; Encephalopathy; Respiratory Failure; Sudden Cardiac Death		Remdesivir Solution Modafinil Trazodone Quetiapine			S C C C					Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
26-May-2020	1782499	90 DIRECT	Υ					60 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased		Remdesivir Tocilizumab	Υ		S C	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	1782499	91 DIRECT	Y	0	Γ			69 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase Liver Function Test Increased	line ed;	Remdesivir Bisacodyl Lansoprazole Metoclopramide Polyethylene Glycol	Y		S C C C	Intravenous bolus				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported
-		Sennosides-Docusate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>		utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	1782499	92 DIRECT	Υ	Н)			45 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury		Remdesivir Injection			S	Intravenous drip				Gilead
		Remdesivir For Injection, Lyophilized Powder, 100 Mg Vial			С	·				Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178249	93 DIRECT	Υ					79 YR	Male	USA
Preferred Term		Product	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Administration Site Extravasation		Remdesivir			S	Intravenous drip		5 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178252	30 EXPEDITED (15-DAY)		DE, OT	US-SA-2020S	A135575		Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19; Disseminate		Lovenox			S	Subcutaneous	40 Mg, Qd			Sanofi
Intravascular Coagulat Intra-Abdominal Haemorrhage;	ion;	Remdesivir			S	Intravenous (not otherwise specified	Unk			Not Reported
Retroperitoneal		Ascorbic Acid			С	Unknown	Unk			Not Reported
Haemorrhage; Septic Shock; Shock		Heparin			С	Unknown	Unk			Not Reported
Haemorrhagic		Fenofibrate			С	Unknown	Unk			Not Reported
		Methylprednisolone			С	Unknown	Unk			Not Reported
		Sodium Chloride			С	Unknown	Unk			Not Reported
		Sitagliptin			С	Unknown	Unk			Not Reported
		Midazolam			С	Unknown	Unk			Not Reported
		Pantoprazole			С	Unknown	Unk			Not Reported
		Nph Insulin			С	Unknown	Unk			Not Reported
		Insulin Human;Insulin Human Injection, Isophane			С	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178265	68 EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2 0467857	020-	73 YR	Female	e USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury		Remdesivir			S	Intravenous (not	100 Mg, Qd			Gilead

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						otherwise specif	ied)				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178265	EXPEDITED (15-DA	AY)			US-GILEA 0467774	D-2020-			Female	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Product Storage Error		Remdesivir			S	Unknown	Unk			G	ilead
FDA Received Date	Case #	<u>Case Type</u>	Health	Prof O	utcomes	Mfr Cont	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178279	02 DIRECT	Υ	D	S, HO, LT				67 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Crystal Nephropathy;		Remdesivir			S	Intravenous drip				G	ilead
Hydronephrosis; Rena Tubular Necrosis; Respiratory Disorder; Urine Analysis Abnorm		Acetominophen Duonebs Amiodarone 150mg Iv Bolus Once			C C C					N	ot Reported ot Reported ot Reported
		Azithromycin 500mg Iv Once Cefepime 2gm Iv Potassium Chloride 20meq Iv Tocilizumab 400mg Iv			C C C					Ne Ne	ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178279	08 DIRECT	Υ	0	Т				59 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfera Increased; Aspartate	ase	Remdesivir			S	Intravenous (no otherwise specif				G	ilead
Aminotransferase Increased; Blood Alkal Phosphatase Increase Condition Aggravated; Enteritis	ed;	Atorvastatin Lovenox Imodium Losartan Pantoprazole Phosphorus Toradol			0000000	outerwise speen	icaj			Ni Ni Ni Ni	ot Reported ot Reported ot Reported ot Reported ot Reported ot Reported ot Reported

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	Lopre Metop Aspiri Diltiaz	prolol in			C C C				N N	ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17827943	DIRECT	Υ	D	E			53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Atrial Fibrillation; Bradycardia; Cardio- Respiratory Arrest; Hypotension; Respirato Failure		desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17827959	DIRECT	Υ	0	Т			72 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Acute Kidney Injury; Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased		desivir desivir			S C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17828102	DIRECT	Υ					85 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Gallbladder Disorder; Hepatic Enzyme Increased	Remo	desivir 100 Mg/20 MI			S	Intravenous (not otherwise specified)		G	ilead
	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date										

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Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u> :	<u>fr</u>
Blood Creatine Phosphokinase Increased		esivir (Eua) 100 Mg Vial			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			G	iilead
	Remid	ade Inj 100mg Vial			S	Intravenous (not otherwise specified)			G	ilead
	Acetai	minophen			С				N	ot Reported
		zolamide			C					ot Reported
		omycin			C					ot Reported
	Cellra				Č					ot Reported
	Furos				C C					ot Reported
		Glargine			Č					ot Reported
	Insulin				Č					ot Reported
		prazole			Č				N	ot Reported
	Linozo				Č					ot Reported
	Merop				Č					ot Reported
		lprednisolone			Č					ot Reported
		orazole			Č					ot Reported
		hylene Glycol			Č					ot Reported
FDA Received Date Ca	ise #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	Age	Sex	Country
			<u> </u>					_		
27-May-2020 17	828748	DIRECT	Υ	0	l			63 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury; Blood Creatinine Increased; Glomerular Filtration Rate Decreased		esivir	Y		S	Intravenous (not otherwise specified)			G	iilead
FDA Received Date Ca	ise #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020 17	828807	DIRECT	Υ	0	Γ			66 YR	Female	USA
<u>Preferred Term</u>	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Cardiac Arrest	Remd	esivir	Υ		S	Intravenous drip			C-	ilead
			•			mavenous unp				
	Δzithr	omycin			С				N	ot Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17829752	DIRECT	Υ		ОТ			49 YR	Prefer not to disclose	USA
Preferred Term	Pr	oduct	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increas	sed Re	mdesivir Injection	Υ		S	Intravenous drip		3 DAY	Gile	ead
	All As Be De Cr Do En Fa Gu Co	etaminophen 500 Mg puterol 90 Mcg Hfa corbic Acid 500 Mg nzonatate 100 Mg examethasone 20 Mg extromethorphan-Guaifenesin 30-600 ecusate 100 Mg ecusate-Senna 50/8.6 Mg exaparin 40 Mg motidine 20 Mg maifenesin 100/5 peramide 2mg/15ml edansetron 4mg/2ml ec Sulfate 220mg			000000 00000000				Not Not Not Not Not Not Not Not Not Not	Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
27-May-2020	17829758	DIRECT	Υ		ОТ			48 YR	Female	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	ОТО	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Acute Kidney Injury; Ischaemic Hepatitis; M Organ Disorder; Thera Interrupted	ulti-	emdesivir			S	Intravenous bolus			Gile	ead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17829764	DIRECT	Υ					46 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Blood Creatine	Re	mdesivir Injection			S	Intravenous (not	Other Frequency:Once;		Gile	ead

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Phosphokinase Increase	sed;					otherwise spec	fied)			
Therapy Cessation	Rer	ndesivir			S	Intravenous (no otherwise spec		6 DAY	(Gilead
		rvastatin 40 Mg Tablet			С				1	Not Reported
		triaxone 1 Gm Injection			С					Not Reported
		xaparin 100 Mg Injection			С					Not Reported
		osemide 40 Mg Injection			С					Not Reported
		Iromorphone 1 Mg Injection			С					Not Reported
	Tab				С					Not Reported
		azepam 2 Mg Injection			С					Not Reported
		openem 1 Gm Injection			C					Not Reported
		toprazole 40 Mg Injection			С					Not Reported
		assium Chloride Injection			С					Not Reported
		iramate 100 Mg Tablet			С					Not Reported
		comycin 1 Gm Injection			С					Not Reported
		pofol 10 Mg/MI Injection			С					Not Reported
		lium Bicarbonate Injection curonium Injection			C					Not Reported Not Reported
		taminophen Tablet			C					Not Reported
EDA Deseived Date		•	Heelth	Dungt C		Mfr Com		nailite. A ma		•
FDA Received Date	Case #	Case Type	Health	Prot C	<u>Outcomes</u>	Mfr Con	rol # 503B F	acility Age	<u>Sex</u>	<u>Country</u>
27-May-2020	17830125	EXPEDITED (15-DAY)				US-GILEA 0468001	D-2020-	52 YR	Male	USA
Preferred Term	Pro	<u>educt</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Product Dose Omission	n Rer	ndesivir			S	Unknown	200 Mg		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Con	rol # 503B Fa	acility Age	<u>Sex</u>	Country
27-May-2020	17830843	EXPEDITED (15-DAY)		C	ΣT	CH-JNJF0 20200514	=	61 YR	Female	CHE
	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>N</u>	<u>lfr</u>
Preferred Term					S	Unknown				Janssen
<u> </u>	Hal	dol			_					
.		dol triaxone			S	Unknown			1	Not Reported
Preferred Term Rash Erythematous	Cef									Not Reported 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	Olikilowii	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/ Diamox /00016901/ Diamox /00016901/ Distraneurin /00027501/ Novorapid Ipramol Heparine /00027701/ Lexotanil Movicol Morphine Nozinan /00038601/ Solu-Medrol Dexdor Dexdor Dexdor Sintenyl		Olikilowii	Not Reported
Sintenyl Dormicum /00036201/ Dormicum /00036201/ Dormicum /00036201/ Noradrenaline /00127501/ Noradrenaline /00127501/	00000		Not Reported



		N dramatina /00497504/				Dotalioa No	Port			
	Pro Pro Pro Pro Roc Trac Trac	adrenaline /00127501/ pofol pofol pofol curonium crium crium			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17831674	EXPEDITED (15-DAY)		(OT	US-GILEAD-20 0468136	20-	52 YR	Female	e USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypertension	Rer	ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Rer	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Dige	oxin			С		Unk			Not Reported
	End	xaparin			С		Unk			Not Reported
	Fur	osemide			С		Unk			Not Reported
	Hyd	Iralazine			С		Unk			Not Reported
	Los	artan			С		Unk			Not Reported
		hylprednisolon thylprednisolone]			С		Unk			Not Reported
		pivolol			С		Unk			Not Reported
	Нус	Iroxychloroquine			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833395	DIRECT	Υ	[DE			63 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Death	Rer	ndesivir	Υ		S	Intravenous drip				Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833398	DIRECT	Υ					41 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Ren	ndesivir	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833410	DIRECT	Υ	0	Т			67 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Ace Asc Ceft Dex Dox Hep Hyd Lop Pota Sod Mul Onc Dex Zinc	ndesivir Injection staminophen sorbic Acid triaxone samethasone sycycline sarin dralazine eramide assium Chloride dium Chloride tivitamin dansetron stromethorphan-Guaifenesin c Sulfate cusate-Senna	Y		» 00000000000000	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833414	DIRECT	Υ	0	Т			53 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Acute	ress Ren	ndesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Respiratory Failure;	Ami	iodarone Infusion			С					Not Reported

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Alanine Aminotransfer		axone			С					Not Reported
Increased; Aspartate		tamine Infusion			C C					Not Reported
Aminotransferase Increased; Blood Alka		cycline Iv aparin 40mg Q12			C					Not Reported Not Reported
Phosphatase Increase		apann 40mg Q12 otidine 20mg Iv Q12			C					Not Reported
Blood Bilirubin Increas		anyl Infusion			C					Not Reported
Blood Creatinine		ocortisone 50mg lv Q6hr			Č					Not Reported
Increased; Hypoxia;		zolam Infusion			Č					Not Reported
Shock; Viral		oinephrine Infusion			Č					Not Reported
Cardiomyopathy		ylephrine Infusion			C					Not Reported
, , ,	Propo	ofol Infusion			С					Not Reported
		ım Bicarbonate Inusion			С					Not Reported
		pressin Infusion			С					Not Reported
	Digo	rin Bolus Iv			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833420	DIRECT	Υ	D	E			64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Hypotension	Remo	desivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833421	DIRECT	Υ	0	Т			24 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Epigastric Discomfort; Nausea	; Remo	desivir			S	Intravenous (not otherwise specified	Other Frequency:Once;		1	Gilead
	Asco	rbic Acid			С					Not Reported
		astatin			С					Not Reported
		romycin			С					Not Reported
		axone			С					Not Reported
		aparin			С					Not Reported
	lohex	ol			С					Not Reported
						Mfr Control	# 503B Facility	٨٥٥	Cov	Country
FDA Received Date	Case #	Case Type	<u>Health</u>	Prot O	utcomes	WIII COILLIOI	# <u>303B Facility</u>	<u>Age</u>	<u>Sex</u>	Country



Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Pressure Decreased; Cardiac	ed; Cardiac ethargy; Remdesivir chorax; ory Failure Albuterol Ascorbic Acid				S	Intravenous (not otherwise specified)				Gilead
Arrest; Lethargy; Pneumothorax; Respiratory Failure					S	Intravenous (not otherwise specified)				Gilead
toophatory randro					С					Not Reported
					С					Not Reported
	A	torvastatin			С					Not Reported
	A	ztreonam			С					Not Reported
	E	Bisacodyl			С					Not Reported
		Buspirone			С					Not Reported
		Carbidopa-Levodopa			С					Not Reported
		Celebrex			С					Not Reported
	Clonazepam Digoxin				С					Not Reported
					С					Not Reported
		Depakote			С					Not Reported
		ovenox			С					Not Reported
	Fentanyl Guaifenesin Er Metoprolol				С					Not Reported
					С					Not Reported
					С					Not Reported
		Propofol			С					Not Reported
		Risperidone			С					Not Reported
		Dexmedetomindine Additive			С					Not Reported
	Epinephrine Fentalnyl Vancomycin				С					Not Reported
					С					Not Reported
					С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	1783343	3 DIRECT	Υ	0	Т			57 YR	Male	USA
Preferred Term	eferred Term Prod		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfe	rase F	Remdesivir Injection	Υ		S	Intravenous drip				Gilead
Increased; Aspartate	Acetaminophen Albuterol Hfa Ascorbic Acid Aspirin Atorvastatin				С					Not Reported
Aminotransferase					С					Not Reported
Increased					С					Not Reported
					С					Not Reported
					С					Not Reported
		zithromycin			С					Not Reported

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		<u>-</u>					•				
		onide-Formoterol			С						Not Reported
	Ceftria				С						Not Reported
		calciferol			000000000000000000000000000000000000000						Not Reported
		nethasone			C						Not Reported
		ate-Senna			C						Not Reported
	Enoxa				C						Not Reported
		Lispro			C						Not Reported
		Glargine			C						Not Reported
	Linagli				C						Not Reported
	Lisino				C						Not Reported
		orazole			C						Not Reported
		hylene Glycol			C						Not Reported
	Seline				С						Not Reported
	Trama				С						Not Reported
	Zinc S	ulfate			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833438	DIRECT	Υ						43 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Hypokalaemia	Remd	esivir			S	Intravenous bolus			10 DAY		Gilead
	Cefep	me			С						Not Reported
	Enoxa	parin			С						Not Reported
		cysteine Inh. Solution 20%			С						Not Reported
		rol-Ipratropium Inh.			С						Not Reported
	Solution										·
	Amlod	ipine			С						Not Reported
		l Nutrition (Vital Hp)			С						Not Reported
	Famot				Ċ						Not Reported
		cillin/Tazobactam			C C						Not Reported
	Vanco				Ċ						Not Reported
	Fentar				C						Not Reported
		Lispro			Č						Not Reported
	Propo				C						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833450	DIRECT	Υ						52 YR	Female	USA
Preferred Term	<u>Produ</u>		Comp.	OTC	Role	Route	Dosage		<u>Duration</u>	_	<u>Afr</u>

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Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase R	emdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833453	3 DIRECT	Υ		ОТ			49 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OT</u> (C Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase R	emdesivir	Υ		S	Intravenous bolus	Other Frequency:Once;	1 DAY		Gilead
Increased	R	emdesivir	Υ		S	Intravenous bolus		1 DAY		Gilead
	A A	cetaminophen Prn Ibuterol Hfa Mdi scorbic Acid (Vitamin C) 000mg Po Tid			C C C					Not Reported Not Reported Not Reported
		isacodyl Supp Daily Prn			С					Not Reported
	Е	noxaparin 40mg Subq Q12hr			С					Not Reported
		uaifenesin/Codeine Prn Cough			C					Not Reported
		ussionex Po Bid			С					Not Reported
		olu-Medrol 40mg Iv Q12hr Iorphine Iv Prn			C C					Not Reported Not Reported
		odium Chloride Iv Solution			C					Not Reported
		hiamine 100mg Tablet Po Daily	/		Č					Not Reported
		inc Sulfate 220mg Po Daily			Č					Not Reported
		hlorhexidine Swish/Spit Bid			Ċ					Not Reported
		amotidine 20mg Po Bid			С					Not Reported
	M B	Iupirocin 2% Ointment Nasal			С					Not Reported
		hiamine 100mg Iv Daily			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833459	DIRECT	Υ		ОТ			45 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	C Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer ncreased; Glomerular Filtration Rate Increas		emdesivir			S	Intravenous (not otherwise specified)				Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833468	DIRECT	Υ	0	Т			71 YR	Femal	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Pyrexia	Atorv Bume Carve Dexa Fame Insuli Insuli Mela	methasone otidine n Aspart n Detemir tonin penem arin			%00000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833473	DIRECT	Υ					44 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Hepatic Enzyme Increased	Remo	desivir			S	Intravenous (not otherwise specified))			Gilead
	Aztre Leva Prava Siroli	astatin			C C C C C C	,				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833477	DIRECT		0	Т			71 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Pulmonary Embolism	Remo	desivir			S	Intravenous (not				Not Reported

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						otherwise specified)			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833483	DIRECT	Υ	D	E			61 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Respiratory Arrest	Re	mdesivir	Υ		S	Intravenous drip	Other Frequency:Once;		C	Gilead
	Co	vid-19 Convalescent Plasma			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833489	DIRECT	Υ	D	E			83 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Hepatic Failure; Diarrhoea; Malaise; Pyrexia	Acc Ap Ce Ch En: Ga Ins Lac Ma Me Mo Mo Mo Se So	etaminophen ixaban ftriaxone lorhexidine Oral Solution oxaparin rosemide bapentin culin (Lispro, Regular) ctated Ringers tanoprost Drops tanoprost Drops teronidazole otafinil ometasone/Formoterol ontelukast orphine ttassium Chloride rtraline dium Chloride 0.9% Infusion ncomycin			» 000000000000000000000000000000000000	Intravenous bolus				Gilead Not Reported



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

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833490	DIRECT	Υ		DE			76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acidosis; Acute Respiratory Failure;		desivir			S	Intravenous bolus				Gilead
Cough; Dyspnoea; Hypoxia; Renal Impairment; Sepsis		in bime hexidine Oral Solution			C C C				1 1 1	Not Reported Not Reported Not Reported Not Reported
					C C C				1	Not Reported Not Reported Not Reported Not Reported
	Hydro Triad Insuli	Decortisone Iv Paste Wound Dressing n (Glargine, Regular) nted Ringers			000				1 1 1	Not Reported Not Reported Not Reported Not Reported
	Lactu	ilose nesium Sulfate Iv			C C C				1	Not Reported Not Reported Not Reported Not Reported
	Mida Mido				CCC				1	Not Reported Not Reported Not Reported
	Nore	hine Sulfate pinephrine oprazole			C C				1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833492	DIRECT			ОТ			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	l <u>fr</u>
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remo	desivir			S	Intravenous (not otherwise specified)			١	Not Reported

Note: If the field is blank, there is no data.



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833505	DIRECT	Υ		ОТ				56 YR	Female	e USA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>		<u>Mfr</u>
Abdominal Distension General Physical Heal		mdesivir	Υ		S	Intravenous (not otherwise specified	I)				Gilead
Deterioration; Haemoglobin Decreas	Am	niodarone			С						Not Reported
Intestinal Dilatation;	AIL	pumin			С						Not Reported
Intestinal Ischaemia:		anocobalamin			С						Not Reported
Lactic Acidosis; Neutro		lic Acid			С						Not Reported
Count Decreased; Pla	· ne	parin Sq			С						Not Reported
Count Decreased; Ser	_4:_ □II	oxaparin Sq			С						Not Reported
Shock; Supraventricul	га	motidine			С						Not Reported
Tachycardia; Tissue	1 1 1 1 1 1	drocortisone Sodium ccinate			С						Not Reported
Infiltration		dodrine			С						Not Reported
		ıltivitamin									Not Reported
	Nic	cotine Transdermal			C C C						Not Reported
		iamine									Not Reported
	Do	butamine Infusion			С						Not Reported
	Ep	ineprhrine Infusion			C C						Not Reported
		ntanyl Infusion			С						Not Reported
		tamine Infusion			С						Not Reported
		repinephrine Infusion			С						Not Reported
		enylephrine Infusion			C						Not Reported
	Va	sopressin Infusion			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833510	DIRECT	Υ		ОТ				50 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Re	mdesivir			S	Intravenous drip	Othe	r Frequency:Once;	1 DAY		Gilead
	Re	mdesivir			S	Intravenous drip					Gilead
	Ca	oumin Icium Gluconate fepime			C C C	·					Not Reported Not Reported Not Reported

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	Fur Insi Insi Lev Me Par Ser Var Fer Mid	oxaparin osemide ulin Glargine ulin Lispro rofloxacin thylprednisolone ntoprazole traline ncomycin ntanyl lazolam			00000000000		•			Not Reported
	Pro	pofol			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833527	DIRECT	Υ	C	T			69 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Rhabdomyolysis	Rei	mdesivir			S	Intravenous (not otherwise specified)	4 DAY		Not Reported
	Fer Reç Mic Noi Pro Pep Lov	emet ntanyl glan lodrine repinephrine pofol ocid renox umedrol			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833532	DIRECT	Υ	C	T			68 YR	Femal	e USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Rei	ndesivir	Υ		S					Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833533	DIRECT	Υ					64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>.</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified))	1 DAY	No	ot Reported
	Zithro Roce Lover Solun Huma	phin nox nedrol			0000				No No No	ot Reported ot Reported ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833539	DIRECT	Υ	F	Ю			82 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	1
Blood Pressure Increa Headache; Heart Rate Increased; Migraine; Myalgia; Pain; Pruritus Rash Papular	·	desivir Injection	Y		S	Iontophoresis	Other Frequency:Once;		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833545	DIRECT	Υ	C	T			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	[
Blood Creatine Increas Glomerular Filtration R Decreased	,	desivir	Y		S	Intravenous (not otherwise specified)			Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833603	DIRECT	Υ	H	IO, LT			48 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	ŗ

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Bacterial Infection; White Blood Cell Count Increased	Remdesivir Aspirin 81mg Atorvastatin 10mg Famotidine 20mg Furosemide 20mg Lorazepam 2mg Sodium Chloride Vancomycin Heparin Insulin Aspart Insulin Detemir			% C C C C C C C C C C					Not Reported
FDA Received Date Case	<u>Case Type</u>	Heal	h Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020 1783	33610 DIRECT	Υ	0	Т			69 YR	Male	USA
Preferred Term	<u>Product</u>	Comp	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; Pyrexia; Ventricular	Remdesivir			S	Intravenous (not otherwise specified))			Gilead
Tachycardia	Acetaminophen			С	•	,			Not Reported
	Amlodipine			С					Not Reported
	Apixaban			С					Not Reported
	Aspirin Ec			С					Not Reported
	Atorvastatin			С					Not Reported
	Benztropine			С					Not Reported
	Carvedilol			С					Not Reported
	Divalproex			С					Not Reported
	Donepezil			С					Not Reported
	Famotidine Furosemide			C					Not Reported Not Reported
				C					
	Guaifenesin Insulin Glargine			C					Not Reported Not Reported
	Insulin Glargine Insulin Regular Human			C					Not Reported Not Reported
	Ipratropium/Albuterol Inha	ation		C					Not Reported
	Loratadine	ation		Č					Not Reported
	Methylprednisolone Sodiu	m		C					Not Reported
	Succinate	••		J					1101 Hoportou
	Montelukast			С					Not Reported
	Ibrutinib			Č					Not Reported
	Pantoprazole			Č					Not Reported
	Also: Quetiapine, Tamsulo	sin,		Ċ					Not Reported



	Zinc S	Sulfate, & Zosyn								
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833630	DIRECT	Υ					66 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	Remo	desivir			S	Intravenous drip				Not Reported
Increased	Remo	desivir			С	•				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833637	DIRECT	Υ	DI	Ε			73 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Methy	desivir For Eua ylprednisolone aparin n	Y		S C C C					Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833642	DIRECT	Υ	L7	Г			26 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Pulseless Electrical		desivir			S	Intravenous (not otherwise specified)		1 DAY		Gilead
Activity; Transaminase	es Azithı	omycin			С	, ,				Not Reported
Increased	Cefep				С					Not Reported
		um Gluconate			С					Not Reported
		aparin			С					Not Reported
		/lprednisolone			С					Not Reported
		prazole			С					Not Reported
		Sulfate			С					Not Reported
		minophen			C C					Not Reported
		nsetron			C					Not Reported
	Fenta	•			С					Not Reported
	Midaz	zolam			С					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833647	DIRECT	Υ					42 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Tremor	Re	emdesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Ins	oxaparin sulin Glargine (Lantus) sulin Lispro			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833652	DIRECT	Υ	ŀ	HO, OT			80 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase Re	emdesivir	Υ		S	Intravenous (not otherwise specified	Other Frequency:Once;			Unknown
Aminotransferase Increased; International	5 I	temra			С		,			Not Reported
Normalised Ratio	Pla	aquinil			С					Not Reported
Increased; Liver Disord	dor.	eftiraxone			C C					Not Reported Not Reported
Prothrombin Time		oxycycline Incomycin			C					Not Reported
Prolonged	Va				C					Not Reported
		rsemide			Č					Not Reported
		ırdizem			С					Not Reported
	Lip	pitor			С					Not Reported
		otonix			С					Not Reported
		etoprolol XI			С					Not Reported
	Pre	ednisone			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833668	DIRECT	Y					40 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Re	emdesivir			S	Intravenous (not otherwise specified)			Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833677	DIRECT	Υ	DE	≣			77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated Dyspnoea; Hypoxia; Lethargy; Respiratory Disorder	; Remo	desivir			S				Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833720	DIRECT	Υ					57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Infusion Site Extravas	ation Remo	desivir	Υ		S	Intravenous drip	Other Frequency:Once;		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833738	DIRECT	Υ					1 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Product Formulation Administe Product Dispensing Er Product Use Issue; Therapy Interrupted	ered;	desivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833753	DIRECT		DE	≣			80 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Covid-19		desivir desivir			S C					ead t Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833766	DIRECT		0	Γ			62 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Liver Function Test Increased		desivir desivir			S C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17839011	DIRECT	Υ						Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	[
Liver Function Test	Remo	desivir			S	Intravenous drip			No	ot Reported
Increased	Remo	desivir			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17833859	DIRECT	Υ	0	Γ			78 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Disturbance In Attention Lethargy; Oxygen Saturation Decreased; Palpitations; Tremor; Ventricular Tachycard	;	desivir	Y		S	Intravenous (not otherwise specified	Other Frequency:Once (Loading Dose;		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834192	DIRECT	Υ	0	Γ			92 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Acute Kidney Injury; Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased;		desivir desivir			S C					lead ot Reported

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Glomerular Filtration Rate

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834582	DIRECT	Υ		DE				78 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Нурохіа	Remo	desivir	Υ		S	Intravenous (not otherwise specified)					Gilead
	Metop Enoxa Insuli Diltiaz Fenta Morpl Allopu Dexm Loraz	opium orolol aparin n zem nyl nine			000000000000						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834588	DIRECT	Υ		DE, OT				61 YR	Female	uSA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Febrile Neutropenia; Respirate Failure	Tocili	lesivir zumab			S C	Intravenous drip					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834593	DIRECT	Υ		LT				86 YR	Male	USA
Preferred Term	Prod	uct	Comp.	отс	Role	Route	Dosage	Text	Duration		Mfr

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							-			
Alanine Aminotransfera Increased; Aspartate		emdesivir torvastatin	Υ		s C	Intravenous bolus				Gilead Not Reported
Aminotransferase Increased; Therapy Interrupted		orvasiaiii			Ŭ.					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834597	DIRECT	Υ		DE			38 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Condition		emdesivir	Υ		S	Intravenous bolus				Gilead
Aggravated; Hypotension Inflammatory Marker	A	cetaminophen 650mg Tablet			С					Not Reported
Increased; Ventricular		efepime 2g lvpb exmedetomidine 1.4mg/Kg/Hi	r		C C					Not Reported Not Reported
Fibrillation		fusion								Not Reported
		noxaparin 40mg Bid			С					Not Reported
		comidate 20mg Once entanyl 100mcg Once			C C					Not Reported Not Reported
		sulin Glargine 5 Units Bid			Č					Not Reported
		sulin Lispro Sliding Scale			Č					Not Reported
		orazepam 1mg Inj Once			С					Not Reported
		sulin Regular Sliding Scale			С					Not Reported
		idazolam 5mg Inj Once			С					Not Reported
		ropofol Infusion ocuronium Infusion			C C					Not Reported Not Reported
		ancomycin 1250mg Q6h			C					Not Reported
		agnesium Oxide 400mg Bid			Č					Not Reported
		otassium Chloride 40meq Dai	ly		Č					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834603	DIRECT	Υ		DS			51 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blo Creatinine Increased;	ood R	emdesivir	Υ		S	Intravenous bolus	Other Frequency:1 Time 8	k		Gilead
Blood Pressure	Lo	ovenox 40mg			С		····, ,			Not Reported
Decreased; Blood Urea		ocusate With Senna			С					Not Reported
ncreased	F	amotidine			С					Not Reported



							-			
	Ins Lisi Ace Fer Lac Noi Pro	ntus ulin Lispro nopril etaminophen ntanyl Drip etated Ringers repinephrine epofol curonium			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834607	DIRECT		DI	E			92 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>I</u>	<u>Afr</u>
Acute Kidney Injury		mdesivir mdesivir			S C					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834613	DIRECT	Υ	DI	E			86 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Afr</u>
General Physical Hea		mdesivir	Υ		S	Intravenous bolus				Gilead
Deterioration; Hypoxia	COI	nvalescent Plasma cilizumab			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834623	DIRECT	Υ	0	Т			70 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Afr</u>
Transaminases Increa	ased Rei	mdesivir	Υ		S	Intravenous (not otherwise specified)			Gilead
	End Fer	etaminophen oxaparin ntanyl rosemide ulin			C C C C	·				Not Reported Not Reported Not Reported Not Reported Not Reported

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ACCIVIT		ATTON				Detailed Re	eport			
	M Lo Pi	nezolid eropenem orazepam nenylephrine ropofol			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834646	DIRECT	Υ	0	Т			70 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Atrial Fibrillation; Clinic Trial Participant; Produ Use In Unapproved Indication		emdesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834651	DIRECT	Υ	D	E			61 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participan		emdesivir			S	Intravenous (not otherwise specified))	2 DAY		Gilead
Liver Function Test Increased; Multiple Org	gan _{Pi}	orepinephrine Infusion nenylephrine Infusion			C C					Not Reported Not Reported
Dysfunction Syndrome Product Use In Unapproved Indication; Shock	; Va	asopressin Infusion binephrine Infusion			C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834885	DIRECT	Υ	D	E			83 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Clinical Trial Participan Product Use In		emdesivir			S	Intravenous (not otherwise specified))			Gilead
Unapproved Indications Respiratory Failure	· A	zithromycin peracillin/Tazobactam			C C					Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834887	DIRECT	Υ	DE				66 YR	Femal	e USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Palliative Care; Thera Cessation	py Rem	desivir			S	Intravenous (not otherwise specified)			Gilead
	Conv	alescent Plasma			С	· 	,			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834892	DIRECT	Υ	ОТ	-			56 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Clinical Trial Participal Dysphagia; Headache Product Use In Unapproved Indication	e; Conv	desivir ralescent Plasma			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834894	DIRECT	Υ	ОТ	-			74 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Clinical Trial Participal Product Use In Unapproved Indication	nt; Amlo Ibupr	desivir dipine ofen			S C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834895	DIRECT	Υ	ОТ	-			73 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Hepatic Enzyme Increased; Therapy Cessation	Rem	desivir			S	Intravenous drip				Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	1783491	1 DIRECT	Υ					54 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	F	Remdesivir	Υ		S	Intravenous bolus				Gilead
Increased	H	alproic Acid lydroxychloroquine zithromycin			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	1783494	6 DIRECT	Υ		ОТ			65 YR	Male	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		Mfr
Acute Kidney Injury; R Tubular Necrosis	tenal R	temdesivir			S	Intravenous (not otherwise specified)				Gilead
	E S S F M E Z C E M Ir C V Ir	Morphine Duoneb Dextrose 50% Codium Chloride Flush Codium Chloride 250 MI Dotassium Chloride Magnesium Sulfate Dexmedetomidine Cinc Sulfate Defepime Choxaparin Metoprolol Dantoprazole Dumetanide Methylprednisolone Disulin Lispro Chlorothiazide Mancomycin Desulin Detemir Docilzumab			00000000000000000000					Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834965	DIRECT	Υ		OT				49 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Interrupted	Remo	desivir			S	Intravenous drip					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834973	DIRECT	Υ		ОТ				53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	Remo	desivir			S	Intravenous (not otherwise specified	i)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17834979	DIRECT	Υ						84 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Anaemia; Platelet Cou Increased; White Bloo	d	desivir			S	Intravenous (not otherwise specified	d)				Gilead
Cell Count Decreased	Acyci Allopi Aspiri	ovir 400 Mg Po Bid urinol 300 Mg Po Daily in 325 Mg Po Daily ecalciferol 2000 Units Po			C C C	·					Not Reported Not Reported Not Reported Not Reported
	Furos Levot Mero Ruxo	semide 20 Mg Po Bid hyroxine 88 Mcg Po Daily penem 1 Gram Iv Q12h			C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17835864	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0468283	2020-		38 YR	Female	USA

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Preferred Term		Product		Comp.	OTO	<u>Role</u>	Route	<u>e</u>	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>	
Aspartate Aminotransferase		Remdesivir				S		enous (not vise specified)	200 Mg	, Qd			Gilead	
Increased; Aspartate Aminotransferase		Ceftriaxone				С		. ,	Unk				Not Reporte	∍d
Increased; Septic Sho	ck	Heparin				С			Unk				Not Reporte	∍d
		Insulin				С			Unk				Not Reporte	∍d
		Midazolam				С			Unk				Not Reporte	∍d
		Norepinephrine				С			Unk				Not Reporte	∍d
		Azithromycin				С			Unk				Not Reporte	∍d
		Tocilizumab				С			Unk				Not Reporte	∍d
		Vancomycin				С			Unk				Not Reporte	∌d
FDA Received Date	Case #	Case Typ	<u>oe</u>	Health	Prof	Outcomes		Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Count	try
28-May-2020	178377	91 EXPEDIT	ED (15-DAY)			DS, HO, LT,		US-GILEAD-202 0469042	20-		67 YR	Female	USA	
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	<u>e</u>	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>	
Hydronephrosis; Necro Renal Impairment;	osis;	Remdesivir				S		enous (not vise specified)	200 Mg				Gilead	
Respiratory Disorder		Remdesivir				S		enous (not vise specified)	100 Mg	, Qd			Gilead	
		Acetaminophen				С			Unk				Not Reporte	∍d
		Duoneb				С			Unk				Not Reporte	∍d
		Azithromycin				С			Unk				Not Reporte	∍d
		Amiodarone				С			Unk				Not Reporte	∍d
		Cefepime				С			Unk				Not Reporte	∍d
		Potassium Chloride	Э			С			Unk				Not Reporte	∍d
		Tocilizumab				С			Unk				Not Reporte	∌d
	Case #	Case Typ	<u>oe</u>	<u>Health</u>	Prof	Outcomes		Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Count	try
FDA Received Date														

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							10000			
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	N	<u>lfr</u>
Hypotension; Renal	Remo	desivir			S	Intravenous drip			ı	Not Reported
Impairment	Aspir Atorv Mida	omycin			00000	·			 	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838778	DIRECT	Υ		ОТ			51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatine Phosphokinase Increa		desivir			S	Intravenous (not otherwise specified)			(Gilead
		astatin Tablet axone Injection			C C					Not Reported Not Reported
	Enox	aparin Injection			С					Not Reported
		semide Injection enesin Tablet			C C					Not Reported Not Reported
		oxychloroquine Tablet			C					Not Reported
		oprazole Capsule			Č					Not Reported
		hyroxine Tablet			С					Not Reported
		ylprednisolone Injection			С					Not Reported
		prazole Tablet			С					Not Reported
		omycin Injection			С					Not Reported
		ofol Injection			С					Not Reported
		minophen Tablet			С					Not Reported
		zolam Tablet			С					Not Reported
		epam Injection			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838938	DIRECT	Υ					33 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfera	ase Remo	desivir	Υ		S	Intravenous drip			(Gilead

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							, p - 1 - 1			
Aminotransferase Increased										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838945	DIRECT	Υ		ОТ			60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Transaminases Increa	ised Remo	desivir			S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838949	DIRECT	Υ					90 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Glomerular Filtration R Decreased; Therapy	Rate Remo	desivir	Υ		S	Intravenous (not otherwise specified)			(Gilead
Cessation	Vanc	omycin			С				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838954	DIRECT	Υ		ОТ			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Renal Failure	Remo	desivir	Υ		S	Intravenous drip			(Gilead
	Cefep	ex romycin oime omycin			000000	·			1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838955	DIRECT	Υ		ОТ			63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>

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Acute Kidney Injury; Ischaemic Hepatitis;	Remo	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Transaminases Increas	sed Azithi	omycin			С	,				Not Reported
		axone			Č					Not Reported
		methasone			C C					Not Reported
		aparin			Č					Not Reported
		tidine			C C					Not Reported
	Fenta	inyl			C					Not Reported
		n Glargine			С					Not Reported
		n Lispro			С					Not Reported
		ylephrine			C C					Not Reported
	Piper	acillin/Tazobactam			С					Not Reported
	Propo	ofol			С					Not Reported
		ronium			С					Not Reported
	Zinc	Sulfate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838959	DIRECT	Υ	Н	O, LT			63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838962	DIRECT	Y					73 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate	Remo	desivir			S	Oral				Gilead
Aminotransferase	Cefer	nime			С					Not Reported
Increased	Fenta				Č					Not Reported
	Propo				Č					Not Reported
		razole			Ċ					Not Reported
		pentin			C C					Not Reported
		zapine			С					Not Reported
		/lprednisolone			С					Not Reported
		aparin			С					Not Reported
	Aspiri				С					Not Reported

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	Prazo	otidine osin sulosin			C C				N	lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838968	DIRECT	Υ					82 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
International Normalise Ratio Increased		desivir is 2.5mg Q12h	Υ		S C	Intravenous drip				ilead lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838972	DIRECT	Υ	LT	ī			34 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Ventricular Tachycardi	ia Remo	desivir	Υ		S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838976	DIRECT	Υ					71 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Chills; Hypotension; Infusion Site Extravasation; Infusion Site Reaction; Nausea	1	desivir			S	Intravenous drip			G	bilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838982	DIRECT	Υ	0	Т			62 YR	Male	USA
<u>Preferred Term</u>	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration R		desivir			S	Intravenous drip			G	bilead

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Decreased										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838987	DIRECT	Υ					91 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Glomerular Filtration F Decreased	Rate Remd	lesivir	Υ		S	Intravenous (not otherwise specified))		Gil	ead
	Vanco	omycin			С				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838988	DIRECT	Υ	(ОТ			49 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration F Decreased	Rate		Usalila	Desc.	S	Intravenous drip	Other Frequency:Once;	A		ead
FDA Received Date		Case Type			<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838991	DIRECT	Y	(TC			74 YR	Female	USA
Preferred Term	<u>Prod</u> ı	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration F		lesivir			S	Intravenous drip			Gil	ead
Decreased; Therapy Cessation						Mfr Control	# 503B Facility	Ago	Sex	Country
	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	WIII CONTROL	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Cessation	<u>Case #</u> 17838994	Case Type DIRECT	<u>Health</u> Y	<u>Prof</u> (<u>Outcomes</u>	MIT CONTROL	503B Facility	77 YR	Female	USA

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

Gilead

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838997	DIRECT	Υ						32 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>'r</u>
Hepatotoxicity	Remo	lesivir			S	Intravenous drip				G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839001	DIRECT	Υ	L	Г, ОТ				78 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	<u>'r</u>
Acute Kidney Injury	Remo	lesivir			S	Intravenous drip				G	ilead
		ronium			С						ot Reported
	Sodiu Fenta	m Bicarbonate 50 Meq			C						ot Reported ot Reported
		n Drip			С						ot Reported
	Morpl				С						ot Reported
	Propo Zosyr				C						ot Reported ot Reported
	•	omycin			C						ot Reported
	Bume				C						ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839004	DIRECT	Υ	0	Т				82 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
White Blood Cell Cour Decreased	nt Remo	lesivir	Υ		S	Intravenous (not otherwise specified)	١			N	ot Reported
	Aceta	minophen			С	outerwise specificu,	,			N	ot Reported



						Dotanoa itt	port			
	Allop	urinol			С					Not Reported
		darone			С					Not Reported
	Aspir	in			С					Not Reported
		astatin			C C					Not Reported
	Card	idopa-Levodapa			С					Not Reported
	Diltia				С					Not Reported
		aparin			С					Not Reported
		semide			С					Not Reported
		ocodone-Acetaminophen			C C					Not Reported
		n Aspart			С					Not Reported
		n Glargine			С					Not Reported
		ylprednisolone			С					Not Reported
		prolol Tartrate			С					Not Reported
	Sertr				С					Not Reported
	Topir	amate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839023	DIRECT	Υ	D	E			73 YR	Male	USA
			-							
Droformed Torm	Drod	luet	Comp	OTC	Dolo	Doute	Deceme Text	Duration		ME.
<u>Preferred Term</u>	Prod		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Vifr</u>
Ventricular Fibrillation	Remo	desivir			S	Intravenous drip	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839025	DIRECT	Υ					54 YR	Male	USA
		2(20)	·					• • • • • • • • • • • • • • • • • • • •		00.1
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mf <u>r</u>
									_	<u></u>
Acute Kidney Injury	Remo	desivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839026	DIRECT	Υ	D	F			88 YR	Female	AFG
		2	•					00		C
D. C I T		14	•	0.70	Б.1	5 . 4.	B	5		ane.
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	Ī	<u>VIfr</u>
	. Dom	desivir			S	Intravenous drip				Gilead
Hypotension; Hypoxia;	, Remo									
Hypotension; Hypoxia; Skin Discolouration		romycin			С	•				Not Reported

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	Ceftri Pumo	axone ozyne			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839552	DIRECT	Υ	I	HO, RI, OT			94 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>VIfr</u>
Thrombocytopenia	Remo	desivir 100mg/20ml			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839768	DIRECT	Υ					32 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Liver Function Test Increased	Remo	desivir	Υ		S	Intravenous drip				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839763	DIRECT	Υ					76 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Wfr</u>
Ventricular Tachycardi	a Remo	desivir Injection			S	Intravenous bolus	Other Frequency:200mg X1;			Gilead
	Enox Meto _l Prazo	dipine aparin orolol XI osin enecid			C C C C		•			Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839790	DIRECT	Υ	I	DE			81 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>VIfr</u>

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Dialysis; Renal Failure	; Remo	lesivir			S	Intravenous bolus					Gilead
Tachypnoea	Aceta	minophen			С						Not Reported
	Amloo				С						Not Reported
	Aspiri				С						Not Reported
	· ·	astatin			С						Not Reported
	Benzo	onatate			C C						Not Reported
	Norm	osol-R			С						Not Reported
	Enoxa	aparin			С						Not Reported
	Fenta				С						Not Reported
		emide			C C						Not Reported
	Guaif	enesin/Codeine			С						Not Reported
	Hepa				С						Not Reported
		ochlorothiazide			C C						Not Reported
		morphone			С						Not Reported
		n (Glargine, Lispro And			С						Not Reported
	Regu										•
	Labet				С						Not Reported
	Lacta	ted Ringers			С						Not Reported
		hyroxine			C C						Not Reported
	Lidoc	aine/Epinephrine			С						Not Reported
	Loraz	epam ·			C						Not Reported
		esium Sulfate			С						Not Reported
	Morpl	nine			С						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839798	DIRECT	Υ		DE				74 YR	Male	USA
20 May 2020	17000700	DIRECT	'	'	<i></i>				74 110	Maic	OOA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury;	Remo	lesivir			S	Intravenous (not					Gilead
Haemodialysis;						otherwise specified)					
Pneumothorax;	Conv	alecent Plasma			С	,					Not Reported
Pseudomonal		zumab Or Matching			Č						Not Reported
Bacteraemia	Place										
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839805	DIRECT	Υ	ı	DE				75 YR	Female	USA
,											
Preferred Term				OTC			Dosage				<u>Mfr</u>

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						201000	P P			
Fluid Overload; Hypotension	Remo	lesivir Solution			S	Intravenous (not otherwise specified)			Gilead
	Conv	alescent Plasma			С	•				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839841	DIRECT	Υ		ОТ			48 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Feeling Hot; Flushing; Infusion Related Reac		desivir			S	Intravenous (not otherwise specified	Other Frequency:Once Then 100mg X4;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839991	DIRECT	Υ		ОТ			54 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	desivir			S	Intravenous drip				Not Reported
Increased; Therapy Cessation	Azithı Ceftri Enoxa	minophen romycin axone aparin omycin			0000	·				Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840013	DIRECT	Υ		DE			67 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	lesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840020	DIRECT	Υ		ОТ			34 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	lesivir			S					Not Reported

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

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840027	DIRECT	Υ		ОТ			65 YR	Male	USA
Preferred Term	<u>Pı</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased; Dialysis; Disease Progression	As At Ca Ca Ca Er Fu Hy La Na Mi Ta At Da Pr	emdesivir spirin ovastatin alcium Citrate/Vitamin D efazolin efepime soxaparin srosemide rdrocortisone nsoprazole aloxegol ultivitamin scrolimus enofovir racurium exmedetomidine entanyl orepinephrine opofol asopressin	Y		%0000000000000000000000000000000000000					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840033	DIRECT	Υ		ОТ			55 YR	Male	USA
Preferred Term	<u>Pı</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Continuous	Re	emdesivir			S	Intravenous (not				Gilead

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Haemodiafiltration;

Creatinine Renal

Clearance Decreased;

Endotracheal Intubation;

Renal Impairment;

Therapy Cessation

otherwise specified)

EDA Possived Date	Casa #	Coco Typo	Hoolth	Drof (Outcomes	Mfr Control	# E02D Equility	٨٥٥	Sov	Country
	Case #	Case Type			<u>Outcomes</u>	wir Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840034	DIRECT	Y		DE			71 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Cardiac Ari Cardio-Respiratory Arr Pulse Absent; Shock	rest;	desivir	Y		S	Intravenous drip	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840052	DIRECT	Υ	(T			55 YR	Male	XQZ
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Bilirubin Increas	ed Remo	desivir			S	Intravenous drip				Not Reported
	Propo Nore Mida: Hydro Fluox Fenta	pinephrine zolam omorphone cetine anyl axone			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840058	DIRECT	Y	(T			64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remo	desivir			S	Intravenous bolus				Gilead

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Increased; C-Reactive	Acet	rlcysteine 20% Oral			С		•			Not Reported
Protein Increased; Fibrii					J					Not Nepolied
Dimer Increased;		onam			С					Not Reported
Glomerular Filtration Ra	ate Furos	semide			С					Not Reported
Decreased; Haematuria	i; Levot	floxacin			С					Not Reported
Interleukin Level		zumab			C					Not Reported
Increased; Seizure		aminophen			С					Not Reported
	Albut				С					Not Reported
		ine 1% (Orally)			С					Not Reported
		dogrel			С					Not Reported
	Docu				С					Not Reported
		rin Subq			С					Not Reported
		hyroxine			C					Not Reported
	Mida	zoiam oinephrine			C					Not Reported Not Reported
		prazole			C					Not Reported
	Propo				C					Not Reported
FDA Received Date		Case Type	Health	Prof O	utcomes	Mfr Control :	# 503B Facility	Age	Sex	Country
29-May-2020	17840084	DIRECT	Y					79 YR	Male	USA
29-1VIAY-2020	17040004	DIRECT	Ĭ					79 TK	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Off Label Use	Remo	desivir	Υ		S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840087	DIRECT	Υ	D	E			73 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Disease Progression; Hypoxia; Respiratory Failure; Severe Acute Respiratory Syndrome	Remo	desivir 100mg/20 Ml			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	,			Gilead
	Aspir	in			С					Not Reported
		astatin			С					Not Reported
		romycin			Č					Not Reported
		dopa-Levodopa			С					Not Reported
	Done				С					Not Reported
	Глач	aprin			С					Not Reported



							Dotalioa No	port			
	L II N S	tomidate ispro nsulin Metoprolol Montelukast solifenecin ccetaminophen				C C C C C C C					Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facili	ity Age	<u>Sex</u>	Country
29-May-2020	1784021	3 DIRECT		Υ	[DE			68 YR	Male	USA
Preferred Term	E	Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Distributive Shock; Dru Ineffective	ug F	temdesivir 100mg/20 N	∕ll Eua			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Frequency 4x			Gilead
	E H II F N S S Z A F A C F N F F	colace cliquis clumalog climalog climal	1			00000000000000000					Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facili	ity <u>Age</u>	<u>Sex</u>	Country
29-May-2020	1784026	6 DIRECT		Υ	(ОТ			67 YR	Male	USA
Preferred Term	E	Product		Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Acute Kidney Injury; Bl Bilirubin Increased; Blo		esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Creatinine Increased; Dehydration; Hypotens Transaminases Increased	sion; Fental Norep Rocur Furos Gabap Loven Famol Lactat	ox tidine red Ringers minophen nine			00000000000	otherwise specified)				Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
29-May-2020	17840269	DIRECT	Υ	C	DT			77 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
		emide Iv emide Po			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17841424	EXPEDITED (15-DAY)		C	DΤ	US-GILEAD-20 0468719	20-	56 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Norep	inephrine			С		2-10 Mcg/Min			Not Reported
	Album	minophen nin omycin			0000					Not Reported Not Reported Not Reported



	(Ceftriaxone Clonazepam Desmopressin Docusate Enoxaparin Epoprostenol Famotidine Fentanyl Furosemide Heparin Hydromorphone Ketamine nsulin Midodrine Phenylephrine			000000000000000000000000000000000000000		25-50	Mcg/Min			Not Reported
	 	Rocuronium Sennosides Dopamine			C C C		1-7 M	cg/Kg/Min			Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	1784142	7 EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0468705	20-		69 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	Duration		<u>Mfr</u>
Acute Kidney Injury; Bl Creatinine Increased; Blood Urea Increased	 	Remdesivir nsulin Aspart Metoprolol Disatracurium Norepinephrine			S C C C	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead Not Reported Not Reported Not Reported Not Reported
		Propofol Fentanyl /asopressin /ancomycin Cefepime Enoxaparin Pantoprazole Focilizumab Digoxin			000000000000						Not Reported



	Furos Metol Insuli	tonin in [Acetylsalicylic Acid] semide lazone in Glargine rastatin			00000					N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17842483	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468473)20-		59 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role Role	<u>Route</u>	Dosage '	<u>Text</u>	Duration	<u>M</u> :	<u>fr</u>
Transaminases Increa	ased Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	, Once		G	ilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd		G	ilead
	Hydro	omorphone			С					N	ot Reported
	Aceta	aminophen			С					N	ot Reported
	Zofra	n [Ondansetron]			0000000						ot Reported
	Vitam	nin D3			С					N	ot Reported
		ac [Calcium Carbonate]			С						ot Reported
	Sero				С						ot Reported
		um Gluconate			С						ot Reported
		[Furosemide]			С						ot Reported
		nox [Enoxaparin Sodium]								N	ot Reported
	Mirala				С						ot Reported
		dryl [Diphenhydramine ochloride]			С					N	ot Reported
	Levo				С						ot Reported
		nesium Sulfate			С						ot Reported
		ssium Chloride			00000						ot Reported
	Cloza				С						ot Reported
	Propo				С						ot Reported
		ate [Etomidate]			С						ot Reported
	Queli				C						ot Reported
	Fenta				C						ot Reported
	Verse				C						ot Reported
		uline Regular			C					N	ot Reported
	Huma				С						ot Reported
	Ance	f [Cefazolin Sodium]			С					N	ot Reported



							-				
	Flagyl Rocep Vanco Zenpe Prilose	ec [Omeprazole] sium Bicarbonate ron			00000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17842537	EXPEDITED (15-DAY)		DE	, OT	US-GILEAD-2 0468948	2020-		85 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17844971	DIRECT	Υ						71 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Bradycardia	Guaife Hydro Loper Metop Omep Polyet Spiror Tamsi	cone` entin line an oroex cine us Gluconate enesin xyzine amide orolol Succinate XI razole chylene Glycol nolactone			s 000000000000000000	Intravenous drip	Other	Frequency:Once;			Not Reported

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	Zosyr Saline				C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17844976	DIRECT	Υ		НО			27 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified)			(Gilead
		onin ıminophen aparin			C C C C C				1 1 1	Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17844978	DIRECT	Υ		ОТ			61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Atrial Fibrillation; Hear Rate Irregular	t Remo	desivir			S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17844983	DIRECT	Υ					47 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Disease Progression; Hyperhidrosis; Hypotension	Remo Lover	desivir nox	Υ		S C	Parenteral				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17844998	DIRECT	Υ		НО			77 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>

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Acute Kidney Injury	Remo	desivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17845001	DIRECT	Υ		ОТ			60 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>r</u>
Alanine Aminotransfer Increased; Blood Creatinine Increased; International Normalis Ratio Increased; Thera Cessation	ed	desivir	Y		S	Intravenous bolus			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17845002	DIRECT	Υ		DS			33 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>'r</u>
Hypoxia; Quadripares	is Remo	desivir			S	Intravenous drip	Other Frequency:X1 Loading Dose;		G	ilead
	Senn				С					ot Reported
	Melat	onin otidine			С					ot Reported ot Reported
		aparin			C C C					ot Reported
		cycline Iv			Č					ot Reported
		amycin Iv			С				N	ot Reported
		methasone			С					ot Reported
		axone			C C C					ot Reported
	Glyco				С					ot Reported
	Perid				C C C					ot Reported ot Reported
	Prece	minophen Po			C					ot Reported
	Fenta				Č					ot Reported
	Propo				Č					ot Reported
		ovir Iv			C C C					ot Reported
	Etom				Ċ					ot Reported
		paque			С				N	ot Reported
	Loraz	epam			С				N	ot Reported
	Midaz	zolam			С				N	ot Reported

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		ronium omycin			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17845005	DIRECT	Υ						23 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera	ase Remo	desivir			S					١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17845007	DIRECT	Υ	O	Г				75 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Renal Impairment	Remo	desivir			S	Intravenous drip				(Silead
	Osmo	olite 1.5 Cal Liquid			С	•				١	Not Reported
		astatin 10mg At Bedtime			С						Not Reported
		hexidine Mouthwash			С						lot Reported
		pin 10mg			С						Not Reported
		re Clnical Health romycin Opth Ointment			C C						Not Reported Not Reported
		e Daily			C					I.	Not Reported
		semide 40mg Iv Once			С					١	Not Reported
	Hepa	rin In D5w 25000 Unit Bag			С					1	Not Reported
		ofol 1000mg Titration			С						Not Reported
	Sodiu 50ml/	ım Chloride 0.9% @ 'Hr			С					N	lot Reported
	Aceta	aminophen 325mg Tablet			С						Not Reported
		epam 1mg Injection Once			С						Not Reported
		inephrine 4mg In 500ml			С					١	Not Reported
		ose 5%			0						lat Danamari
		oxychloroquine 200mg n Lispro Per Sliding Scale			C C						Not Reported Not Reported
		thyroxine 137mcg Per Dose			C						Not Reported
		ylprednisolone 125mg lv			C						Not Reported
		6 Hrs			Ü					•	.ctoponou
		ga 3 Fatty Acid 2000mg			С					١	Not Reported
	Twice	e Daily									

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							Dotanoa Ito	port			
		Pantoprazole 40	Omg Iv Twice			С					Not Reported
		Propranolol 40n Sertraline 25mg				C C					Not Reported Not Reported
FDA Received Date	Case #	Case	<u>Type</u>	<u>Health</u>	Prof Ou	tcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	178450)12 DIREC	т	Υ	НС	O, OT			44 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase	Remdesivir				S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Blood Alkal		Cobicistat/ Elvitegravir/Emt	racitahine			С					Not Reported
Phosphatase Increase Blood Creatinine Increased; Therapy Interrupted; Transaminases Increa	sed	Atorvastatin Doxycycline Omnipaque Ceftriaxone Norepinephrine Cisatricarium Cholecalciferol Ascorbic Acid Folic Acid Multivitamin Codeine-Guifen	esin Type	<u>Health</u> Y	Prof Ou	C C C C C C C C	Mfr Control s	± 503B Facility	Age 70 YR		Not Reported
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Angioedema; Therapy Interrupted		Remdesivir Azithromycin Duoneb Ascorbic Acid Budesonide Chlorhexadine Enoxaparin Lasix Lantus		Y		80000000					Gilead Not Reported

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						Detailed Re	port			
	M C F Z C E F	actobacillus Methylprednisolone Dxycodone Pantoprazole Zosyn Disatracurium Dexmedetomidine Fentanyl Propofol			000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	1784505	9 DIRECT	Υ	[DE			76 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	F	Remdesivir			S	Intravenous bolus	Other Frequency:X1;			Gilead
	F	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
	ľ	Kaletra 400/100 Mg Bid Po vermectin 9mg Po Q48h X2 Doses			C C					Not Reported Not Reported
		Actemra 400mg X1			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	1784506	5 DIRECT	N	[DE			59 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acidosis; Aci	ute F	Remdesivir			S	Intravenous drip				Gilead
Kidney Injury; Blood Creatinine Increased;	F	Remdesivir			S	Intravenous drip				Gilead
Blood Pressure Systol	. •	Convalescent Plasma Azithromycin			C C					Not Reported Not Reported
Decreased; Bronchitis Hypotension; Multiple		Medrol			С					Not Reported
Organ Dysfunction		Amlodopine Ascorbic Acid			C C					Not Reported
Syndrome; Oliguria; Pneumonia; Renal		Seftriaxone			C					Not Reported Not Reported
Impairment; Respirato	ry L	ovenox			С					Not Reported
Failure; Sepsis		nsulin Lispro Zosyn			C C					Not Reported Not Reported
		-00y11			U					140t Neported

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	Verse Nore _l Propo	pinephrine			00000				N N N	ot Reported ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17845068	DIRECT	Υ					61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Infusion Site Extravasation; Periphe Swelling		desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17846418	DIRECT	Υ	F	RI, OT			63 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Atrial Fibrillation	Remo	desivir 100mg/20ml			S	Intravenous (not otherwise specified)			G	ilead
	Remo	desivir 100mg/20ml			S	Intravenous (not otherwise specified)			G	ilead
	Remo	desivir 100mg/20ml			S	Intravenous (not otherwise specified)			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17846473	DIRECT	Υ	F	RI, OT			76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>fr</u>
Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Crea Phosphokinase Increa Blood Lactate	atine	desivir 100mg/20ml Vial			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			G	ilead

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

FDA Received Date	Case # Case Type	<u>Healtl</u>	Prof O	<u>Outcomes</u>	Mfr Control #	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845070 DIRECT	Υ	D	E, HO, LT			68 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>r</u>
Death	Emergency Use Remdesiv	r Y		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;		G	ilead
	Emergency Use Remdesiv	r Y		S	Intravenous (not otherwise specified)	-)		G	ilead
	Acetominopohen			С				N	ot Reported
	Amlopidine			C C				N	ot Reported
	Anastrozole			С					ot Reported
	Ascorbic Acid			0000				N	ot Reported
	Atorvastatin			С					ot Reported
	Azithromycin			C					ot Reported
	Cefepime			C					ot Reported
	Clopidogrel								ot Reported
	Combivent Respimat			C					ot Reported
	Compazine			C C C					ot Reported
	Cholecalciferol			C					ot Reported
	Clonidine			C					ot Reported
	Coreg			С					ot Reported
	Cyanocobalamin			C C					ot Reported
	Docusate Senna			C					ot Reported
	Donepezil			С					ot Reported
	Enoxaparin			C C					ot Reported
	Famotidine			C					ot Reported
	Ferrous Sulfate			C C					ot Reported
	Folic Acid			C					ot Reported
	Gabapentin			С				N	ot Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845071	DIRECT	Υ	Н	0			73 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Acute Kidney Injury; Cerebrovascular Accid Mental Status Change	lent;	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Loading/Once Daily;		G	ilead
	Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Loading/Once Daily;		G	ilead
	Venla	afaxine			С					ot Reported
	Topa	max			C C					ot Reported
	Nam				С					ot Reported
	Imdu				С					ot Reported
	Neur				C C C					ot Reported
		Ellipta			C					ot Reported
	Pepo				C					ot Reported
	Aspir				C					ot Reported
	Card				С					ot Reported
		tiracetam			C					ot Reported
		bivent			C					ot Reported
	Hepa				C					ot Reported
	Dext				0000000					ot Reported
	Morp				C					ot Reported
	Roce Zithro				C					ot Reported
					C					ot Reported of Reported
	Nysta Card				C					ot Reported
	Tyler				C					ot Reported
	Eliqu				C					ot Reported
		um Chloride			C					ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
30-May-2020	17845076	DIRECT	Υ	0	Т			64 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>

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Bradycardia	Remo	desivir	Υ		S	Intravenous bolus			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845081	DIRECT	Υ	(DΤ			69 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Laryngeal Oedema; Periorbital Swelling; Peripheral Swelling; Peripheral Swelling	Remo	desivir	Y		S	Intravenous bolus			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845085	DIRECT	Υ	(DΤ			69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remo	desivir	Υ		S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	Age	<u>Sex</u>	Country
30-May-2020	17845113	DIRECT	Υ	(TC			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Infusion Related Read Nausea	tion; Remo	desivir			S	Intravenous (not otherwise specified)		7 DAY	Gil	ead
	Remo	desivir			С				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845123	DIRECT	Υ	(TC			55 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)			Gil	ead

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FDA Received Date 30-May-2020	<u>Case #</u> 17845128	Case Type DIRECT	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	Age 48 YR	<u>Sex</u> Male	<u>Country</u> USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Intercepted Product Preparation Error; Prod Preparation Error	Remd duct	esivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845130	DIRECT	Υ	Н	O, OT			70 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Methy Enoxa Lisino				C C C	outerwise specifical				Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17846348	DIRECT		Н	0				Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Infusion Site Pain	Remd	esivir (Eua)			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17846639	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0469017	20-	82 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Hypoxia	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Famot	tidine			С	. ,	Unk			Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-May-2020	17845136	DIRECT	Υ					63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Chronic Kidney Diseas		lesivir (Eua)	Υ		S	Intravenous (not otherwise specified)				Gilead
	Remo	lesivir (Eua)			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-May-2020	17845140	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Haemorrhage; Thrombocytopenia	Remo	lesivir			S	Intravenous drip				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846453	DIRECT	Υ					61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
	Losar Metfo Tocili: Aspiri Cefur Famo Gaba Guaif	rmin Er zumab n oxime tidine pentin enesin ocholorthiazide			00000000000					Not Reported

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FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846476	DIRECT	Υ					39 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera Increased; Liver Functi		esivir			S	Intravenous (not otherwise specified)			C	Gilead
Test Increased	Loven Ondar Trama	nsetron			C C C C				N N	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846480	DIRECT	Υ					51 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Dose Omissio	n Remd	esivir			S	Intravenous (not otherwise specified)			١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846502	DIRECT	Υ	Н	10			59 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Therapy Cessation	ase Remd	esivir			S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846513	DIRECT		0	T			57 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>M</u>	·



Hyperphosphataemia	Rem	desivir			S	Intravenous (not otherwise specified)				Not Reported
	Ceftr	iaxone			С	,				Not Reported
	Docu	ısate Sodium			С					Not Reported
	Etom	nidate			С					Not Reported
	Famo	otidine			С					Not Reported
	Furo	semide			C C C					Not Reported
	Insul	in Detemir			С					Not Reported
		in Humalog			С					Not Reported
		nesium Sulfate			С					Not Reported
		lazone			C C C					Not Reported
		prolol			С					Not Reported
		na Liquid			С					Not Reported
		etanide Drip			C C					Not Reported
		anyl Drip			C					Not Reported
		arin Infusion			С					Not Reported
	Insul	in Human Regular			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846521	DIRECT		C	T			57 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr_
Thrombocytosis	Rem	desivir			S	Intravenous (not otherwise specified)				Not Reported
	Ceftr	iaxone			С					Not Reported
		isate Sodium								Not Reported
		nidate			C C C					Not Reported
	Famo	otidine			С					Not Reported
	Furo	semide			С					Not Reported
	Insul	in Detemir			C C					Not Reported
	Insul	in Humalog			С					Not Reported
	Magı	nesium Sulfate			С					Not Reported
		lazone			C C C					Not Reported
	Meto	prolol			С					Not Reported
		na Liquid			С					Not Reported
		etanide Drip			С					Not Reported
		anyl Drip			С					Not Reported
		arin Infusion			С					Not Reported
	Insul	in Human Regular			С					Not Reported



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17846712	DIRECT	N	С	ÞΕ			68 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19		lesivir 5mg/Ml entrated Solution	Υ		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Dose Or Amount:	2		Gilead
	Conva	alescent Plasma 213 MI			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17847828	EXPEDITED (15-DAY)				US-GILEAD-20 0468846	020-	67 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Administration Error; Product Storage Error		lesivir			S	Unknown	Unk			Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17848017	EXPEDITED (15-DAY)		L	T, OT	US-GILEAD-20 0469288	20-	79 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Blood Urea	Remd	lesivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
Increased	Remd	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Cefep	zumab iime omycin			C C C					Not Reported Not Reported Not Reported
	Fenta Midaz	nyl			C C C					Not Reported Not Reported
	Propo Album Famo	nin			C C C					Not Reported Not Reported Not Reported
	Aspiri				C					Not Reported

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						Detailed N	Sport			
	Enoxa Insuli Cisati Meroj Simva	semide aparin n racurium penem astatin nin D [Colecalciferol]			C C C C C C C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17848022	EXPEDITED (15-DAY)			HO, LT, OT	US-GILEAD-2 0469201	020-	48 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Endotracheal Intubation	Aspiri Atorv Famo Furos Loraz Sodiu Vano Hepa Insuli Norep	desivir in [Acetylsalicylic Acid] astatin atidine semide sepam um Chloride omycin rin n Aspart n Detemir binephrine axone			8 00000000000	Unknown	Unk			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17848028	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-2 0469174	020-	76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Renal Impairment	Remo	desivir			S	Intravenous (not otherwise specified	200 Mg)			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified	100 Mg, Qd)			Gilead
		erol [Salbutamol]			С		Unk			Not Reported
	Aspiri	in [Acetylsalicylic Acid]			С		Unk			Not Reported



	Cefepi	me		С	Unk				Not Reported
	Chlorh	exidine		С	Unk				Not Reported
	Normo	sol R		С	Unk				Not Reported
	Enoxa	parin		С	Unk				Not Reported
	Fentan	yl		С	Unk				Not Reported
	Hepari	n		С	Unk				Not Reported
	Hydrod	cortisone		С	Unk				Not Reported
	Triad			С	Unk				Not Reported
	Insulin	Glargine		С	Unk				Not Reported
	Insulin	Regular Hm		С	Unk				Not Reported
	Lactate	ed Ringers		С	Unk				Not Reported
	Lactulo	ose		С	Unk				Not Reported
	Magne	sium Sulfate		С	Unk				Not Reported
	Melato	nin		С	Unk				Not Reported
	Metron	idazole		С	Unk				Not Reported
	Midazo	olam		С	Unk				Not Reported
	Midodr	ine		С	Unk				Not Reported
	Morphi	ne Sulfate		С	Unk				Not Reported
	Norepi	nephrine		С	Unk				Not Reported
	Pantop	orazole		С	Unk				Not Reported
	Phenyl	ephrine		С	Unk				Not Reported
	Prisma Prisma Propof Simvas	statin n Bicarbonate mycin		0000000					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17848039	EXPEDITED (15-DAY)		DE, OT	US-GILEAD-2020- 0469173		82 YR	Female	USA

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referred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>D</u>	<u>uration</u>		<u>Mfr</u>
eath	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once				Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd				Gilead
	Aceta	aminophen			С		Unk				Not Reported
	Apixa	aban			С		Unk				Not Reported
	Ceftri	iaxone			С		Unk				Not Reported
	Enox	aparin			С		Unk				Not Reported
	Furos	semide			С		Unk				Not Reported
	Gaba	pentin			С		Unk				Not Reported
	Insuli	n Lispro			С		Unk				Not Reported
	Insuli	n Regular Hm			С		Unk				Not Reported
	Lacta	ated Ringers			С		Unk				Not Reported
	Latar	noprost			С		Unk				Not Reported
	Magn	nesium Sulfate			С		Unk				Not Reported
	Meto	prolol Tartrate			С		Unk				Not Reported
	Metro	onidazole			С		Unk				Not Reported
	Moda	afinil			С		Unk				Not Reported
	Mom	etasone			С		Unk				Not Reported
	Form	oterol			С		Unk				Not Reported
	Monte	elukast			С		Unk				Not Reported
	Morp	hine			С		Unk				Not Reported
	Potas	ssium Chloride			С		Unk				Not Reported
	Sertra	aline			С		Unk				Not Reported
	Sodiu	um Chloride 0.9%			С		Unk				Not Reported
	Vanc	omycin			С		Unk				Not Reported
DA Received Date	Case #	Case Type	Health	Prof Ou	itcomes	Mfr Control #	503B Faci	lity A	<u>ge</u>	Sex	Country
1-Jun-2020	17848077	EXPEDITED (15-DAY)		ОТ	-	US-GILEAD-202	20-	7	1 YR	Male	USA

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Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Platelet Count Increased	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Flomax [Tamsulosin Hydrochloride]			С		Unk			Not Reported
	Vitamin C [Ascorbic Acid]			С		Unk			Not Reported
	Zinc			С		Unk			Not Reported
	Allopurinol			С		Unk			Not Reported
	Azithromycin			С		Unk			Not Reported
	Benzonatate			С		Unk			Not Reported
	Ceftriaxone			С		Unk			Not Reported
	Dipyridamole			С		Unk			Not Reported
	Enoxaparin			С		Unk			Not Reported
	Insulin Glargine			С		Unk			Not Reported
	Insulin Lispro			С		Unk			Not Reported
	Zestoretic			С		Unk			Not Reported
	Meropenem			С		Unk			Not Reported
	Methylprednisolone			С		Unk			Not Reported
	Prednisone			С		Unk			Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020 17849	9181 DIRECT	Υ	O	Γ			36 YR	Femal	e USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Diarrhoea; Nausea; Vomiting	Remdesivir Eua Convalescent Plasma Zinc Sulfate			S C C					Not Reported Not Reported Not Reported



FDA Received Date Ca	ase#	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020 17	'849209	DIRECT	Υ	0	Γ			80 YR	Male	USA
<u>Preferred Term</u>	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	ŗ
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Culture Positive; International Normalised Ratio Increased; Staphylococca Infection	Warfa Vanco Amlod Asprin Carve Insulin Insulin Levoth Pravas	rin Imycin Iipine Idilol I Glargine I Lispro Inyroxine Istatin			8 00000000	Intravenous (not otherwise specified)		5 DAY	No No No No No No No No No No No No No N	ot Reported of Reported
	Terazo				C					ot Reported
FDA Received Date Ca	ase #	Case Type	<u>Health</u>		utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020 17	849214	DIRECT	Υ	0	Γ			63 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Liver Function Test Increased; Liver Function	Remd	esivir	Y		S	Intravenous (not otherwise specified)			Gi	lead
Test Increased	Remd	esivir	Y		S	Intravenous (not otherwise specified)			Gi	lead
	Oxybu Losart Enoxa Potass Gabap Duloxe Loraze Rocur Melato Levoth	an parin sium pentin etine epam onium			000000000				No No No No No No No No	of Reported of Reported of Reported of Reported of Reported of Reported of Reported of Reported of Reported of Reported

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							Dotallou It	oport.			
		Norep Hydroi Famot Lipase	ipine sone fol Ilin V Potassium inephrine morphone			000000000					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849	220	DIRECT	Υ	0	Γ			25 YR	Female	e USA
Preferred Term		<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Liver Function Test Increased		Remd	esivir			S	Intravenous (not otherwise specified	l)			Gilead
		Docus Enoxa Famot Metop	idine			C C C C C					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849	260	DIRECT	Υ	DI	≣			56 YR	Male	USA
Preferred Term		<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Cough; Oxygen Satura Decreased; Pulse Abs		Remd				S	Intravenous drip				Gilead
Decieased, Fuise Abs	oci il	Prazos Prover Aspirir Lactine Lasix 4 Lipitor Loven	enil 200mg sin 1mg ntil Inhaler n 81mg ex Granules 40mg/4ml Iv 40mg ox 40mg in 25000 Unit/250ml			00000000					Not Reported

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						Detailed N	Sport			
	Robitu Ascor Vitam Zinc S Zoloft				000000000				7 7 7 7	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849266	DIRECT	Υ	D	ÞΕ			79 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Palliative Care; Therap Cessation	by Remd	lesivir			S	Intravenous (not otherwise specified	Other Frequency:Once;		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849270	DIRECT	Υ	D	ÞΕ			80 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Death	Follov Aspiri Atorva Carve Loven Ivig Losar Methy Pyrido	astatin edilol nox			s				7 7 7 7 7	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849276	DIRECT	Υ	D	ÞΕ			63 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>

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

							P			
Palliative Care; Therap Cessation	у	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	178492	282 DIRECT	Υ		ОТ			70 YR	Female	USA
Preferred Term		Product	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Cells In Urine; Fungal		Remdesivir Eua			S	Intravenous drip	Other Frequency:Once;			Gilead
Infection; Glomerular Filtration Rate Decreas	ad.	Remdesivir Eua			S	Intravenous drip	• • • • • • • • • • • • • • • • • • • •			Gilead
Renal Tubular Necrosi Urine Analysis Abnorm White Blood Cells Urin Positive	nal;	Vancomycin 1.25g Iv Q24hrs Vancomycin 1.25g Iv Q12hrs Vancomycin 1g Iv X One Do Vancomycin 1g Iv X One Do Zosyn 4.5g Iv X One Dose Zosyn 3.375g Iv Q8hrs Exte Infusion Midazolam Iv Infusion Continuous Insulin Iv Infusion Continuous Fentanyl Iv Infusion Clonidine 0.2mg Transderms Patch Q 7 Days	s se se nded		000000000000000000000000000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	178492	287 DIRECT	Υ		DE, OT			64 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OT(</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>]	<u>Mfr</u>
Acute Kidney Injury; A Respiratory Distress	cute	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Syndrome; Disease Progression; Hypoxia; Myalgia; Pneumonia Staphylococcal; Pyrexi	ia	Convalescent Plasma			С	canorwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country



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Preferred Term	Proc	duct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	lfr
Aspartate Aminotransferase Increased; Blood Album Decreased; Blood Bicarbonate Decreased Blood Bilirubin Increase Blood Creatinine Increased; Blood Gluco Decreased; Blood Ph Decreased; Haematocr Decreased; Haematocr Decreased; Haemoglobin Concentration Decrease Mean Cell Haemoglobin Decreased; Mean Plate Volume Increased; Metabolic Acidosis; Oxygen Saturation Decreased; Pco2 Increased; Platelet Cou Decreased; Po2 Decreased; Po2 Decreased; Po1 Decreased; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased; Sepsis	nin l; ed; se d; est; ate it bin ed; n	desivir			S	Intravenous (not otherwise specified)				Gilead
	Case #	Case Type			utcomes	Mfr Control i	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849289	DIRECT	Y	0	Т			70 YR	Male	USA



							-			
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase Remd	esivir Injection			S	Intravenous (not otherwise specified	1)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849304	DIRECT	Υ					66 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase	Actem	esivir Ira 600 Mg Iv Once			S C	Intravenous bolus		4 DAY		Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849309	DIRECT	Υ	(TC			54 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Renal	Remd	esivir			S	Intravenous drip	Other Frequency:One Time;			Gilead
Impairment; Therapy Interrupted	Remd	esivir			S	Intravenous drip				Gilead
·	Reguli Cefep Dexmi Fental Verse Propo Hepar D5/So	edetomidine nyl d fol			000000000					Not Reported Not Reported



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849315	DIRECT	Y	DI	E, OT			70 YR	Female	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Respiratory Failure		emdesivir onvalescent Plasna	Υ		s C	Intravenous bolus				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849320	DIRECT	Υ	DI	E			80 YR	Female	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Atrioventricular Block; Cardiogenic Shock; General Physical Heal Deterioration; Hypotension; Lethargy Malaise; Pulmonary Embolism; Right Atrial Enlargement; Right Ventricular Dysfunction Right Ventricular Enlargement; Vomiting	ith Co Az Fin	emdesivir onvalescent Plasma ithromycin ioxaparin			S C C C	Intravenous (not otherwise specified)	Other Frequency:Once- Loading Dose;			Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849324	DIRECT	Υ	D	S, OT			55 YR	Male	USA
referred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased; Creatinine Renal Clearance Decreased; Oliguria; Prerenal Faild Therapy Interrupted	Ac All ure; Az Fe	emdesivir etaminophen 650 Mg outerol ithromycin olchicine entanyl rdrocortisone 50 Mg Q8h antoprazole 40 Mg Iv			8 000000	Intravenous drip				Gilead Not Reported

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	Predn Tocilu	acillin Tazobactam isone zumab 800 Mg omycin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849330	DIRECT	Υ	DI	E			64 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cerebral Infarction;	Remd	esivir			S	Intravenous drip				Gilead
Dysphagia; End Stage Renal Disease; Failure Thrive; Pneumonia Vir Respiratory Failure	e To	omycin			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849357	DIRECT	Υ	Н	0			57 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Respiratory Failure	Remd	esivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849363	DIRECT	Υ					41 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Liver Funct Test Increased; Thera	ion	lesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
Cessation		•	•				# 503B Facility		_	
	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Haemodialysis; Renal		desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Failure; Therapy	Remo	desivir	Υ		S					Gilead
Cessation		astatin	•		Ċ					Not Reported
	Melat				Ċ					Not Reported
		hyroxine			Č					Not Reported
	Propo				Ċ					Not Reported
		pinephrine			Ċ					Not Reported
		n Regular			Č					Not Reported
		n Lispro			Č					Not Reported
		phorphone			Č					Not Reported
		penem			Č					Not Reported
		assol			č					Not Reported
	Linez				č					Not Reported
	Famo				Č					Not Reported
	Hepa				Č					Not Reported
		pril-Hydrochlorothiazide			Č					Not Reported
	Diclof				C					Not Reported
		n Aspart			C					Not Reported
		n Glargine			C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849369	DIRECT	Y	0	Т			70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypotension; Supraventricular Extrasystoles; Ventricu Tachycardia		desivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849373	DIRECT	Υ	0	Т			60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Therapy	ase Remo	desivir	Υ		S	Intravenous bolus	Other Frequency:Once;			Gilead

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Cessation	Rem	desivir	Υ		S	Intravenous bolus				Gilead
		aminophen Prn			С					Not Reported
		codyl Supp Prn			С					Not Reported
		rhexidine Po Bid			С					Not Reported
		tussin Dm Prn			С					Not Reported
		arin 7.500 U Subq Tid			С					Not Reported
		atonin Prn Insomnia			С					Not Reported
		thol Lozenge Prn			С					Not Reported
	Prn	nocarbamol 750mg Po Bid			С					Not Reported
	Beng	gay Cream Prn			С					Not Reported
	Solu	-Medrol 40mg Iv Bid			С					Not Reported
		roban Oint Nasal Bid			С					Not Reported
		√ Solution			С					Not Reported
		an Po/Iv Prn			С					Not Reported
		oprazole			С					Not Reported
	Mira	lax Daily Prn			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849387	DIRECT	Υ	0	Γ			28 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Hypotens	sion Rem	desivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17849393	DIRECT	Υ	DI	≣			47 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rem	desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
						outer Mee opcomea)				Not Reported
	Fent	anyl Drip			С					Not Reported
		anyl Drip arin Drip			C C					Not Reported
	Hepa	arin Drip			C C C					Not Reported
	Hepa Levo				C C					Not Reported Not Reported
	Hepa Levo Roca	arin Drip opred Drip uronium Drip			C C C					Not Reported Not Reported Not Reported
	Hepa Levo Roca Vaso	arin Drip opred Drip			C C					Not Reported Not Reported

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		Mucomyst 600mg Bid Vi Ascobic Acid Cholecalciferol Docusate Regular Insulin Protonix Miralax Selenium Vitamin A Vitamin E Zinc Sulfate	a Tube		0000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	178493	99 DIRECT	Y	0	Т			52 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	;	Remdesivir Cefepime Hydrocortisone Lantus Humalog Slicing Scale Protonix Vancomycin Zinc Sulfate Fentanyl Drip Heparin Drip Norepinephrine Drip Propofol Drip Rucuronium Drip	Y		8 00000000000	Intravenous (not otherwise specified				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	1784940	07 DIRECT	Υ					55 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Blood Pressure Decreased		Remdesivir			S	Intravenous (not otherwise specified)			Gilead

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FDA Received Date Case	#	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020 17849	9442	DIRECT	Υ		ОТ				77 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>отс</u>	Role Role	<u>Rou</u>	<u>te</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Dialysis; Oliguria; Renal Impairment; Therapy Interrupted	Remde	sivir	Y		S		venous (not rwise specified)				Gilead
FDA Received Date Case	<u>#</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020 17794	1570	EXPEDITED (15-DAY)			DE, HO, LT	, OT	NL-BRISTOL-M SQUIBB COMP BMS-2020-0372	ANY-	66 YR	Male	NLD
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Rou	<u>ite</u>	Dosage Text	Duration		<u>Mfr</u>
Covid-19; Haematoma	Apixaba	an			S	Unkn	nown	Unk			Bristol Myers Squibb
Muscle; Lactic Acidosis; Off Label Use; Renal Failure; Respiratory	Remde	sivir			S		venous (not wise specified)	200 Milligram, Qd			Not Reported
Failure; Subcutaneous Abscess	Remde	sivir			S		venous (not wise specified)	100 Milligram, Qd			Not Reported
	Nadrop	arine			S	Unkn	nown	Unk			Not Reported
		atine [Pravastatin			С	Unkn	nown	Unk			Not Reported
	Sodium Metoclo	opramide			С	Unkn	nown	Unk			Not Reported
	Nifedipi	ne			С	Unkn	nown	Unk			Not Reported
	Perindo	pril			С	Unkn	nown	Unk			Not Reported
	Oxycod Hydrocl	one [Oxycodone hloride]			С	Unkn	nown	Unk			Not Reported
		ol;lpratropium			С	Unkn	nown	Unk			Not Reported
	Cotrima	axazol			С	Unkn	nown	Unk			Not Reported
	Valacic	lovir			С	Unkn	nown	Unk			Not Reported

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							-p			
	Allopu	urinol			С	Unknown	Unk			Not Reported
	Parac	cetamol			С	Unknown	Unk			Not Reported
	Panto	prazol [Pantoprazole]			С	Unknown	Unk			Not Reported
	Flucio	oxacillin			С	Unknown	Unk			Not Reported
	Folic	Acid			С	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17849531	DIRECT	Υ					64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase Remo	desivir	Υ		S	Intravenous bolus	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17849543	DIRECT	Υ	DI	E			85 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
General Physical Heal Deterioration	lth Remo	desivir	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17849845	DIRECT	Υ	Н	0			23 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate	Remo	desivir	Υ		S	Intravenous drip				Gilead
Aminotransferase Increased	Cefep	zumab oime omycin			C C C					Not Reported Not Reported Not Reported
	Enoxa Thian	aparin nine			C C					Not Reported Not Reported
	Zinc				C C					Not Reported
		etanide azepam			C C					Not Reported Not Reported
	Famo				C					Not Reported Not Reported

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						Detailed IN	port			
	D D F N	nsulin Lispro Jexmedetomidine Jobutamine entanyl Jethylprednisolone Joetaminophen			00000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	1785077	5 DIRECT	Υ	0	Т			86 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Myocardial Infarction; Alanine Aminotransferase Increased; Glomerular Filtration Rate Decreas Rales	A A A A A Sed; C C C E H C C P M	temdesivir cetaminophen spirin torvastatin seftriaxone sholecalciferol sitalopram noxaparin lydroxyzine sisinopril ondansetron antoprazole liralax odium Chloride Infusion			%000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	1785081	7 DIRECT	Υ					71 YR	Male	USA
Preferred Term	E	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Inappropriate Schedul Product Administration		emdesivir	Υ		S	Intravenous (not otherwise specified)			Gilead
		noxaparin			C					Not Reported
		nsulin Glargine Povidone Iodine			C C					Not Reported Not Reported
	P	otassium Chloride, Extended			C					Not Reported
		imvastatin			С					Not Reported



	Insu	ılin Lispro			С				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850823	DIRECT	Υ		DS, HO, OT			72 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Acute Kidney Injury; B Creatinine Increased; Haemodialysis		ndesivir comycin			S C	Parenteral				ilead ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850829	DIRECT	Υ		DS, HO, OT			53 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Acute Kidney Injury; B	lood Ren	ndesivir			S	Parenteral			N	ot Reported
Creatinine Increased; Blood Urea Increased; Urine Output Decrease	Mot	comycin hylprednisolone			C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850833	DIRECT	Υ		НО			68 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Ren	ndesivir			S	Intravenous drip	Other Frequency:Once;		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850839	DIRECT	Υ		DE, HO, OT			42 YR	Female	USA
Preferred Term	Pro	duct	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Blood Creatinine Increased; Haemodial Renal Impairment		ndesivir			S	Parenteral			G	ilead

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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850843	DIRECT	Υ		DS, HO, OT			61 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased; Blood Urea Increased; Haemodialysis; Urine Output Decreased	Vanc	desivir omycin			S C	Parenteral				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850847	DIRECT	Υ		ОТ			59 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>∕/fr</u>
Blood Alkaline	Remo	desivir			S	Intravenous drip				Not Reported
Phosphatase	Enox Insuli Aceta Azith Cefep	axone			00000000	,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850883	DIRECT	Υ		ОТ			77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Chills; Musculoskeleta	I Remo	desivir	Υ		S	Intravenous drip	Other Frequency:Once;			Gilead
Stiffness	Gaba Magr Meto Panto	in Chewable 81 Mg pentin lesium Oxide prolol Tartrate pprazole astatin			00000	·				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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						Dotalloa IX	sport .			
	Rivaro Ropin Tams				C C C				N	lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850888	DIRECT	Υ	[DE, DS, HO	, OT		55 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Blood Creatine Increat Haemodialysis; Multip Organ Dysfunction Syndrome; Renal Impairment; Respirato Failure	le	esivir			S	Parenteral			G	Silead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850892	DIRECT	Υ	0	DΕ			68 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Medical Observation		omycin oenem			s C C	Parenteral			N N	Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850895	DIRECT	Υ	C)T			78 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase Remo	esivir			S	Intravenous (not otherwise specified)		G	ilead
			Haalda	Drof (Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	Case #	Case Type	Health	FIOI C	<u>Julcomes</u>	<u> </u>	<u></u>			<u>oountry</u>

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Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Creatinine Increased	Remde	esivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gile	ead
	Allopu	rinol 100mg Po Daily			С				Not	Reported
	Albute				С					Reported
	Apixab	an 5mg Po Bid			С					Reported
		oic Acid 250mg Po Daily			С				Not	Reported
	Aspirir	Ec 81mg Po Daily			С				Not	Reported
		anide 1mg Po Daily			С					Reported
		idine 40mg Po Daily			С					Reported
		s Sulfate 325mg Po Bid			С					Reported
		entin 300mg Po Bid			С					Reported
		yroxine 100 Mcg Po Daily			С					Reported
		ine 5% Patch Td Daily			С					Reported
		oril 10mg Po Daily			С					Reported
		tamin 1 Tablet Po Daily			C					Reported
		prazole 40mg Po Daily			C					Reported
		ninophen 650mg Po Q6h			C					Reported
	Prn Fe				_					
	Guaife	nesin 200mg Po Q4h Prn			С				Not	Reported
	Cough				-					
		l 350mg lodine/MI Inj:			С				Not	Reported
		75ml Once			-					
DA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
2-Jun-2020	17850905	DIRECT	Υ	L	T, OT			50 YR	Female	USA
referred Term	Produ	<u>ct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	Mfr	
lood Creatinine	Remde	esivir Injection			S	Intravenous (not	Other Frequency:X1. Ther	1	Gile	ead
ncreased; Dehydratior ulmonary Oedema; enal Disorder	1;					otherwise specified)	100mg/Day;			
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
)2-Jun-2020	17850908	DIRECT	Υ	D	E, OT			45 YR	Male	USA
referred Term	Produ			OTC	<u>Role</u>	Route	Dosage Text			

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Blood Creatinine Increased; Cardiac Arr Hypoxia; Nausea; Respiratory Failure; Vomiting		desivir	Y		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850912	DIRECT	Υ		НО			67 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase Rem	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Aminotransferase Increased	Rem	desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
		iaxone			С					Not Reported
		aminophen			C C					Not Reported
		conatate odipine			C					Not Reported Not Reported
		romethorphan			Č					Not Reported
		aparin			С					Not Reported
		fenesin			C C					Not Reported
	Hepa Lacta	arm ated Ringers			C					Not Reported Not Reported
		um Chloride 0.9%			Č					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850927	DIRECT	Y		ОТ			47 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased	Rem	desivir Injection			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	17850931	DIRECT	Υ					28 YR	Male	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransferase Increased; Liver Function	Remdesivir			S	Intravenous (not otherwise specified))			Gilead
Test Increased; Therapy	Cefepime			С					Not Reported
Interrupted	Vancomycin			С					Not Reported
	Cholecalciferol			C C					Not Reported
	Ascorbic Acid			C C					Not Reported
	Methylprednisolone			С					Not Reported
	Midazolam			С					Not Reported
	Norepinephrine			С					Not Reported
	Famotidine			C C					Not Reported
	Topiramate			С					Not Reported
	Vecuronium			Ç					Not Reported
	Thiamine			C					Not Reported
	Zinc Sulfate			С					Not Reported
	Propofol			С					Not Reported
FDA Received Date Case	e # Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020 1785	DIRECT	Υ	D	E, HO, LT			68 YR	Female	USA
<u>Preferred Term</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
General Physical Health Deterioration; Pyrexia;	Emergency Use Remdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;			Gilead
Respiratory Distress	Emergency Use Remdesivir	Υ		S	Intravenous (not otherwise specified))			Gilead
	Hydralazine			С					Not Reported
	Imdur			C C					Not Reported
	Ketorolac			С					Not Reported
	Levemir			С					Not Reported
	Linezolid			C C					Not Reported
	Memantine			С					Not Reported
	Novolog			С					Not Reported
	Potassium Chloride			С					Not Reported
	Potassium Phosphate Sodium			С					Not Reported
	Phosphate			_					
	Percocet			C					Not Reported
	Primidone			С					Not Reported
	Pyridoxine			С					Not Reported

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	Vanco Vitami				C C						t Reported t Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17850940	DIRECT	Y		ОТ				50 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	C Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Device Connection Iss Drug Dose Omission E Device; Product Leaka Product Supply Issue	Зу	esivir	Υ		S	Intravenous (not otherwise specified)				Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17852138	EXPEDITED (15-DAY)			DE, HO, OT	FR-VALIDUS PHARMACEUT LLC-FR- 2020VAL00043				Unknown	FRA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>Mfr</u>	
Coronavirus Infection; Pancreatitis	Furose	emide			S	Intravenous (not otherwise specified)	Unk			Va	lidus
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd		No	t Reported
	Karde	gic			С		Unk				t Reported
	Coum				С		Unk				t Reported
	Perfal	-			С		Unk				t Reported
		c /00885601/			С		Unk				t Reported
	Pipera				С		Unk				t Reported
	Corda				С		Unk				t Reported
	Rovan	nycine /00074401/			С		Unk				t Reported
	Cefota	axime			С		Unk				t Reported
	Hepar	in Al			С		Unk			No	t Reported
	Ciprofl	loxacin			С		Unk			No	t Reported
	Tazob	actam			С		Unk			No	t Reported

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	Solup Bisoc	ored /00016217/ e			C C		Unk Unk				Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17853588	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469405	20-		76 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Cardiac Arrest	Remo	desivir			S	Intravenous (not otherwise specified)	200 M	g			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
	Albute Brova Anoro Lasix Predr Insulii Proto Atorva Metfo Methy Roce	o Ellipta [Furosemide] nisone n nix [Omeprazole] astatin			000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17853597	EXPEDITED (15-DAY)			DE, HO	US-GILEAD-20 0469416	20-		88 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Covid-19; General Physical Condition		desivir			S	Intravenous (not otherwise specified)		g, Once			Gilead
Abnormal; Hypotensio Oxygen Consumption Decreased	n; Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17853613	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469516	20-		78 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Нурохіа	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Cefepi	ime			С		Unk				Not Reported
	Ipratro	pium			С		Unk				Not Reported
	Metop	rolol			С		Unk				Not Reported
	Enoxa	parin			С		Unk				Not Reported
	Insulin	l			С		Unk				Not Reported
	Diltiaz	em			С		Unk				Not Reported
	Fentar	nyl			С		Unk				Not Reported
	Morph	ine			С		Unk				Not Reported
	Allopu	rinol			С		Unk				Not Reported
	Dexme	edetomidine			С		Unk				Not Reported
	Loraze	epam			С		Unk				Not Reported
	Furose	emide			С		Unk				Not Reported
	Pipera Vanco	icillin / Tazobactam mycin			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17854398	DIRECT	Υ		ОТ				68 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; Cough; Dyspnoea; Hypertension; Malaise		esivir			S	Intravenous (not otherwise specified)					Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17854534	DIRECT	Υ						61 YR	Male	USA

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Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remd	esivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020 178	354539	DIRECT	Υ	0	Γ			59 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Condition Aggravated; Dialysis; General Physical Health Deterioration	Remd Remd		Υ		S C	Intravenous drip		2 DAY		Gilead Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020 178	854546	DIRECT	Υ	Н)			39 YR	Male	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remd	esivir	Υ		S	Intravenous (not otherwise specified		5 DAY		Gilead
Aminotransferase Increased	Remd	esivir			С	culor mice opecimed				Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020 178	354552	DIRECT	Υ	0	Γ			78 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased	Remd	esivir			S	Intravenous (not otherwise specified)			Gilead
	Cefep Omnip Vanco	aque 350 Mg			C C C					Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	1785456	0 DIRECT	Υ	D	E			61 YR	Female	USA
Preferred Term	ļ	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Ejection Fraction Decreased; Glomerula Filtration Rate Abnorm Oxygen Saturation Decreased	ar	Remdesivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	1785456	6 DIRECT	Υ	0	Т			76 YR	Male	USA
Preferred Term	ļ	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Cholecystitis; Cholelithiasis; Chronic	;	Remdesivir	Υ		S	Intravenous (not otherwise specified	()		G	ilead
Kidney Disease; Cond Aggravated; Hepatic Enzyme Increased; Re	Г	Remdesivir	Υ		S	Intravenous (not otherwise specified	,		G	ilead
Enzyme increased; Re Failure	F 1 1 1 1 1 1 1 1 1	Propofol Norepinephrine Melatonin nsulin Regular nsulin Lispro Hydromorphone Famotidine Levothyroxine Atorvastatin Linezolid nsulin Glargine Defepime Metolazone nsulin Isophane Bumetanide Losartan Metformin Metoprolol Succinate			000000000000000000				N N N N N N N N N N N N N N N N N N N	ot Reported

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	Liragl	utide			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17854573	DIRECT	Υ					56 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Hepatic Enzyme Increased; Respiratory Arrest; Therapy Interrupted	Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17854578	DIRECT	Υ		DE			51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Remo	lesivir	Υ		S	Intravenous (not otherwise specified)			G	Gilead
	Norep Rocul Vasop Verse Pheny Tpn Vanco Merop Huma Ascor Chole Esom Folic Hepal Selen Vitam	rin For Crrt ium			000000000000000000000000000000000000000					lot Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17854729	DIRECT	Υ	0	Т			44 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Renal Impairment	Remo	desivir	Υ		S	Intravenous (not otherwise specified)			Gi	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17855372	DIRECT	Υ	0	Т			60 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Renal Impairment	Remo	desivir 100mg Vial	Υ		S	Intravenous (not otherwise specified)			Gi	ilead
	Remo	desivir 100mg Vial			S	Intravenous (not otherwise specified)			Gi	lead
	Furos Lovei Unas Proto Metoj Kepp Fenta Verse	yn nix prolol ra anyl			0000000				No No No No No No	ot Reported of Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17855700	EXPEDITED (15-D	AY)			US-GILEAD-20 0468459	20-	78 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mf	<u>r</u>
Product Administration Error; Product Storage Error		desivir			S	Intravenous (not otherwise specified)	Unk		Gi	ilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17855745	DIRECT	Υ					66 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)			C	Silead
	Albute	erol opium			C C					Not Reported Not Reported
	Fenta				C					Not Reported
	Propo				C					Not Reported
		prazole			С					Not Reported
	Cefep				С					lot Reported
		omycin			С					lot Reported
		aparin n Aspart			C C					Not Reported Not Reported
		/lprednisolone			C					lot Reported
FDA Received Date	•	Case Type	Health	Prof C	outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17855748	DIRECT	Υ	D	S, HO, LT	OT		55 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blood Creatinine Increased	Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		C	Gilead
	Ascor	bic Acid			С				N	Not Reported
	Atorv	astatin			С					Not Reported
		omycin			С					Not Reported
		axone			С					lot Reported
		alciferol			С					lot Reported
	Hepa				C C					lot Reported
		oxychloroquine n Glargine			C					Not Reported Not Reported
	Ketar				C					Not Reported
	Melat				č					lot Reported
		nsetron			C C					lot Reported
		prazole			С				N	Not Reported
		ronium			С					Not Reported
	Succi	nylcholine			С				N	Not Reported

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	Zinc S Aceta Album	omycin Gulfate minophen nin n Regular			0000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17856141	EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-20 0468702	20-		82 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia	Remd	esivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	<u> </u>	503B Facility	Age	Sex	Country
03-Jun-2020	17856201	EXPEDITED (15-DAY)		C	T	US-GILEAD-20 0468990	20-		69 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Covid-19; Respiratory	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	9			Gilead
Failure; Shock	Fenta	nyl			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Insulir	n Regular Hm			С		Sliding	Scale			Not Reported
	Propo	fol			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Loven	ox [Enoxaparin Sodium]			С		Unk				Not Reported
	Furos	emide			С		Unk				Not Reported
	Insulir	n Glargine			С		Unk				Not Reported
	Norep	inephrine			С		Unk				Not Reported
	Vasop	pressin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17856753	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0469662	20-		59 YR	Male	USA

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Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Bronchitis; Hypotension;	Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Multiple Organ Dysfunction Syndrome; Oliguria; Pneumonia;	Remdes	sivir			S	Intravenous (not otherwise specified)	100 Unk			Gilead
Renal Impairment; Respiratory Failure;	Rocuror Azithror				C C	, ,	Unk			Not Reported Not Reported
Sepsis	Amlodip	vine			С		Unk			Not Reported
	Medrol	[Methylprednisolone]			С		Unk			Not Reported
	Ascorbi	c Acid			С		Unk			Not Reported
	Ceftriax	one			С		Unk			Not Reported
	Loveno	k [Enoxaparin Sodium]			С		Unk			Not Reported
	Insulin l	Lispro			С		Unk			Not Reported
	Zosyn				С		Unk			Not Reported
	Vancom	nycin			С		Unk			Not Reported
	Versed				С		Unk			Not Reported
	Norepin	ephrine			С		Unk			Not Reported
	Propofo	I			С		Unk			Not Reported
	Vasopre	essin			С		Unk			Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020 178	57103	EXPEDITED (15-DAY)		(ОТ	US-GILEAD-20 0468777	20-	60 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury	Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remdes	sivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Albumin				С					Not Reported
	Albutero	ol [Salbutamol] nide			C C					Not Reported Not Reported
		e Citrate			Č					Not Reported

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	Chlor	othiazide			С					Not Reported
	Enox	aparin			С					Not Reported
	Famo	otidine			0000000					Not Reported
	Furos	semide			С					Not Reported
	Gaba	pentin			С					Not Reported
		n Glargine			С					Not Reported
		n Lispro			С					Not Reported
		n Regular Hm			С					Not Reported
	Lactu				С					Not Reported
		nesium Sulfate			С					Not Reported
	Methy	ylprednisolone			С					Not Reported
		lazone			С					Not Reported
	Midaz	zolam			0000000					Not Reported
	Midoo				С					Not Reported
		odone			С					Not Reported
		acillin/Tazobactam			С					Not Reported
		ssium Chloride			С					Not Reported
		apine			С					Not Reported
		ronium			С					Not Reported
		omycin			0000000					Not Reported
		nedetomidine			С					Not Reported
		rostenol			Ç					Not Reported
	Hepa				C					Not Reported
		omorphone			C C C					Not Reported
	Ketar				С					Not Reported
		pinephrine			С					Not Reported
	Propo				C C					Not Reported
		pressin			С					Not Reported
		aminophen			С					Not Reported
	Fenta	anyl			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17857107	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-2 0469610	020-	81 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Renal Failure;	Remo	desivir			S	Intravenous bolus	100 Mg, Qd			Gilead
Tachypnoea	Aceta	aminophen			С		Unk			Not Reported
	Amlo	dipine			С		Unk			Not Reported
	Aspir	in (E.C.)			С		Unk			Not Reported



	Benzo	astatin onatate			C					Not Reported Not Reported
		osol R			С		Unk			Not Reported
	Enoxa	•			С		Unk			Not Reported
	Fenta	nyl			С		Unk			Not Reported
	Furos	emide			С		Unk			Not Reported
	Guaif	enesin/Codeine			С		Unk			Not Reported
	Hepa	rin			С		Unk			Not Reported
	Hydro	ochlorothiazide			С		Unk			Not Reported
	Hydro	morphone			С		Unk			Not Reported
	Insuliı Labet				C C		Unk			Not Reported Not Reported
	Lacta	ted Ringers			С		Unk			Not Reported
	Levot	hyroxine			С		Unk			Not Reported
	Lidoc	aine			С		Unk			Not Reported
	Loraz	epam			С		Unk			Not Reported
	Magn	esium Sulfate			С		Unk			Not Reported
	Morph	nine			С		Unk			Not Reported
	Conva	alescent Plasma			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17857141	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0469657	20-	73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19; Hypoxia; Respiratory Failure	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg Once			Gilead
	Atorva Azithr	n [Acetylsalicylic Acid] astatin omycin dopa + Levodopa			C C C					Not Reported Not Reported Not Reported Not Reported



							Detailed Ne	port			
		Donepez Enoxapa Lispro Ir Metopro Montelul Solifena Acetami	arin Isulin Iol Kast Cin			0000000					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	178571	44	EXPEDITED (15-DAY)		ı	DE, OT	US-GILEAD-20 0469659	20-	71 YR	Male	USA
Preferred Term		Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Cardiac Art Shock		Remdes				s C	Intravenous (not otherwise specified)	200 Milligram Per Millilitre Once	,		Gilead Not Reported
		Midazola Propofol	am [Cisatracurium Besilate] nycin one			0000000					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	178571	71	EXPEDITED (15-DAY)		I	DE, OT	US-GILEAD-20 0469603	20-	68 YR	Male	USA
Preferred Term		Product	1	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19; Respiratory Failure		Remdes	ivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
		Remdes	ivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Colace Eliquis Humalog Lantus	9			C C C					Not Reported Not Reported Not Reported Not Reported
			Famotidine]			Č					Not Reported

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						Dotalica Itt	P O · · ·				
	Acetan Piperad Azithro Diclofe Propof Norepil Fentan	uel air [Ondansetron] ninophen cillin/Tazobactam nac ol			00000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17857185	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0469616	020-		69 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	Duration		<u>Mfr</u>
Death	Remde	esivir			S	Unknown					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17857269	EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-20 0468988	020-		45 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Acute Kidney Injury	Remde	esivir			S	Intravenous (not otherwise specified		lg, Once			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified	100 M	lg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17858737	DIRECT	Υ	0	Т				57 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remde Furose Potass		Υ		S C C						Gilead Not Reported Not Reported



		ulose			С					lot Reported
		lproex			C C C					lot Reported
		lecalciferol			C					lot Reported
		eridone			C					lot Reported
		nelteon			C					lot Reported
		azepam			С					lot Reported
		apentin			C					lot Reported
		Inisone			C C C					lot Reported
		racillin Tazobactam			C					lot Reported
		otrigine			C C					lot Reported
	ram	sulosin			C				יו	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17858747	DIRECT	Υ	0	Т			51 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Condition Aggravated; Liver Function Test	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)		C	Silead
Increased	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)		C	Gilead
	Aripi	prazole			С				N	lot Reported
	Fam	otidine			С				N	lot Reported
	Hydı	romorphone			С				N	lot Reported
	Insu	lin Lispro			0000000				N	lot Reported
	Insu	lin Regular			С					lot Reported
		riaxone			С					lot Reported
		xaparin			С					lot Reported
		epinephrine			С					lot Reported
		ssium			С					lot Reported
	Prop				С					lot Reported
		atonin			C C C C C					lot Reported
		ropion			С					lot Reported
		rizine			C					lot Reported
		abpentin			С					lot Reported
		Inisone			C C					lot Reported
		raline			C					lot Reported
		odone			C					lot Reported
	Ocre	elizumab			Ü					lot Reported



FDA Received Date	Case #	<u>C</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	178589	15 E	DIRECT	Υ						58 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Therapy		Remdesivi	ir			S	Intravenous drip					Gilead
Interrupted		Dilaudid D Propofol D				C C	mavonoue unp					Not Reported Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	178589	34 [DIRECT	Υ						69 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Pressure Decreased; Chills; Hea	art	Remdesiv	ir	Υ		S	Intravenous (not otherwise specified)		r Frequency:Once;			Gilead
Rate Decreased; Hyperhidrosis; Infusior Related Reaction; Trer			phen Proventil) Nebulizer			C C	, ,					Not Reported Not Reported
,		Solution Azithromy Mg In Ns I	cin (Zithromax) 500			С						Not Reported
		Benzonata	ate (Tessalon) Capsule			С						Not Reported
		Ns Ivpb	e (Rocephin) 1 G In			С						Not Reported
			Porcine Injection 7,500 Tid			С						Not Reported
		Ipratropiur (Combiver	n-Albuterol nt) Inhaler			С						Not Reported
		Methylpre	dnisolone *Pf* (Solu- jection 40 Mg			С						Not Reported
		Morphine				C						Not Reported
		Ns				С						Not Reported
		Ondansetr				С						Not Reported
		Pravastati	n 100mg Tablet			C C						Not Reported Not Reported
			mnipaque) 350 Mg			C						Not Reported
			(Seroquel) Tablet			С						Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17858974	DIRECT	Υ	С	T			62 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Liver Function Test	Remo	desivir	Υ		S	Intravenous drip			(Gilead
Increased	Zosyi Meth Fenta	ylprednisolone anyl pinephrine			000000	·			1 1 1	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17858982	DIRECT	Υ	Н	O, OT			62 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury	Remo	desivir Injection	Υ		S	Intravenous bolus			(Gilead
	Enox	semide aparin otidine			C C C				1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17858990	DIRECT	Υ	С	т			67 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; Therapy Cessation	Remo	desivir			S	Intravenous (not otherwise specified)			(Gilead
		aminophen (Prn) erol Inhaler			C C	. ,				Not Reported Not Reported
	Aspir				С				1	Not Reported
		astatin			С					Not Reported
	Atrop	onatate			C C C					Not Reported Not Reported
		etanide			C					Not Reported
		v (Prn)			Č					Not Reported

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							•			
		DoxycyclineIntravenous			С					lot Reported
		EpinephrineIntravenous Drip			C					lot Reported
		HydromorphoneIntravenous			С				ľ	lot Reported
		Orip nsulin Glargine			С				N	Not Reported
		Regular Insulin Drip/Sliding			C					Not Reported
		Scale			•				·	
		ubricant Eye Ointment (And			С				1	Not Reported
		Also Natural Tears Drops)								
		Methylprednisolone Sodium			С				1	lot Reported
		Succinate Multivitamin Tablet			0					Not Reported
		Nebivolol			C C					Not Reported
		Pantoprazole			C					Not Reported
		PropofolIntravenous Drip			C C					Not Reported
		Rocuronium			C					Not Reported
	2	Zosyn			С				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	1785901	1 DIRECT	Υ	D	E			71 YR	Female	USA
Preferred Term	!	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>fr</u>
Bradycardia; Cardiac Arrest; Cough; Epistax		Remdesivir			S	Intravenous (not otherwise specified)			(Gilead
Haemoptysis;		Rivaroxaban			С	outer mos opcomos,			1	lot Reported
Hypotension; Pulseles	s .	(IVAI OAGDAI)			Ū					tot rtoponou
Electrical Activity;										
Respiratory Arrest; Retching										
	0#	O T	I I I II -	Desct 0		Mfs Ossafas I d	food Facility	A	0	0
FDA Received Date	Case #	Case Type	Health	Prot U	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2020	1785901	7 DIRECT	Υ	D	E			99 YR	Female	USA
<u>Preferred Term</u>	<u> </u>	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Atrial Fibrillation; Blood Pressure Decreased; Mental Status Change Somnolence		Remdesivir			S	Intravenous bolus			(Gilead



							•			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17859024	DIRECT	Υ	(ТС			75 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Anuria; Anuria; Blood Creatinine Increased; Cardiac Dysfunction; Dialysis; International Normalised Ratio Increased; Renal Impairment		desivir desivir			S S	Intravenous bolus Intravenous bolus	Other Frequency:Once;			ilead ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17859029	DIRECT	Υ	(ТС			86 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Gastrointestinal Ulcer Haemorrhage; Haemoglobin Decreas Melaena	Remo	desivir desivir			S S	Intravenous drip	Other Frequency:Once;			ilead ilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17859036	DIRECT	Υ	(ТС			50 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
White Blood Cell Coun Decreased	t Remo	desivir			S	Intravenous (not otherwise specified)		G	ilead
	Remo	desivir			S	Intravenous (not otherwise specified)		G	ilead
	Azithi Benz Ceftri	aminophen romycin onatate iaxone ocodone/Acetaminophen			C C C C				N N N	ot Reported ot Reported ot Reported ot Reported ot Reported

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

							Detailed No	port			
		Butalbit Caffeine	al-Acetaminophen-			С					Not Reported
		Ondans				С					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17859	043	DIRECT	Υ					44 YR	Male	USA
Preferred Term		Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase	Remde	sivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Aminotransferase Increased		Enoxap	arin			С					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2020	17859	048	DIRECT	Υ		ОТ			67 YR	Female	USA
Preferred Term		Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; A Respiratory Distress Syndrome; Alanine	cute	Remde:				s s	Intravenous bolus	Other Frequency:Once;			Gilead Gilead
Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Biliru Increased; Hypoperfus Jugular Vein Thrombo Pneumonia; Sepsis	sion;	Convale	escent Plasma			С					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17793	631	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0466952	020-	65 YR	Male	USA
Preferred Term		Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Pulselo Electrical Activity; Ventricular Fibrillation	ess	Remde	sivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead

Note: If the field is blank, there is no data.



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	1786001	6 DIRECT	Υ					65 YR	Female	USA
Preferred Term	!	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Incorrect Drug Administration Rate; Infusion Site Haemorrhage; Infusior Site Pain		Remdesivir			S	Intravenous drip	Other Frequency:Once;		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	1786002	d DIRECT	Υ	C	T			71 YR	Male	USA
Preferred Term	!	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	l <u>fr</u>
Alanine Aminotransfer Increased; Aspartate	ase l	Remdesivir			S	Intravenous (not otherwise specifie	d)		(Gilead
Aminotransferase Increased; Blood Biliru Increased	ıbın ,	Kaletra Actemra Zithromax			C C C	·	,		1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	1786007	5 DIRECT	Υ					48 YR	Female	USA
Preferred Term]	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Alkaline	-	Remdesivir	Υ		S	Intravenous bolus			(Gilead
Phosphatase Increase	ed -	Tocilizumab			С				1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	1786007	9 DIRECT	Υ	C	T			27 YR	Female	USA
Preferred Term	!	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	l <u>fr</u>
Acute Kidney Injury; B	lood l	Remdesivir	Υ		S	Intravenous drip			(Gilead
Creatinine Increased;	,	Ascorbic Acid			С	•			١	Not Reported

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Haemodialysis	Cefep	oime			С					Not Reported
-	Chole	calciferol			С					Not Reported
	Enoxa	aparin			С					Not Reported
	Fluco	nazole			С					Not Reported
	Insulii	n Glargine			С					Not Reported
	Insulii	n Lispro			С					Not Reported
	Melat	onin			С					Not Reported
	Methy	/lprednisolone			С					Not Reported
		prazole			С					Not Reported
	Propo				С					Not Reported
	Fenta	nyl			С					Not Reported
		n Regular			С					Not Reported
		oinephrine			С					Not Reported
		sium Chloride			С					Not Reported
		m Phosphate			C C					Not Reported
		nylcholine			С					Not Reported
	Midaz				С					Not Reported
	Metop	orolol			С					Not Reported
DA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17860084	DIRECT	Υ	DI	Ξ			48 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Cardiac Arrest; Dyspn			Comp.	OTC	Role S	Route Parenteral	Dosage Text	<u>Duration</u>		<u>Mfr</u> Gilead
Cardiac Arrest; Dyspn Hypoxia	oea; Remo							<u>Duration</u>		
Cardiac Arrest; Dyspn Hypoxia FDA Received Date	oea; Remo	lesivir			S utcomes	Parenteral				Gilead
Preferred Term Cardiac Arrest; Dyspndypoxia FDA Received Date 04-Jun-2020 Preferred Term	oea; Remo	Case Type DIRECT	<u>Health</u>	Prof O	S utcomes	Parenteral		<u>Age</u>	<u>Sex</u> Female	Gilead Country
Cardiac Arrest; Dyspn Hypoxia FDA Received Date 04-Jun-2020 Preferred Term Blood Alkaline	Oea; Remo Case # 17860088 Produ	Case Type DIRECT	<u>Health</u> Y	Prof O	S utcomes	Parenteral Mfr Control s	# 503B Facility	Age 37 YR	Sex Female	Gilead Country USA
Cardiac Arrest; Dyspn Hypoxia FDA Received Date 04-Jun-2020 Preferred Term Blood Alkaline	Case # 17860088 Producted Enoxal Insulin	Case Type DIRECT uct lesivir	<u>Health</u> Y	Prof O	S utcomes	Mfr Control a	# 503B Facility	Age 37 YR	Sex Female	Gilead Country USA Mfr
Cardiac Arrest; Dyspn Hypoxia FDA Received Date 04-Jun-2020	Case # 17860088 Produced Remoded Enoxal Insuling Aceta	Case Type DIRECT uct lesivir aparin Aspart	Health Y Comp.	Prof O	S Litcomes Role S C C	Mfr Control a	503B Facility Dosage Text	Age 37 YR	Sex Female	Country USA Mfr Not Reported Not Reported Not Reported Not Reported

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Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>n</u>	<u>Mfr</u>
Multiple-Drug Resistar Pneumonia	nce;	Remdesivi	r	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #	<u> </u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	178601	00 [DIRECT	Υ		НО			56 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransfer Decreased; Covid-19 Pneumonia; Nephropa Toxic; Renal Impairme Renal Ischaemia; Respiratory Failure; Se Shock	athy ent;	Remdesivi Ceftriaxon Azithromyo Norepinep	e cin	Y		S C C C	Intravenous drip				Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>C</u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	178604	12 E	EXPEDITED (15-DAY)			LT	US-ACS-00169	8	67 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Sepsis		Meropene	m			S	Unknown				Not Reported
		Remdesivi	r			S	Intravenous (not otherwise specified)	From 01-Apr-2020 To 09- Apr-2020, The Patient Received Remdesivir 100 Mg Iv			Not Reported
		Chloroquir	ne			С	Unknown				Not Reported
		Metoprolol	Tartrate			С	Unknown				Not Reported
		Atorvastati				С	Unknown				Not Reported
		Furosemid				С	Unknown				Not Reported
		Albuterol/I	•			С	Unknown				Not Reported
		Oxycodon	е			С	Unknown				Not Reported
		Fentanyl				С	Unknown				Not Reported



	Diaz	zepam			С	Unknown				Not Reported
	Van	comycin			С	Unknown				Not Reported
	Pro	oofol			С	Unknown				Not Reported
	Nor	epinephrine			С	Unknown				Not Reported
	Phe	nylephrine			С	Unknown				Not Reported
	Digo	oxin			С	Unknown				Not Reported
	Asp	irin			С	Unknown				Not Reported
	Dilti	azem			С	Unknown				Not Reported
	Fluc	exetine Hydrochloride			С	Unknown				Not Reported
	Insu	ılin			С	Unknown				Not Reported
	Lev	othyroxine			С	Unknown				Not Reported
	Ami	odarone			С	Unknown				Not Reported
	Bup	ropion Hydrochloride			С	Unknown				Not Reported
	Cefa	azolin			С	Unknown				Not Reported
	End	xaparin			С	Unknown				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17860990	DIRECT	Υ		ОТ			40 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO		Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate			Comp.	ото		Route Intravenous drip	Dosage Text	<u>Duration</u>		
Preferred Term Aspartate Aminotransferase Increased; Blood Biling Increased	Ren Ace Fan Hep Hyd Proj Cefi Dox	duct	Comp.	ОТС	Role Role		Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Biling	Ren Ace Ubin Fan Hep Hyd Pro Cefi Dox Epo	duct ndesivir taminophen notidine parin romorphone pofol triaxone ycycline	•		Role S C C C C C C C C			<u>Duration</u>	<u>Sex</u>	Mfr Not Reported Not Reported

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<u>Preferred Term</u>		<u>Product</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Cognitive Disorder;		Remdesivir			S	Intravenous drip			G	Gilead
Lethargy; Mechanical Ventilation; Mental Sta Changes; Walking Aid User		Ascorbic Acid Aspirin Atorvastatin Cholecalciferol Codeine/Guaifenesin Docusate Enoxaparin Fentanyl Furosemide Hydralazine Insulin Levetiracetam Levothyroxine Multivitamin Pantoprazole			0000000000000					lot Reported
FDA Received Date	Case a	<u>Case Type</u>	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17860	999 DIRECT	Υ	DI	Ε			49 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Respiratory Dist Syndrome; Antibiotic Therapy; Renal Replacement Therapy		Remdesivir Under Emergency Use Authorization	, Y		S	Intravesical			G	ilead
FDA Received Date	Case #	<u>Case Type</u>	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17861	003 DIRECT	Υ	Н)			85 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Adrenal Disorder		Remdesivir	Υ		S	Intravenous drip			G	Gilead
		Azithromycin Ceftriaxone Dexamethasone Famotidine Epoprostenol			C C C C				N N N	lot Reported lot Reported lot Reported lot Reported lot Reported

Date - Time: 05-Aug-2020 11:28:24 AM EST

Note: If the field is blank, there is no data.



						Detailed K	eport			
	Nore _l Propo	rin Drip Dinephrine			C C C C				N N	lot Reported lot Reported lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17861008	DIRECT		0	Т			30 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Transaminases Increa	ased Remo	desivir			S	Intravenous (not otherwise specified	d)		N	lot Reported
	Methy Q8h	ylprednisolone 60mg lv			С				٨	lot Reported
		ylprednisolone 40mg lv			С				Ν	lot Reported
	Tocili	zumab 400mg lvpd			С				N	lot Reported
		minophen 1000mg lvpb			С				N	lot Reported
		Prn odone/Acetaminophen 325mg Q6h Prn			С				Ν	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17861033	DIRECT	Υ	D	E			79 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Respiratory Arrest	Remo	desivir	Υ		S	Intravenous (not otherwise specified	d)		G	Gilead
		amenophen			С					lot Reported
		depine			С					lot Reported
		astatin			C C					lot Reported
		etanide axone			C					lot Reported lot Reported
		gatran			C					lot Reported
		us Sulfate			C C					lot Reported
		enesin			Č					lot Reported
		is Insulin			С					lot Reported
	Novo	log Insulin			С				N	lot Reported

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						Dotalloa Itt	port			
		Levothyroxine Magnesium Sulfate Senna S Tiotropium Vancomycin			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	178610	39 DIRECT						48 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased		Remdesivir Remdesivir			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	178619	07 EXPEDITED (15-DAY)		LT	T, OT	US-GILEAD-20 0469837	020-	66 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Hepatic Failure; Acute Kidney Injury; Blo		Remdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd			Gilead
Creatinine Increased; Cardiovascular Disorde	er:	Aspirin [Acetylsalicylic Acid]			С	•	Unk			Not Reported
Gastrointestinal	•	Diltiazem			С		Unk			Not Reported
Haemorrhage; Glomeru Filtration Rate Decreas		Insulin Lispro			С		Unk			Not Reported
Hyperkalaemia;	cu,	Methylprednisolone			С		Unk			Not Reported
Hypovolaemic Shock; Metabolic Acidosis; Sho	ock	Protonix [Omeprazole]			С		Unk			Not Reported
Haemorrhagic	UCK	Atarax [Alprazolam]			С		Unk			Not Reported
-		Lovenox [Enoxaparin Sodium]			С		Unk			Not Reported
		Ativan			С		Unk			Not Reported
		Ketamine			С		Unk			Not Reported
		Versed			С		Unk			Not Reported
		Fentanyl			С		Unk			Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17862396	EXPEDITED (15-DAY)				US-GILEAD 0469055)-2020-		44 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Medication Error	Remo	desivir			S	Intravenous (not otherwise specific		lg			Gilead
	Dextr	ose Water			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17862427	EXPEDITED (15-DAY)			HO, OT	US-GILEAD 0468936)-2020-		80 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosag	e Text	Duration	<u>N</u>	<u>Mfr</u>
Burning Sensation; Dyspnoea; Feeling Ho		desivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17862432	EXPEDITED (15-DAY)				US-GILEAD 0468996)-2020-			Male	USA
<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	Duration	<u>N</u>	<u>Mfr</u>
Medication Error	Remo	desivir			S	Unknown					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17863082	EXPEDITED (15-DAY)				US-GILEAD 0469009)-2020-		44 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Intercepted Product Dispensing Error; Prod		desivir			S	Intravenous (not otherwise specific		lg, Qd			Gilead
Administration Error; Product Dispensing Er	ror Carve	edilol			С	·	Unk				Not Reported
	Cefe	pime			С		Unk				Not Reported
	Furos	semide			С		Unk				Not Reported
	Hepa	ırin			С		Unk				Not Reported



	Hydro	cortisone			С		Unk				Not Reported
	Norep	inephrine			С		Unk				Not Reported
	Vanco	mycin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	Sex	Country
04-Jun-2020	17863105	EXPEDITED (15-DAY)		(ОТ	US-GILEAD-20 0469189)20-		56 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Renal Impairment	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Ur	nk, Qd			Gilead
	Acetar	ninophen			С						Not Reported
		rol;Ipratropium			C C						Not Reported
	Apixat										Not Reported
		edetomidine			C C						Not Reported
	Baclof				C						Not Reported
	Cefepi				C						Not Reported
	Ceftria				С						Not Reported
	Doxyc				C						Not Reported
	Midaz				C						Not Reported
	Flucor	s Sulfate			C						Not Reported
	Folic A				C						Not Reported Not Reported
	Furose				C						Not Reported Not Reported
	Hepar				C						Not Reported Not Reported
	Merop				C						Not Reported
	Tociliz				C						Not Reported
	Vanco				č						Not Reported
		inephrine			000000000000000000000000000000000000000						Not Reported
	Propo				C						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17863108	EXPEDITED (15-DAY)		I	НО	US-GILEAD-20 0469179)20-		52 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>



Alanine Aminotransfera Increased; Aspartate	ase Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
Aminotransferase Increased	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Azithr	omycin			С						Not Reported
		axone			С						Not Reported
	Benzo	onatate			С						Not Reported
	Enoxa	aparin			С						Not Reported
	Famo	tidine			С						Not Reported
	Metop				С						Not Reported
		sium Bicarbonate;Sodium			С						Not Reported
	Phosp				_						
		sium Chloride			C						Not Reported
		omycin			С						Not Reported
	Aceta	minophen			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17863182	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469222	20-		46 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage '	<u>Text</u>	Duration	<u>!</u>	<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
	Pipera	acillin+Tazobactam			С						Not Reported
	Vanco	omycin			С						Not Reported
		aparin			С						Not Reported
		nazole			С						Not Reported
		asone			C						Not Reported
		n Lispro			С						Not Reported
		hyroxine			С						Not Reported
		a [Senna Alexandrina Leaf]			С						Not Reported
		bic Acid Sulfate			C C						Not Reported
		m Chloride			C						Not Reported Not Reported
		minophen			C						Not Reported
		onatate			C						Not Reported
	lopan				C						Not Reported
		nsetron			Č						Not Reported
		ethazine			Č						Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Faci	<u>lity</u> <u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17863307	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470071	20-	56 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Sulfate	-			С		Unk			Not Reported
	Prazos				С		Unk			Not Reported
	Prover	ntil [Salbutamol]			С		Unk			Not Reported
	Aspirir	n [Acetylsalicylic Acid]			С		Unk			Not Reported
	Acidop				С		Unk			Not Reported
	· ·	[Furosemide]			С		Unk			Not Reported
	· ·	[Atorvastatin]			С		Unk			Not Reported
	Loven	ox [Enoxaparin Sodium]			С		Unk			Not Reported
	Hepar	in			С		Unk			Not Reported
	Proton	nix [Omeprazole]			С		Unk			Not Reported
	Robitu	ıssin A C			С		Unk			Not Reported
	Ascort	bic Acid			С		Unk			Not Reported
	Vitami	in D [Colecalciferol]			С		Unk			Not Reported
	Zinc S	Sulfate			С		Unk			Not Reported
	Zoloft				С		Unk			Not Reported
	Zylopr	rim			С		Unk			Not Reported
	Propor	fol			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Faci	lity Age	<u>Sex</u>	Country
04-Jun-2020	17864171	DIRECT	Υ		ОТ			33 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Hepatic Enzyme Increased	Re	mdesivir	Υ		S	Intravenous (not otherwise specified))		•	Gilead
	Co	ciluzimab Ilchine xycycline			C C C				!	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17864177	DIRECT	Υ	Н	0			82 YR	Female	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer	ase Re	mdesivir			S	Intravenous drip			(Gilead
Increased; Aspartate Aminotransferase Increased	Ac	etaminophen			С	·			1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17864180	DIRECT	Υ					77 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	rase Re	mdesivir			S	Intravenous (not otherwise specified))		(Gilead
Aminotransferase Increased	Re	mdesivir			S	Intravenous (not otherwise specified))		•	Gilead
	Ce Az Fe Pro Fa	dazolam iftriaxone ithromycin ntanyl opofol motidine examethasone			000000				 	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control #	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17864182	DIRECT	Υ	0	Т			39 YR	Female	USA



Alanine Aminotransferase

Remdesivir

Not Reported

Increased; Aspartate Aminotransferase

Increased: Transaminases

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17864201	DIRECT	Υ		НО			50 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury; Haemodialysis	Alpra: Azithr Bupro Calciu Enoxa Famo Fenta Gaba Hydro Iopan Losar Methy Norep Pipera Propo Rocu	minophen zolam omycin opion um Gluconate aparin tidine nyl pentin oxychloroquine nidol tan //prednisolone oinephrine acillin/Tazobactam	Y		% 000000000000000000000000000000000000	Intravenous bolus	Other Frequency:Once;			tilead lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020	17864223	DIRECT	Υ		LT			42 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Myocardial Infarction; Oxygen	Remo	lesivir minophen			s C	Intravenous drip				ilead ot Reported

S



Gua	aifenesin			C C C					Not Reported Not Reported Not Reported
Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17864252	DIRECT	Υ		DE			59 YR	Male	USA
Pro	<u>oduct</u>	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Rer	ndesivir			S	Intravenous bolus	Other Frequency:X1;			Gilead
Rer	ndesivir			S	Intravenous bolus	. ,			Gilead
	Iroxychloroquin 200mg Po			С					Not Reported
	emra 400mg X1			С					Not Reported
Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17864258	DIRECT	Υ		ОТ			82 YR	Female	USA
Pro	duct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
ed Rer	ndesivir	Υ		S	Intravenous drip	Other Frequency:Once;			Gilead
Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17864265	DIRECT	Υ		DE, HO			66 YR	Female	USA
Pro	oduct	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
	ndesivir			S	Intravenous drip				Gilead
				С	·				Not Reported
inec				С					Not Reported
				C					Not Reported Not Reported
				С					Not Reported
Var	icomycin			С					Not Reported
Mai	ropenem			С					Not Reported
	Gualbur Case # 17864252 Pro Rer Rer Hyce Bid Acte 17864258 Pro ed Rer ed Case # 17864265 Pro Rer Hyce Bid Acte Rer Hyce Bid Acte Lev Ver Nim Van	Product Remdesivir Remdesivir Hydroxychloroquin 200mg Po Bid Actemra 400mg X1 Case # Case Type 17864258 DIRECT Product Remdesivir d Case # Case Type 17864265 DIRECT Product Remdesivir h Levophed Neo-Synephrine Fentanyl Drip Versed Drip Nimbex Drip Vancomycin	Guaifenesin Ibuprofen Case # Case Type Health 17864252 DIRECT Y Product Comp. Remdesivir Remdesivir Hydroxychloroquin 200mg Po Bid Actemra 400mg X1 Case # Case Type Health 17864258 DIRECT Y Product Comp. dd Remdesivir Y dd Case # Case Type Health 17864265 DIRECT Y Product Comp. Remdesivir Y dd Case # Case Type Health 17864265 DIRECT Y Product Comp. Remdesivir th Levophed Neo-Synephrine Fentanyl Drip Versed Drip Nimbex Drip Vancomycin	Guaifenesin Ibuprofen Case # Case Type Health Prof 17864252 DIRECT Y Product Comp. OTC Remdesivir Remdesivir Hydroxychloroquin 200mg Po Bid Actemra 400mg X1 Case # Case Type Health Prof 17864258 DIRECT Y Product Comp. OTC ed Remdesivir Y d Case # Case Type Health Prof 17864265 DIRECT Y Product Comp. OTC Remdesivir A Case Type Health Prof 17864265 DIRECT Y Product Comp. OTC Remdesivir Comp. OTC Comp. OTC Comp. OTC Remdesivir Comp. OTC Product Comp. OTC Remdesivir Comp. OTC Remdesivir Comp. OTC Neo-Synephrine Fentanyl Drip Versed Drip Nimbex Drip Versed Drip Nimbex Drip Vancomycin	Guaifenesin buprofen	Guaifenesin Ibuprofen C C C Case # Case Type Health Prof Outcomes Mfr Control # 17864252 DIRECT Y DE Product Comp. OTC Role Route Remdesivir S Intravenous bolus Intravenous Dolus Intravenous Dolus Intravenous Dolus Intravenous Dolus Intravenous Int	Case # Case Type Health Prof Case Case	Guaifenesin C C C	Case # Case Type Health Prof Dutcomes Mfr Control # 503B Facility Age Sex



							- PO: 1			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020 1	7864269	DIRECT	Υ	0	Γ			64 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>fr</u>
Alanine Aminotransferas Increased; Aspartate Aminotransferase Increased; Blood Creatin Increased	Azithr Ceftria ie Fenta	omycin axone nyl Infusion olam Infusion	Y		S C C C C C				N N N	ot Reported lot Reported lot Reported lot Reported lot Reported lot Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020 1	7864279	DIRECT	Υ	0	Γ			76 YR	Female	USA
Preferred Term	<u>Prod</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>fr</u>
Blood Creatine Increased Creatinine Renal Clearance Decreased; Therapy Interrupted	d; Remd	esivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	iilead
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020 1	7864306	DIRECT	Υ					25 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>fr</u>
Product Preparation Erro	or Remd	esivir	Υ		S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jun-2020 1	7864803	DIRECT	Υ	0	Γ			57 YR	Male	USA
<u>Preferred Term</u>	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>fr</u>
Hypotension	Remd 100m	esivir For Injection g/Vial	Υ		S	Intravenous (not otherwise specified)			G	ilead
	Zinc				С					ot Reported

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	Merc Leve Hydr Fam Enox Cipro Azith Asco Dopa	oprazole openem thyroxine tiracetam ocortisone otidine taparin o oromycin orbic Acid amine pinephrine			00000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865473	DIRECT	Υ	C	T				28 DAY	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased; Bilirubin Conjugated Abnormal	Aspin Atory Cisar Senr Docu Enox Epop Fami Fent Insul Insul Keta Meth Nore Zosy Prop Timo	desivir rin 81 Mg vastatin 40 Mg tracurium Drip nosides 5 Ml usate 50 Mg kaparin 40 Mg prostenol Inhaled otidine 20 Mg anyl Drip semide 40 Mg in Lispro in Nph mine Drip pylprednisone 60 Mg pinephrine Drip rn 4.5 Grams ofol Drip somycin 1.5 Gram			s	Intravenous drip					Gilead Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865479	DIRECT	Υ	D	E				70 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Cardiac Arrest	Rem	desivir			S	Intravenous (no otherwise specif				G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865482	DIRECT	Υ						29 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Device Delivery Syster	m Rem Ns	desivir 100mg lv In 100ml	Υ		S	Intravenous drip)			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865487	DIRECT	Υ	D	E				65 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Cardiac Arı		desivir			S	Intravenous drip)			G	bilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865494	DIRECT	Υ	D	E, LT				58 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Brain Death; Infarction	ed	desivir			S	Intravenous (no otherwise speci				G	ilead
Ratio Increased; Miosi Respiratory Failure; Thrombocytopenia; Troponin Increased; Unresponsive To Stim	Acet Aspii	pinephrine aminophen rin nedetomidine			C C C		,			N N	lot Reported lot Reported lot Reported lot Reported

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						Detailed Ke	port			
		Fentanyl Midazolam Propofol Rocuronium Succinylcholine Argatroban			00000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>tcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178655	06 DIRECT	Υ	DE				74 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardiac Arrest; Circula Collapse; International Normalised Ratio Increased	atory I	Remdesivir Amiodarone Drip Cefepime 1g Iv Q24h Norepinephrine Drip Phytonadione 10 Mg Sc Propofol Drip Vancomycin 1g Iv Q12h Vasopressin Drip	Y		s c c c c c c	Intravenous drip	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178655	10 DIRECT	Υ	DE	, OT			75 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Disseminated Intravascular Coagulat	tion;	Remdesivir			S	Intravenous drip	Other Frequency:Once- Loading Dose;			Gilead
Dyspnoea; Pulmonary Embolism; Shock		Remdesivir			S	Intravenous drip				Gilead
Zinsoneni, Grison		Convalescent Plasma Doxycycline Acetaminophen Ceftriaxone Docusate Sodium Donepezil Enoxaparin Fluoxetine Melatonin Omeprazole			0000000000					Not Reported



		Propofo Risperid Senna T Quetiap	lone Fablet ine ylene Glycol I nide tte			000000000					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178655	14	DIRECT		C	T			25 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypokalaemia		Remdes	sivir			S	Intravenous (not otherwise specified))			Not Reported
			nide 20mg Ivp X1 nide 40mg Ivp X4			C C					Not Reported Not Reported
FDA Received Date	Case #		Case Type	Health	Prof C	outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178655	19	DIRECT		C	T			25 YR	Female	USA
<u>Preferred Term</u>		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypophosphataemia		Remdes	sivir			S	Intravenous (not otherwise specified))			Not Reported
			nide 20mg Ivp X1 nide 40mg Ivp X4			C C					Not Reported Not Reported
FDA Received Date	Case #		Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178655	24	DIRECT		C	T			25 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed	Remdes Acetami	sivir inophen 650mg Q4h			S C					Not Reported Not Reported



								оро: -				
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Contro	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178655	47	DIRECT	Υ						40 YR	Male	USA
Preferred Term		Product	<u>t</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Disease		Remdes	ivir Injection			S	Intravenous (not otherwise specified	d)				Gilead
Progression		Tocilizur Merrem	nycin Ivpb			C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	178655	89	DIRECT		(TC				80 YR	Female	USA
Preferred Term		Product	Ŀ	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Renal Impairment		Remdes	ivir			S	Intravenous (not otherwise specified	d)				Not Reported
			ycin 750mg Iv Once ycin 1g Iv Daily			C C	·	,				Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	178655	94	DIRECT	Y						64 YR	Female	USA
Preferred Term		Product	<u>t</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B	lood	Remdes	ivir	Υ		S	Intravenous drip					Gilead
Creatinine Increased		Bumetar Carvedil Clopidoo Isosorbio	81mg Tab Po Daily nide 1mg Po Bid ol 25mg Po Bid grel 75mg Po Daily de Mononitrate 30mg Po			C C C C	·					Not Reported Not Reported Not Reported Not Reported Not Reported
		Pantopra	kast 10mg Po Daily azole 40mg Po Daily Ilin 75mg Po Tid			C C C						Not Reported Not Reported Not Reported

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		ramadol 50mg Po Q6h Prn ain			С				No	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865599	DIRECT		C	T			80 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Leukocytosis	R	emdesivir			S	Intravenous (not otherwise specified))		No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17865627	7 DIRECT			DΕ			80 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Pneumonia; Respirato Arrest; Septic Shock	ry R	emdesivir			S	Intravenous (not otherwise specified)			No	ot Reported
	In	cetaminophen 650mg Q4h Prn sulin Human Regular Sliding cale			C C					ot Reported ot Reported
	N	orepinephrine Iv Drip			С					ot Reported
		ocuronium 50mg lvp X1 lonazepam 0.5mg Q8h			C					ot Reported ot Reported
		alproic Acid 125mg Q6h			С					ot Reported
		torvastatin 10mg Daily			C					ot Reported
		evothyroxine 25mcg Daily amotidine 20mg Q12h			C C					ot Reported ot Reported
		noxaparin 80mg Q12h			C					ot Reported
	P	iperacillin/Tazobactam 3.375g Q6h			Ċ					ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866073	B DIRECT	Υ	C	T			77 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Heart Rate Decreased Respiratory Depressio	,	emdesivir			S	Intravenous bolus			Gi	ilead

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						Dotalloa No	port			
	Propo	ofol			S	Intravenous drip	Other Frequency:50- 75mcg/Kg/Min;			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866082	DIRECT	Υ	(ЭТ			94 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Blood Creatine Increas Creatinine Renal Clearance Decreased	sed; Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866086	DIRECT		(ТС			55 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Renal Function Test Abnormal; Renal Impairment	Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866090	DIRECT	Υ	(ТС			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Infusion Site Reaction		desivir desivir			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866091	DIRECT		(ТС			55 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Atrial Fibrillation	Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
		oinephrine Iv Drip Inyl Iv Drip			C C	. ,				Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866098	DIRECT		F	Ю				67 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatine Phosphokinase Increas Hepatitis; International Normalised Ratio ncreased; Ischaemic Hepatitis; Liver Functio Fest Increased; Rhabdomyolysis	Apixal	or			S C C						Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866101	DIRECT	Υ	C)T				80 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
acunar Infarction; Seizure	Remd	esivir	Υ		S						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866105	DIRECT	Υ	C	T				50 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferancreased	ase Remd	esivir			S	Intravenous (not otherwise specifie	d)				Gilead
	Enoxa Ceftria Atorva	axone			C C C						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866451	EXPEDITED (15-DAY)		H	Ю	US-GILEAD- 0469160	2020-		82 YR	Female	e USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosag	e Text	Duration		Mfr

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Headache; Myalgia; Ra Papular	ash Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facili	<u>ty Age</u>	<u>Sex</u>	Country
05-Jun-2020	17866498	EXPEDITED (15-DAY)		DE	Ē, OT	US-GILEAD-20 0470010	20-	80 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Death	Remo	desivir			S	Unknown	100 Mg, Qd		G	ilead
	Atorv Carve Lovei Losai Meth Pyrid	nox [Enoxaparin Sodium]			0000000				N N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facili	ty Age	<u>Sex</u>	Country
05-Jun-2020	17866546	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0470050	20-	57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Infusion Related React Nausea	tion; Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Remo	desivir			S	Intravenous (not otherwise specified)	Unk		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facili	ty Age	<u>Sex</u>	Country
05-Jun-2020	17866936	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0469248	20-	41 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Chills; Tremor	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	ilead
	Lantu	IS			С		Unk		N	ot Reported

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	Insu	lin Lispro			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868108	EXPEDITED (15-DAY)				US-GILEAD-2 0469266	2020-		66 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		Mfr
Product Dose Omissio		ndesivir ndesivir			s s	Unknown Unknown	200 M 100 U	•			Gilead Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868192	EXPEDITED (15-DAY)		C	T	US-GILEAD-2 0469449	2020-		57 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Transaminases Increa	ased Rem	desivir			S	Intravenous (not otherwise specified	100 M	g, Qd			Gilead
	Asco Aspi Ator Azith Bude Cefti Chol Dexa Doci Enoo Insul Insul Lina Lisin Pant Poly Selir Tran	terol Hfa orbic Acid rin (E.C.) vastatin nromycin esonide riaxone lecalciferol emethasone usate;Senna kaparin lin Lispro lin Glargine gliptin opril coprazole ethylene Glycol 3350 nexor nadol Sulfate			000000000000000000000000000000000000000						Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868685	DIRECT	Υ	0	Т			62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Shock	Remo	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
	Aceta Acety Albute Aspiri Azithr Ceftri D50w Enox: Etomi Intuba Hydro Insuli Ipratre Methy Succi Propo Rocu Intuba	romycin axone romycin axone r Prn Hypoglycemia aparin idate (1 Dose For ation) romorphone Drip n LisproSliding Scale opium Inhaler rylprednisolone Sodium nate (X 1 Dose) ofol Drip ronium (1 Dose For ation)								Not Reported
		ım Chloride Drip n 3.375 G Iv			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868686	DIRECT	Υ	LT	Γ			39 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest	Hepa	desivir rin romycin			S C C					Not Reported Not Reported Not Reported

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Nore	pinephrine			С					Not Reported
Aceta	minophen			С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
Acety	lcysteine			С					Not Reported
				С					Not Reported
				С					Not Reported
				_					
				C					Not Reported
				C					Not Reported
									Not Reported
Chlor	hexidine			С					Not Reported
Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17868688	DIRECT	Υ	07	-			43 YR	Male	USA
Drod	uot	Comp	OTC	Polo	Pouto	Docago Toyt	Duration		Mfr
<u>P10u</u>	ucı	Comp.	<u>010</u>	Kole	Koule	Dosage Text	Duration		<u>IVIII</u>
Remo	desivir			S					Not Reported
Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17868690	DIRECT	Υ	01	-			62 YR	Male	USA
Drad		Comp	OTC	Dele	Davita	Deceme Toyt	Duration		Mfr
<u>FIOU</u>	ucı	Comp.	<u>010</u>	Kole	Koute	Dosage Text	Duration		<u>IVIII</u>
Remo	desivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Calci	um Gluconate			С					Not Reported
Calci				_					Not Reported
	tidine			C					Not Reported
				C					
Famo Fenta				C					Not Reported
Famo Fenta	ınyl us Sulfate			C C C					Not Reported Not Reported
Famo Fenta Ferro Hepa	ınyl us Sulfate			0000					Not Reported
Famo Fenta Ferro Hepa Hydro	inyl us Sulfate rin			C C C					Not Reported Not Reported Not Reported
Famo Fenta Ferro Hepa Hydro Phyto	inyl us Sulfate rin ocortisone			0000000					Not Reported Not Reported Not Reported Not Reported
	Aceta Midaz Cefep Hydro Bisac Vasop Propo Ipratr Acety Insuli Hydro Succi Famo Albute Perflu Chlor Case # 17868688 Prod Remo Case # 17868690 Remo Calcid	17868688 DIRECT Product Remdesivir Case # Case Type 17868690 DIRECT Product Remdesivir Calcium Gluconate	Acetaminophen Midazolam Cefepime Hydromorphone Bisacodyl Vasopressin Propofol Ipratropium-Albuterol Acetylcysteine Insulin Regular Hydrocortisone Sodium Succinate Famotidine Albuterol Perflutren Lipid Microspheres Chlorhexidine Case # Case Type Health 17868688 DIRECT Y Product Comp. Remdesivir Case # Case Type Health 17868690 DIRECT Y Product Comp. Remdesivir Calcium Gluconate	Acetaminophen Midazolam Cefepime Hydromorphone Bisacodyl Vasopressin Propofol Ipratropium-Albuterol Acetylcysteine Insulin Regular Hydrocortisone Sodium Succinate Famotidine Albuterol Perflutren Lipid Microspheres Chlorhexidine 17868688 DIRECT Y OT Product Comp. OTC Remdesivir Product Comp. OTC Remdesivir Case # Case Type Health Prof Out Remdesivir Camp. OTC Remdesivir	Acetaminophen C C	Acetaminophen	Acetaminophen	Acetaminophen	Acetaminophen C C

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	Piper	acillin/Tazobactam			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868691	DIRECT	Υ		DS				44 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Pruritus	Remo	lesivir	Υ		S	Intravenous drip			5 DAY		Gilead
	Hydro Lisino Amloo Ferro Omep Hydro Cyan	nazole ochlorothiazide opril dipine us Sulfate orazole ocodone/Acetaminophen ocabalamin			00000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868692	DIRECT	Υ		DE				70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Multiple Organ Dysfunction Syndrome Respiratory Failure; SI	e ;	desivir Eua			S						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868694	DIRECT	Υ		НО				87 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	ото	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Disease Progression; Renal Failure	Remo	desivir	Y		S	Intravenous (not otherwise specified)	<u> </u>				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased	Remo	desivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868696	DIRECT	Υ	C	T			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Creatinine Increased; Hepatic Enzyme Increased	Remo	desivir	Y		S	Intravenous (not otherwise specified	()			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17868697	DIRECT	Υ	С	ÞΕ			56 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Cardia Arrest	c Remo	desivir			S	Intravenous bolus	Other Frequency:Once Loading Dose;	1 DAY		Gilead
		minophen			С					Not Reported
		ial Tears			C					Not Reported
	Aspiri				С					Not Reported
		romycin			С					Not Reported
		ecalciferol nopressin			C					Not Reported Not Reported
	Famo				C					Not Reported
	Fenta				C					Not Reported
	Hepa	•			C					Not Reported
		n Lispro			Č					Not Reported
	Insulii				Č					Not Reported
		penem			Ċ					Not Reported
		/lprednisolone			C					Not Reported
	Midaz				С					Not Reported
	Moror	pinephrine			С					Not Reported



FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	17870	105	DIRECT	Υ					53 YR	Male	USA
Preferred Term		Product	i.	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Leukopenia; Neutrope Respiratory Failure	nia;	Remdes (Eua))	ivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)	Other Route:Iv			Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178707	709	DIRECT	Υ		DE			77 YR	Male	USA
Preferred Term		Product	i.	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		Mfr
Condition Aggravated; Covid-19 Pneumonia		Remdes (Eua))	ivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020	178708	330	DIRECT	Υ		DE			69 YR	Male	USA
Preferred Term		Product	1	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney Injury; Areflexia; Cardi		Remdes (Eua))	ivir (Eua) (Remdesvir			S	Intravenous (not otherwise specified)				Not Reported
Arrest; Condition Aggravated; Hypotens Miosis; Nodal Rhythm; Pulmonary Arterial Pressure Increased; Pulmonary Fibrosis; P Absent; Respiratory Failure; Right Ventricu Dilatation; Right Ventricular Failure; Sir Bradycardia; Unresponsive To Stim	ulse Iar nus	Vancom 1gm/Vil	ycin (Vancomycin Hcl Inj)			S	Intravenous (not otherwise specified)	Other Strength:1 Gm/Vil;			Not Reported

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					Detailed Ne	port			
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020 17870	0880 DIRECT	Υ	0	Γ			72 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Distress Syndrome; Ammonia Increased; Aspartate Aminotransferase Increased; Atrial Fibrillation; Blood Lactic Acid Increased; Body Temperature Increased; Candida Test Positive; Chest Pain; Covid-19 Pneumonia; Fluid Overload; Haemodynamic Instability; Hypotension; Interleukin Level Increased; Lung Opacity; Metabolic Acidosis; Oxygen Saturation Decreased; Renal Failure; Septic Shock	Remdesivir Pantoprazole 40mg Atorvastatin 40mg Albuterol Neds Albumin Thiamine 100mg Furosemide 20mg Lantus Multivitamin With Minerals			888000000		Other Route:Iv			Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2020 17871	1070 DIRECT	Υ	0	Γ			60 YR	Female	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir 200mg	Υ		S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Blood Alkaline Phosphatase Increased;	Remdesivir 100mg			S	Intravenous (not otherwise specified)				Gilead
Oxygen Saturation Decreased; Therapy	Bupropion 300mg 24 Hour Release Tablet			С	Oral				Not Reported
Interrupted	Acetaminophen Azltromycin Benzocaine-Menthol Lozenge			C C C					Not Reported Not Reported Not Reported

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Bisacody C C Not Reported Not Reported		Bisac				С						Not Reported
Hydromorphone C						С						
Hydromorphone C C Not Reported Not Repor						С						
Hydromorphone C C Not Reported Not Repor						С						
Hydromorphone C C Not Reported Not Repor						С						
Hydromorphone C C Not Reported Not Repor						С						
Midazolam C						С						
Midazolam C						С						
Potassium Bicarbonate-Citric C Acid Effervescent Acid Eff						С						
Potassium Bicarbonate-Citric C Acid Effervescent Acid Eff						С						
Potassium Bicarbonate-Citric C Acid Effervescent Acid Eff						С						
Potassium Bicarbonate-Citric C Acid Effervescent Acid Eff						С						
Potassium Bicarbonate-Citric C Acid Effervescent Acid Eff						С						
Potassium Bicarbonate-Citric C Acid Effervescent Acid Eff						C						
Acid Effervescent						C						
Propofol Senna (Senokot) Sentraline C C Sentraline C C Sentraline C C Sentraline C C Not Reported Not Repo						С						Not Reported
Senna (Senokot) C C Not Reported Not Rep						_						
Temazepam C Not Reported						C						
Temazepam Trazodone C Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported						C						
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country						C						
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 06-Jun-2020 17868624 EXPEDITED (15-DAY) HO, OT US-GILEAD-2020- 0469292 60 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Dialysis; Off Label Use Remdesivir S Unknown 50 Mg Gilead FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 06-Jun-2020 17868698 DIRECT Y OT 74 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead												
O6-Jun-2020 17868624 EXPEDITED (15-DAY) HO, OT O469292 US-GILEAD-2020-0469292 60 YR Male USA Preferred Term Product Comp. OTC Role Route Route Dosage Text Duration Mfr Dialysis; Off Label Use Remdesivir S Unknown 50 Mg Gilead FDA Received Date O5-Jun-2020 Case Type Health Prof Outcomes Mfr Control # S03B Facility Age Sex Country 06-Jun-2020 17868698 DIRECT Y OTC Role Route Dosage Text Duration Mfr Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead		Trazo	odone			С						Not Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Dialysis; Off Label Use	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Dialysis; Off Label Use Remdesivir S Unknown 50 Mg Gilead FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 06-Jun-2020 17868698 DIRECT Y OT 74 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead	06-Jun-2020	17868624	EXPEDITED (15-DAY)		НС	O, OT		020-		60 YR	Male	USA
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 06-Jun-2020 17868698 DIRECT Y OT 74 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead	Preferred Term	<u>Prod</u>	uct	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 06-Jun-2020 17868698 DIRECT Y OT 74 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead	D: 1 : 0" 1 1 1 1 1 1 1 1 1	_				•						0.1
O6-Jun-2020 17868698 DIRECT Y OT Fourth Fourth Fourth OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead	Dialysis; Off Label Use	e Remo	desivir			S	Unknown	50 Mg				Gilead
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead	06-Jun-2020	17868698	DIRECT	Υ	ТО	-				74 YR	Male	USA
Acute Kidney Injury Remdesivir Y S Intravenous (not Gilead												
intravologo (not	Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
	Acute Kidney Injury	Remo	desivir	Υ		S)				Gilead



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

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2020	1786869	9 DIRECT	Υ		НО			69 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Pressure Increa Chest X-Ray Abnorma	ıl;	Remdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Chills; Dyspnoea; Hea Rate Increased; Infusion Related Reaction; Leukocytosis; Pyrexia	on I\ F	Pantoprazole 40mg Lactated Ringers Jumalog Sliding Scale Insulin Covid-19 Convalescent			C C C	,				Not Reported Not Reported Not Reported Not Reported
		o Acetaminophen 650mg			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2020	1786870	0 DIRECT	Υ		LT, OT			47 YR	Male	USA
Preferred Term	E	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Increase Renal Disorder		Remdesivir	Υ		S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2020	1786870	1 DIRECT	Υ		LT, OT			35 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OT(</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase R	Remdesivir			S	Intravenous drip				Gilead
Increased	M A M	Cholecalciferol 2000 Units Daily Melatonin 6 Mg Hs torvastatin 40 Mg Daily At 6pm Methylprednisolone 60 Mg Iv D6h			C C C	·				Not Reported Not Reported Not Reported Not Reported
	E	inoxaparin 40 Mg Sq Q12h Iumalog Sliding Scale			C C					Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2020	17868702	DIRECT	Υ	0	Γ			65 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Aspartate Aminotransferase Increased	Remo	desivir	Υ		S				G	iilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2020	17868703	DIRECT	Υ	0	Γ			74 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Blood Alkaline		desivir			S	Intravenous bolus			G	ilead
Phosphatase Increase General Physical Heal Deterioration; Hypoxia Liver Function Test Abnormal	th Hepa . Mero Metol Sodiu Tolva	penem orolol ım Chloride			C C C C C C				N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2020	17869696	DIRECT	Υ	0	Γ			76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Renal Failure	Remo	desivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2020	17869704	DIRECT	Υ	0	Γ			53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified)		G	ilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2020	17869707	DIRECT	Υ	0	Т			52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Acute Kidney Injury	Remo	desivir	Υ		S	Intravenous bolus		5 DAY		Gilead
	Propo Nore Mida: Fenta Dexn Mirat Busp Bisac Citald Chole Vanc Cefe Diltia: Hepa Insuli	pinephrine zolam anyl nedetomidine azepine irone podyl pram ecalciferol pime zem rin			000000000000000000					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2020	17869710	DIRECT	Υ	0	Т			47 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Haemodialysis; Metab Acidosis; Renal Failure		desivir			S	Intravenous (not otherwise specified)				Not Reported
	Tocili Anak Colch				C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2020	17869716	DIRECT	Υ	0						

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Preferred Term	rred Term Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Creatine Increas Creatinine Renal Clearance Decreased					S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control # 503B Facility		<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17818529 EXPEDITED (15-DAY)		DE, LT		US-GILEAD-20 0468184	20-	77 YR	Male	USA	
Preferred Term	<u>Product</u>		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		Mfr
Oxygen Saturation Decreased	Remdesivir				S	Intravenous (not otherwise specified)	Unk			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Cefepi				С					Not Reported
		pic Acid			С					Not Reported
	Thiam				С					Not Reported
	Doxyc				С					Not Reported
		Iprednisolone			C C					Not Reported
	Sertral	orazole line A			C					Not Reported Not Reported
	Tamsu				C					Not Reported Not Reported
	Zinc	2103111			C					Not Reported
	Ipratro	muiam			Č					Not Reported
	Enoxa	-			Ċ					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17856716	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469671	20-	73 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	Duration		<u>Mfr</u>
Ventricular Fibrillation	Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Acetar	minophen			С		Unk			Not Reported
	Enoxa	parin			С		Unk			Not Reported
	Fluoxe	etine			С		Unk			Not Reported

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							-					
	Heparin				С		Unk			Not Reported		
	Hyd	Iroxyzine			С		Unk		Not Reported			
	Lor	azepam			С		Unk		Not Reported			
	Mel	atonin			С		Unk		Not Reported			
	Par	ntoprazole			С		Unk			Not Reported		
	Tra	zodone			С		Unk			Not Reported		
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country		
08-Jun-2020	17871341	DIRECT	Υ					83 YR	Female	USA		
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>		
Acute Kidney Injury	Rer	ndesivir	Υ		S	Intravenous (not otherwise specified)			Gilead		
	Pip	eracillin-Tazobactam			С	- по	,			Not Reported		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country		
08-Jun-2020	17871346	DIRECT	Υ	Н	0			71 YR	Female	USA		
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>VIfr</u>		
Alanine Aminotransfera Increased	Am Asp Ato	ndesivir lodipine 5 Mg iirin 81 Mg rvastatin 40 Mg oxaparin 40 Mg			s C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
08-Jun-2020	17871365	DIRECT	Y					76 YR	Male	USA		
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>]	<u> Mfr</u>		
Product Storage Error; Wrong Technique In Product Usage Proces		ndesivir Eua			S					Not Reported		



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871387	DIRECT	Υ	D	E, OT			81 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Toci	ndesivir Iizumab valescent Plasma	Y		S C C	Intravenous bolus				Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871406	DIRECT	Υ	0	т			42 YR	Female	e USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypotension; Ischaem Hepatitis; Pneumonia Bacterial	nic Rem	ndesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871437	DIRECT	Υ					37 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Toci Azith Acet	ndesivir lizumab nromycin aminophen xaparin			s C C C C	Intravenous drip		4 DAY		Gilead Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871442	DIRECT	Υ					60 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Administration Error; Product Prepara Error		ndesivir	Υ		S	Intravenous (not otherwise specified)		1 DAY		Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871448	DIRECT	Υ	07	-			33 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Creatinine Renal Clearance Decreased			S			Intravenous (not otherwise specified)	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871461	DIRECT	Υ	DE	<u> </u>			90 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dehydration; Disease Progression; Hypoxia;		desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Pain; Renal Failure	Enox	aparin			С					Not Reported
	Lisino				С					Not Reported
	Meto	orolol oprazole			C C					Not Reported Not Reported
	Zosyr				C					Not Reported
		abalin			Č					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17871973	DIRECT	Υ	DE				68 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest	Remo	desivir 100mg Iv			S	Intravenous (not otherwise specified)				Not Reported
	Amlo	dipine			С					Not Reported
		aparin _.			С					Not Reported
		hyroxine			C C					Not Reported
	Fenta	nedetomidine			C					Not Reported Not Reported
		oinephrine			C					Not Reported
	Propo				Č					Not Reported
		pressin			C					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872168	DIRECT	Υ	D	E			43 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Hospice Care	Remd	esivir			S				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872171	DIRECT	Υ					37 YR	Female	USA
Preferred Term Product		<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Product Administration Error; Product Prepara Error; Product Prepara Issue	tion	lesivir	Y		S	Intravenous (not otherwise specified)	2 DAY	G	Silead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872244	DIRECT	Υ	0	Т			74 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Hepatic Enzyme Increased	Aceta Insulir Insulir Ondar Sodiur Albute Dexar Dexm Etomic Furosc	aparin mine/D5w minophen n Glargine n Lispro nsetron m CI Flush erol Inhaler methasone edetomidine date emide ted Ringers aine			% 000000000000000000000000000000000000	Intravenous drip				cilead lot Reported

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	Pantoprazole Potassium Azithromycin Hydromorphone Fentanyl Ceftriaxone				00000				1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872250	DIRECT	Υ					43 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Product Dispensing Er Product Preparation E Wrong Product Administered		desivir	Y		S	Intravenous (not otherwise specified)		2 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872251	DIRECT	Y		ÞΕ			83 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Hospice Care	Rem	desivir			S				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872254	DIRECT	Υ	C	T			49 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Transaminases Increa	sed Rem	desivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872258	DIRECT	Υ	[ÞΕ			65 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Cardiac Arrest	rdiac Arrest Remdesivir				S	Intravenous (not			(Gilead

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						otherwise specified)				
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872280	DIRECT	Υ					42 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Product Dispensing Er Product Preparation Er Wrong Product Administered		desivir	Υ		S	Intravenous (not otherwise specified)		2 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872285	DIRECT	Υ					47 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Product Dispensing Er Product Preparation E Wrong Product Administered		desivir	Y		S	Intravenous (not otherwise specified)		2 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872288	DIRECT	Υ					65 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Product Preparation Is	sue Rem	desivir	Υ		S			1 DAY	(Gilead
	Rem	desivir	Y		S	Intravenous (not otherwise specified)		2 DAY	(Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17872289	DIRECT	Υ					60 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Product Administration	n Rem	desivir	Υ		S	Intravenous (not		2 DAY	(Gilead

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Error; Product Prepara Issue	tion					otherwise specified)							
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country			
08-Jun-2020	17872290	DIRECT	Υ					56 YR	Female	USA			
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>			
Product Administration Error; Product Prepara		esivir	Y		S	Intravenous (not otherwise specified)		1 DAY	C	Gilead			
Issue	Remd	esivir	Y		S	Intravenous (not otherwise specified)		2 DAY	C	Gilead			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>			
08-Jun-2020	17872293	DIRECT	Υ	(TO			45 YR	Female	USA			
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>			
Transaminases Increas	sed Remd	esivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		C	Gilead			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country			
08-Jun-2020	17872296	DIRECT	Y					70 YR	Male	USA			
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>			
Product Administration Error; Product Prepara Error; Product Prepara Issue	tion	esivir	Y		S	Intravenous (not otherwise specified)		1 DAY	C	Bilead			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country			
08-Jun-2020	17872300	DIRECT	Y					27 YR	Male	USA			
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>			
Product Administration Remdesivir		Υ		S	Intravenous (not		1 DAY	C	Gilead				

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

Error: Product Preparation otherwise specified) Error; Product Preparation Issue FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age **Sex** Country Υ USA 08-Jun-2020 17872303 DIRECT 61 YR Male **Preferred Term Product OTC** Role Route **Dosage Text** Duration Mfr Comp. S **Product Administration** Remdesivir Υ Gilead Intravenous (not 1 DAY Error: Product Preparation otherwise specified) Error: Product Preparation Issue FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Sex Age Country 17872307 Υ 77 YR USA 08-Jun-2020 DIRECT Female **Preferred Term** Comp. **Dosage Text** Mfr **Product** OTC Role Route Duration Υ S Product Administration Remdesivir Gilead Intravenous (not 1 DAY Error; Product Preparation otherwise specified) Error: Product Preparation Remdesivir Υ S Gilead Intravenous (not 2 DAY Issue otherwise specified) **Health Prof Outcomes** 503B Facility FDA Received Date Case # Case Type Mfr Control # Age Sex Country 08-Jun-2020 17872312 DIRECT Υ 79 YR Male USA **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr Υ S Gilead Product Administration Remdesivir Intravenous (not 1 DAY Error: Product Preparation otherwise specified) Error; Product Preparation Issue FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Country Age Υ 08-Jun-2020 17872315 DIRECT 69 YR Male USA

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Product Administration Error; Product Preparation		esivir	Υ		S	Intravenous (not otherwise specified))		1 DAY		Gilead
Error; Product Preparation Issue	on Remde	esivir	Υ		S	Intravenous (not otherwise specified))		2 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	<u># 50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	`			С	T	US-GILEAD-20 0469297)20-		53 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	Duration		<u>Mfr</u>
Alanine Aminotransferas Increased	se Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg, G	d			Gilead
	Ceftria Dobuta				С						Not Reported
		ycline 3ddd			C C						Not Reported Not Reported
		parin Becat			С						Not Reported
	Famoti				С						Not Reported
	Fentan	iyl cortisone			C C						Not Reported Not Reported
	Midazo				C						Not Reported
		nephrine			Č						Not Reported
		ephrine			С						Not Reported
	Propof				С						Not Reported
	Vasopi	n Bicarbonate			C C						Not Reported Not Reported
	Digoxii				Č						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020 1	17873015	EXPEDITED (15-DAY)		С	T	US-GILEAD-20 0469646)20-		60 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Remde	esivir			S	Unknown	Unk				Gilead
				D (0							
FDA Received Date	Case #	Case Type	<u>Health</u>	Prot U	utcomes	Mfr Control	<u>#</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage To	ext	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blood Creatinine Increased	Remde	esivir	S Intravenous (not Unk Unk otherwise specified)		, Qd		C	Gilead			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17873048	EXPEDITED (15-DAY)			НО	US-GILEAD-2 0469609	020-		27 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	ext	Duration	<u>M</u>	<u>fr</u>
Liver Function Test Increased	Remde	esivir			S	Intravenous (not otherwise specified	100 Mg, (Qd		C	Gilead
	Sertral	ine			С	·	Unk			١	lot Reported
	Melato	nin			С		Unk			N	lot Reported
	Acetan	ninophen			С		Unk			١	lot Reported
	Enoxa	parin			С		Unk			١	lot Reported
	Ketoro	lac			С		Unk			١	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	<u># 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17873100	EXPEDITED (15-DAY)		1	ОТ	US-GILEAD-2 0469628	020-		47 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Oxygen Saturation Decreased	Remde	esivir			S	Intravenous (not otherwise specified	200 Mg			C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874653	DIRECT	Υ		ОТ				41 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>



Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cardiomyopathy; Remdesivir Solution (Emergency Use Authorization) Tocilizumab S Intravenous drip

С

Gilead

Not Reported

Cardiomyopathy; Transaminases Decreased											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	178746	57 DIRECT	Υ		DE				61 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosa	age Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury		Remdesivir			S	Intravenous (not otherwise specifi	ed)			G	Bilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	178746	59 DIRECT			НО				35 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosa	age Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury; Nephropathy Toxic		Remdesivir			S	Intravenous bolu	s			G	Silead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	178746	73 DIRECT	Υ						26 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosa	age Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer	rase	Remdesivir	Υ		S	Intravenous bolu	S			G	Gilead
Increased; Drug Interaction; Liver Fund Test Increased	ction	Azithromycin 500 Mg Po Daily Ceftriaxone 1 Gram Iv Q24h Dextromethorphan 60 Mg Po Q12h	/		C C					N	lot Reported lot Reported lot Reported
		Enoxaparin 60 Mg Q12h Guaifenesin Er 600 Mg Po Bio Methylprednisolone 20 Mg Iv Q6h	d		C C C					N	lot Reported lot Reported lot Reported
		Acetaminophen/Hydrocodone	;		С					N	lot Reported



							1			
	A	/235 1 Tab Q4h Prn Pain Iprazolam 0.5 Mg Q8h Prn nziety			С					Not Reported
	В	denzonatte 100 Mg Po Tid Prn Cough			С					Not Reported
	C	codeine-Guaifenesin 10-100 Mg	9		С					Not Reported
	D	o Q4h Prn Cough Dexmedetomidine 400 Mcg At .2 Mcg/Kg/Hr Iv			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	1787467	7 DIRECT	Υ					60 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase R	temdesivir	Υ		S	Intravenous (not otherwise specified)		5 DAY		Gilead
Aminotransferase Increased		cetazolamide Extended			С	omermee opeemee,				Not Reported
	А	delease Atorvastatin 10 Mg Geftriaxone 1gm			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	1787468	1 DIRECT	Υ	(ЭТ			67 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased; Transamina Increased		emdesivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	1787468	6 DIRECT	Υ	(ТС			45 YR	Male	USA
Preferred Term	Е	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed R	temdesivir Inj			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;			Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874702	DIRECT	Υ		DE			68 YR	Female	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Alanine Aminotransfera	ase Re	mdesivir	Υ		S	Intravenous bolus				Gilead
Increased; Aspartate Aminotransferase Increased; Bacterial Infection; Blood Creati Increased; Respiratory Failure; White Blood C Count Increased	nine Fu Lis Fu Lis Fu No Fe Ga Mc En As Do Pa Ins Ve	ncomycin eropenem rosemide inopril etoprolol repinephrine ntanyl bapentin erphine pofol oxaparin pirin cusate ntoprazole ehtylprednisolone culin Glargine nlafaxine oneb iaifenesin			000000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874708	DIRECT	Υ	(ОТ			64 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Alanine Aminotransfera Increased; Aspartate	ase Re	mdesivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Renal Impairment	Ato Ce De En	opurinol orvastatin ftriaxone xmedetomidine oxaparin motidine			C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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	Gaba _l Melat				C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874713	DIRECT	Υ	(ЭТ			25 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remd	esivir			S	Intravenous bolus			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874717	DIRECT	Υ					39 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Orthostatic Hypotensic	on Remd	esivir			S	Intravenous (not otherwise specified)			•	Gilead
	Carve Enoxa Levotl	bic Acid dilol aparin nyroxine prazole			000000				 	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874751	DIRECT	Υ	(ТС			63 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Transaminases Increa	sed Remd	esivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;		(Gilead
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17874927	DIRECT	Y					63 YR	Female	USA

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Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Intercepted Product Preparation Error	Remo	desivir	Υ		S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17875016	DIRECT	Υ	0	Γ			91 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Creatinine Increased; Glomerular Filtration Rate Decreas Renal Impairment	Amio- sed; Apixa Cova Bume Plavix Dexa Hepa Insuli Proto Metol Nitrog Hydra	lescent Plasma ex c methasone rin n nix			%0000000000000					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17875022	DIRECT	Y					59 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2020	17875057	DIRECT	Υ	0	Γ			63 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Alanine Aminotransfera					S						Not Reported	
Increased; Aspartate	Aspiri				С						Not Reported	
Aminotransferase		astatin			С						Not Reported	
ncreased; Procalcitoni					С						Not Reported	
Increased; Respiratory		axone			С						Not Reported	
Distress; Troponin		omycin			С						Not Reported	
Increased; White Blood		onatate			С						Not Reported	
Cell Count Increased		ım Gluconate			С						Not Reported	
		tamine			С						Not Reported	
		aparin _.			С						Not Reported	
		rostenol			C						Not Reported	
	Etomi				С						Not Reported	
	Famo				С						Not Reported	
	Fenta				С						Not Reported	
		ylephrine			С						Not Reported	
	Hepa				С						Not Reported	
	Vitam				С						Not Reported	
		cortisone			С						Not Reported	
	Thiam				С						Not Reported	
		pinephrine			С						Not Reported	
	Propo				С						Not Reported	
	Midaz	rolam			С						Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
08-Jun-2020	17875136	DIRECT	Υ		RI				46 YR	Female	USA	
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	
Liver Injury	Remo	lesivir 100mg			S	Intravenous (not otherwise specified))				Gilead	
	Tocilia	zumab			С	. ,					Not Reported	
		/lprednisolone			Ċ						Not Reported	
		axone			C						Not Reported	
	Doxyo	cycline			C						Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
09-Jun-2020	17800831	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0467444)20-		69 YR	Male	USA	



Death		Remdes	ivir			S	Intravenous (not otherwise specified)		g, Once			Gilead
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17863	292	EXPEDITED (15-DAY)		[DE, OT	US-GILEAD-20 0470078	20-		64 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Cerebral Infarction; Dysphagia; End Stage		Remdes	sivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
Renal Disease; Failure Thrive; Pneumonia Vir		Zosyn				С		Unk				Not Reported
Respiratory Failure	ai,	Vancom	ycin			С		Unk				Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875	072	DIRECT	Υ						47 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Product Preparation Is	sue	Remdes	sivir			S						Not Reported
FDA Received Date	Case :	<u>#</u>	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875	074	DIRECT	Υ	(TC				69 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test		Remdes	sivir	Υ		S	Intravenous bolus					Gilead
Increased		Ascorbio	Acid 500mg			С						Not Reported
		Aspirin 8				С						Not Reported
			atin 20 Mg			С						Not Reported
		Duoneb				С						Not Reported
			,			С						Not Reported Not Reported
		Loveno	•									NOLKEDOMEO
		Zosyn				C						
		Zosyn Vancom	ycin Iv			С						Not Reported
		Zosyn Vancom Acetami	ycin Iv nophen 650mg Prn			C C						Not Reported Not Reported
		Zosyn Vancom	ycin Iv nophen 650mg Prn ex			С						Not Reported

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						Detailed IN	eport			
	Dox	anyl Iv Drip ycycline otidine			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875122	DIRECT	Υ	DI	≣			57 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Cardio	- Rem	ndesivir	Υ		S	Intravenous drip				Gilead
Respiratory Arrest; Hypoxia; Ventricular Tachycardia	Asco Diph Eno Furo Zino	aminophen orbic Acid nenhydramine xaparin osemide Gluconate dnisone			000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875235	DIRECT	Υ	DI	Ē, OT			85 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Cardio-Respiratory Arr		ndesivir			S	Intravenous (not otherwise specified	1)			Gilead
Respiratory Failure	Rem	ndesivir			S	Intravenous (not otherwise specified	,			Gilead
	Ceft Dex Fam Fent Lora D5w Epo Hep Keta Nore	zepam With 3 Amps Bicarb prostenol			000000000000					Not Reported

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		onium alescent Serum			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875456	DIRECT	Υ	C	T			74 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Blood Magnesium Increased Condition Aggravated	Resm				S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875590	DIRECT	Υ	0	ÞΕ			78 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Unresponsive To Stime	uli Remo	esivir			S	Intravenous (not otherwise specified)				Gilead
	Apixa Chlor Diltiaz Glyco Levot Melat Duler: Panto Predr Sertra	oromazine rem pyrrolate nyroxine onin a prazole isone			00000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875594	DIRECT	Υ	F	Ю			78 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury	Remo	esivir			S	Intravenous bolus				Gilead

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							, p = 1			
		Ascorbic Acid 500 Mg Candesartan 16 Mg Enoxaparin 40 Mg Lantus 5 Units Methylprednisolone 50 Mg Metoprolol Succinate 25 Mg Nifidipine 30 Mg Pravastatin 20 Mg Zinc Sulfate 220 Mg Fentanyl Infusion			0000000000					Not Reported
	-	Dexmedotomidine Infusion			C					Not Reported
		Epinephrine Infusion Heparin Infusion			C C					Not Reported Not Reported
		/asopressin Infusion			C					Not Reported
EDA D		·		D 1						·
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	1787560	0 DIRECT	Y					88 YR	Male	USA
Preferred Term	1	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury;		Remdesivir			S	Intravenous bolus				Gilead
Transaminases Increa Urinary Bladder Haemorrhage; Urinary Retention	, , , , , , , , , , , , , , , , , , ,	Albuterol Atorvastatin Enoxaparin Levofloxacin Methylprednisolone Pantoprazole Senna Warfarin Acetaminophen			000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	1787564	7 DIRECT	Υ		ОТ			37 YR	Male	USA
Preferred Term	1	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme	I	Remdesivir			S	Intravenous drip				Gilead
Increased		Propofol Hydromorphone Norepinephrine			C C C					Not Reported Not Reported Not Reported

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					Botanoa 1to	P			
	Docusate-Senna Enoxaparin Pantoprazole			C C C					Not Reported Not Reported Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020 17875	DIRECT	Υ	DE				52 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Cardiac Arrest; Hypotension; Hypoxia; Lung Infiltration; Paralysis; Procalcitonin Increased; Renal Failure	Remdesivir Eua Vancomycin Tocilizumab Pentoxifylline Rocuronium Norepinephrine Midazolam Metoprolol Kaletra Heparin Cisatricurium Cefepime Acetaminophen			<i>∞</i> ∪ ∪ ∪ ∪ ∪ ∪ ∪ ∪ ∪ ∪ ∪ ∪					Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020 17875	DIRECT	Υ	LT				59 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest;	Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
Cardio-Respiratory Arrest; Pulse Absent	Heparin Hydromorphone Insulin Regular Midazolam Propofol Clonazepam Oxycodone			000000	. ,				Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17875891	DIRECT	Υ		ОТ				59 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir			S	Intravenous drip					Gilead
	Vitam Clonic Famo Furos Guaife Midoc Multiv Potas Potas Sodiu Sodiu	erol n Im Gluconate in D3 dine tidine emide enesin drine itamin sium Chloride sium Phosphate m Chloride Inhaled m Phosphate methoxazole/Trimethoprim hine			000000000000000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876085	DIRECT	Υ		ОТ				42 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Hypertensive Urgency Renal Impairment					S	Intravenous bolus					Gilead
кона траннен	Amloo Aspiri Enoxa Famo Gaba	n aparin tidine			000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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							P			
	Lad Qu Fer Ket Mic Pro	petalol Prn ctulose etiapine ntanyl Drip camine Drip dazolam Drip pofol Drip curonium Drip			00000000				No No No No No No	ot Reported out Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876090	DIRECT	Υ	DE				42 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Aggression; Cardiac Arrest; Confusional Sta Hypoxia; Obstructive Airways Disorder; Pneumothorax; Pulse Absent; Rales; Swellin	ate; Thi Ser Hal Par 9 Me Ket Hyd Hej End Cet	mdesivir amine roquel loperidol ntoprazole thylprednisolone corolac drocortisone parin pxaparin fepime corbic Acid			8 00000000000	Intravenous bolus			No No No No No No No No No No No No No N	lead of Reported of Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876168	DIRECT	Υ	0	Γ			39 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	:
Liver Function Test Increased	Rei	mdesivir			S	Intravenous bolus			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876171	DIRECT	Υ	0	Γ			89 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	Mf	:

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Manine Aminotransferancreased; Aspartate Aminotransferase		desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
ncreased; Blood Alkal Phosphatase Increase	ine	rastatin			С				ı	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9-Jun-2020	17876176	DIRECT	Υ		DE			85 YR	Female	USA
referred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
eath	Rem	desivir			S	Intravenous (not otherwise specified)			(Gilead
	Rem	desivir			S	Intravenous (not otherwise specified)			(Gilead
		rbic Acid			С					Not Reported
		etanide			С					Not Reported
		iaxone			С					Not Reported
		methasone			C C				ſ	Not Reported
		alopram otidine			C					Not Reported Not Reported
		ocortisone			C					Not Reported
	Insuli				C					Not Reported
		thryoxine			C C					Not Reported
		zepam			Č					Not Reported
		nesium Sulfate			Č					Not Reported
		racillin-Tazobactam			C					Not Reported
		ıronium			C C					Not Reported
	Vano	comycin			С					Not Reported
	Fenta				С					Not Reported
		zolam			С					Not Reported
		nedetomidine			C C					Not Reported
	Hepa				С					Not Reported
		pinephrine ralenscent Serum			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9-Jun-2020	17876180	DIRECT	Υ		НО			56 YR	Male	USA



Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Hospitalisation	Rem	desivir	Υ		S	Intravenous drip				Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876191	DIRECT	Υ		ОТ			62 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		Mfr
Neuropathy Peripheral	I Rem	desivir			S	Intravenous (not otherwise specified))			Not Reported
	Hyco Aspi				C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876212	DIRECT	Υ		ОТ			66 YR	Male	USA
Preferred Term	Prod	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Creatinine Renal Clearance Decreased	Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once) (Loading Dose;			Gilead
		aminophen			С					Not Reported
		kaparin			C C C					Not Reported
	Fent				C					Not Reported
		alazine			C					Not Reported
		lin Aspart lin Glargine			C C					Not Reported Not Reported
	Lisin				C					Not Reported
		ormin			C					Not Reported
		izolam			Č					Not Reported
	0.9%				C C C					Not Reported
		pinephrine			Č					Not Reported
		oprazole			С					Not Reported
	Pipe	racillin/Tazobactam			C C					Not Reported
	Prop				С					Not Reported
	Roci	uronium			С					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876217	DIRECT	Υ					47 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Aceta Albut Azithi Cefep Ceftri Enox	axone aparin semide			8 00000000	Intravenous drip		3 DAY		Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876300	DIRECT	Υ	0	Γ			72 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Monitoring Procedure Incorrectly Performed; Incorrect D Administered; Product Dispensing Error; Prod Preparation Error	Oose	desivir	Y		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876302	DIRECT	Y	0	Γ			37 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Empty Sella Syndrome	e Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
	Metfo	aparin Irmin Odone			C C C					Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17876309	DIRECT	Υ		ОТ			65 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Liver Function Test Increased	Remd	esivir	Υ		S	Intravenous drip	Other Frequency:5 Day Treatment;	5 DAY	G	ilead
	Atorva	astatin 10mg			С				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17877925	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470627	20-	48 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Acute Respiratory Dist Syndrome	ress Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17877930	EXPEDITED (15-DAY)			DE	US-GILEAD-20 0470607	20-	75 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	Duration	<u>Mf</u>	<u>'r</u>
Fluid Overload; Hypotension	Remd	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	ilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Conva	alescent Plasma			С		Unk		N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17879118	DIRECT	Υ		ОТ			51 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Acute Respiratory Dist Syndrome; Blood Magnesium Increased	Resm				S C					ot Reported ot Reported

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

Alanine Aminotransferase Re Increased; Creatinine Renal Clearance Decreased; Therapy Va	Case Type DIRECT oduct mdesivir etronidazole ncomycin fepime	Y Comp. Y	Prof Ou HC OTC		Mfr Control #	503B Facility Dosage Text	Age 79 YR Duration	<u>Sex</u> Female	<u>Country</u> USA I fr
Preferred Term Alanine Aminotransferase Increased; Creatinine Renal Clearance Decreased; Therapy Va	oduct mdesivir etronidazole ncomycin	Comp.		<u>Role</u>	<u>Route</u>	Dosage Text			
Alanine Aminotransferase Re Increased; Creatinine Renal Clearance Me Decreased; Therapy Va	mdesivir etronidazole ncomycin	-	<u>OTC</u>		<u>Route</u>	Dosage Text	Duration	<u>N</u>	Nfr
Increased; Creatinine Renal Clearance Decreased; Therapy Va	etronidazole ncomycin	Υ		S					
Renal Clearance Decreased; Therapy Va	ncomycin			Ŭ	Intravenous (not otherwise specified)		1 HR	(Gilead
Ce	repime			C C C	otherwise specifical			1	Not Reported Not Reported Not Reported
FDA Received Date Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020 17879147	DIRECT	Υ	ОТ	-			72 YR	Male	USA
Preferred Term Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
	mdesivir	Υ		S	Intravenous bolus			(Gilead
Increased; Blood Lactate Do	cilizumab xycycline cephin			C C C				1	Not Reported Not Reported Not Reported
FDA Received Date Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020 17879156	DIRECT	Υ	ОТ	-			38 YR	Female	USA
Preferred Term Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
	mdesivir			S	Intravenous drip			(Gilead
Hallucination Auditory:	nzonatate (Tessalon Perles			С					Not Reported
Suicidal Ideation De	xtromethorphan ftriaxone			C C					Not Reported Not Reported
	xycycline			С					Not Reported
Ac	etaminophen			С				1	Not Reported
	lorhexidine Oral			С					Not Reported
	oxaparin			С					Not Reported
	betolol laifensin Ac			C C					Not Reported Not Reported



						Detailed IN	port			
	Hepa	ipine o 5-325 rin Porcine insetron			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17879174	DIRECT	Υ	D	E			67 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Hepatotoxicity; Nephropathy Toxic	Aspir Atorv Cefer Chlor Clopi Dexa Enox Famo Insuli Insuli Levor Meth Vanc Acea Fenta Hepa Nore Propo	desivir in 81mg astatin 40mg bime 2g rhexidine Mouthwash digrel 75mg methasone 20mg iparin 40mg bitidine 20mg n Glargine n Regular floxacin 750mg ylprednisolone 40mg omycin minophen 650mg anyl Drip prin Drip pinephrine Drip ylephrine Drip ylephrine Drip zolam Drip	Y		» 000000000000000000000000000000000000	Intravenous bolus	Other Frequency:X 1;			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17879183	DIRECT	Υ	Ľ	Γ			76 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation		desivir desivir			S C					Not Reported Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2020	17879308	DIRECT	Υ		ОТ				61 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted	Rem	ndesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17818539	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0468282	020-		53 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Pulseless Electrical Activity	s Rem	ndesivir			S	Intravenous (not otherwise specified		g, Once			Gilead
	Oxc	arbazepine			С		, Unk				Not Reported
	Amlo	odipine			С		Unk				Not Reported
	Eno	xaparin			С		Unk				Not Reported
	Fam	notidine			С		Unk				Not Reported
	Insu	lin Lispro			С		Unk				Not Reported
	Leve	etiracetam			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17818552	EXPEDITED (15-DAY)			DE, LT, OT	US-GILEAD-20 0468312	020-		72 YR	Femal	e USA
Preferred Term	Pro	duct	Comp.	OTO	Role Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Hypoxia; Respiratory	Rem	ndesivir			S	Intravenous (not otherwise specified	100 M)	g, Qd			Gilead
Failure; Shock	Con	valescent Plasma			С		Unk				Not Reported
	Pan Phe	ansetron toprazole nylephrine assium Phosphate Dibasic			C C C						Not Reported Not Reported Not Reported Not Reported

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							Detailed IV	срогі				
	 	Prismas Prismas Propofol Scopola	mine Aminoxide Chloride			0000000		Unk				Not Reported
		Zinc Sul Cefepim Chlorhe: Cisatrac Dexmed Normosi Enoxapa Epineph Fentany Heparin Hydroxy Iopamid Lactatec Lorazep Magnes Melaton	312 Aaa fate e kidine urium etomidine ol urin rine chloroquine ol Ringers am um Sulfate n ol Tartrate			00000000000000000000						Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	1788027	73	DIRECT	Υ						57 YR	Male	USA
Preferred Term	ļ	Produc		Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Erythema; Flushing; Infusion Related Reac	tion I	MI Solut Aspirin 8 Atorvast Cefepim Choleca	1 Mg atin 40 Mg	Υ		8 00000	Intravenous drip					Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported



	Ferrou Levoth Midod Predn	tidine 20 Mg us Sulfate 300 Mg nyroxine 75 Mcg rine 5 Mg isone 5 Mg omycin 1gm			00000				! ! !	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17880274	DIRECT	Υ					36 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Alanine Aminotransfer Increased	ase Remd	esivir			S	Intravenous (not otherwise specified)	7 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17880275	DIRECT	Υ	ОТ	-			48 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Electrocardiogram Qt	Remd	esivir	Υ		S	Intravenous bolus			(Gilead
		CSIVII	•							
Prolonged	Furos	emide nethasone	·		C C C				1	Not Reported Not Reported Not Reported
	Furos Dexar Enoxa	emide nethasone		Prof Ou	C C	Mfr Control	# 503B Facility	Age	1	Not Reported
Prolonged	Furos Dexar Enoxa	emide nethasone aparin		Prof Ou	C C	Mfr Control	# 503B Facility	Age 68 YR	1	Not Reported Not Reported
FDA Received Date	Furose Dexar Enoxa Case #	emide nethasone sparin Case Type DIRECT	Health	Prof Ou	C C	Mfr Control Route	# 503B Facility Dosage Text		Sex Female	Not Reported Not Reported Country
FDA Received Date 10-Jun-2020	Furosi Dexar Enoxa Case # 17880279	emide nethasone sparin Case Type DIRECT	<u>Health</u> Y		C C utcomes		-	68 YR	Sex Female	Not Reported Not Reported Country USA



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17880282	DIRECT	Υ					93 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Hypotension; Hypovolaemia; Infusion Related Reaction		lesivir 4.5g			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17880286	DIRECT	Υ	Н	0			68 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17880769	DIRECT	Υ	0	Т			71 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remo	lesivir			S	Intravenous drip				Gilead
Increased	Insuli Hepa Midoo Zosyr Predr	tidine n rin drine			00000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17880876	DIRECT	Υ					64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir	Υ		S	Intravenous bolus				Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	1788088	2 DIRECT	Υ	C	T			64 YR	Female	e USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated;	F	temdesivir			S	Intravenous drip				Gilead
Hypoxia; Renal Impairment	F F A C Z	Vancomycin Iv Viperacillin/Tazobactam Iluconazole Ilydroxychloroquine Izithromycin Veftriaxone Inc Iscorbic Acid			00000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	1788123	6 DIRECT	Υ					73 YR	Male	USA
Preferred Term	E	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Device Kink; Product D Omission	ose F	temdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	A C F H L	atorvastatin Azithromycin Ceftriaxone Furosemide Jeparin Actobacillus Rhamnosus Methyliprednisolone Sodium			000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	F L N	succinate Potassium Chloride r Infusion Is Bolus Melatonin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	1788124	1 DIRECT	Υ	_)T			21 YR	Male	USA

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Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransferas Increased; Aspartate	se Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased	Enoxa Guaife Hydro Levotl Potas	pressin aparin enesin cortisone Iv hyroxine sium Chloride minophen			00000000					Not Reported
FDA Received Date (Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17881248	DIRECT	Υ					74 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17881252	DIRECT	Υ						Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blo Creatinine Increased	od Remd	esivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17881257	DIRECT	Υ					73 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remd	esivir			S			3 DAY		Gilead
ncreased; Renal Impairment; Renal Tubu Injury	ılar Lisino Dexm	pril edetomidine			C C					Not Reported Not Reported

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	H N F S S S F III III F C C	amotidine lydralazine lydrocortisone Sod Succinate licardipine lotassium Chloride limvastatin lodium Chloride Infusion lodium Phosphate In D5w lotassium Phosphate linsulin Lispro linsulin Glargine lentanyl lefepime leftriaxone linsulin Signal			00000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	1788126	4 DIRECT	Υ		DE, DS, LT			61 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Flutter; Ischaemi Stroke; Nervous Syste Disorder	m C N A V Z A F E E T E	Remdesivir Injection Covid-19 Convalescent Plasma Iorepinephrine Drip Amiodarone Drip Cosyn Azithromycin Prophylactic Lovenox (40 Mg Sq Bid)			8 0000000 0 0	Intravenous (not otherwise specified)				Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jun-2020	1788126	9 DIRECT	Υ					64 YR	Male	USA
Preferred Term	Ē	Product	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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						Dotanica	· · · op o · ·	•			
Liver Function Test Increased	Remo	desivir	Υ		S	Intravenous (no otherwise spec				G	illead
	Asco Docu Enox Furos Meth	romycin rbic Acid sate aparin semide ylprednisolone Sulfate			000000	·	ŕ			N N N N	ot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17881367	EXPEDITED (15-DAY)				US-GILE/ 0469487	D-2020-		16 YR	Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Medication Error; Prod Storage Error	luct Remo	desivir			S	Unknown				G	iilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17881967	EXPEDITED (15-DAY)		0	DE, OT	US-GILE/ 0470949	D-2020-		70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	Duration	<u>Mf</u>	<u>ir</u>
Multiple Organ Dysfunction Syndrome Shock		desivir			S	Unknown				G	iilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17882192	EXPEDITED (15-DAY)		С	DE, HO, LT,	OT US-GILE, 0471151	D-2020-		68 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Body Temperature ncreased; Death; Oxy	gen	desivir			S	Intravenous (no otherwise spec		Mg, Once		G	ilead
Consumption Increase Respiratory Distress	ed; Remo	desivir			S	Intravenous (no otherwise spec		Mg, Qd		G	iilead
	ما المنابا	alazine			С		Unk			N	ot Reported



		•	
Imdur	С	Unk	Not Reported
Ketorolac	С	Unk	Not Reported
Levemir	С	Unk	Not Reported
Linezolid	С	Unk	Not Reported
Memantine	С	Unk	Not Reported
Novolog	С	Unk	Not Reported
Potassium Chloride	С	Unk	Not Reported
Potassium Phosphate	С	Unk	Not Reported
Dibasic;Sodium Phosphate Percocet [Oxycodone Hydrochloride;Paracetamol]	С	Unk	Not Reported
Primidone	С	Unk	Not Reported
Pyridoxine	С	Unk	Not Reported
Vancomycin	С	Unk	Not Reported
Vitamin D [Colecalciferol]	С	Unk	Not Reported
Convalescent Plasma	С	Unk	Not Reported
Combinent Respimat	С	Unk	Not Reported
Amlodipine	С	Unk	Not Reported
Anastrozole	С	Unk	Not Reported
Atorvastatin	С	Unk	Not Reported
Azithromycin	С	Unk	Not Reported
Coreg	С	Unk	Not Reported
Cefepime	С	Unk	Not Reported
Clopidogrel	С	Unk	Not Reported
Cyanocobalamin	С	Unk	Not Reported
Donepezil	С	Unk	Not Reported
Famotidine	С	Unk	Not Reported
Ferrous Sulfate	С	Unk	Not Reported
Folic Acid	С	Unk	Not Reported
Gabapentin	С	Unk	Not Reported
		=	



						Detailed Ne	port				
	Inst	ulin			С		Unk				Not Reported
	Lov	renox [Enoxaparin Sodium]			С		Unk				Not Reported
	Nitr	oglycerin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17882290	EXPEDITED (15-DAY)			НО	US-GILEAD-20 0470081	20-		23 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Abnormal; Aspartate	ase Rer	mdesivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
Aminotransferase Increased	Rer	mdesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Cef Var Enc Thia Zind Bur Clo Far Insi Dea Dol Fer Mei	cilizumab depime ncomycin-Mip [Vancomycin] depime ncomycin-Mip [Vancomycin] depime dep			000000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882668	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470292	20-		28 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Hypotens	sion Rer	mdesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	Sex	Country
10-Jun-2020	17882688	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469668	020-	49 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mf</u> ı	
Acute Kidney Injury	Remde	sivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17882689	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469669)20-	32 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mfı</u>	
Hepatotoxicity	Remde	sivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17882771	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469821)20-	76 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mfı</u>	[
Arrhythmia Supraventricular; Atrial		sivir			S	Intravenous (not otherwise specified)	200mg X1, 100mg X 1		Gi	lead
Fibrillation; Atrial Flutte Ejection Fraction; Hear Rate Increased:		sivir			S	Intravenous (not otherwise specified)	100 Mg, Daily X3		Gi	lead
Hypotension; Ischaemi	a Levoflo	xacin			S	Unknown				ot Reported
	Levoth	yroxine			S	Unknown			No	ot Reported
	Metron Amioda				C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17882790	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0469839)20-	73 YR	Female	USA
Preferred Term	Produc	ct	Comp.	ОТС	Role	Route	Dosage Text	Duration	Mfı	•

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Cerebrovascular Accident; Creatinine Renal	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Clearance Decreased	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Topan	nax			С					Not Reported
	Name	nda			С					Not Reported
	Imdur				С					Not Reported
	Neuro				C C					Not Reported
	Breo E				С					Not Reported
	Pepcio				С					Not Reported
		n (E.C.)			С					Not Reported
		em Cd			C C C C					Not Reported
		racetam			С					Not Reported
	Combi				С					Not Reported
	Hepari				C					Not Reported
	Dextro				С					Not Reported
	Morph				C C C					Not Reported
		hin Biochemie			C					Not Reported
	Zithror				C					Not Reported
	Nystat				С					Not Reported
		em Cd			С					Not Reported
	Tylend				C					Not Reported
	Eliquis	n Chloride			C					Not Reported
		Furosemide]			C C C					Not Reported Not Reported
		sium Chloride			C					Not Reported
		ron [Dexamethasone]			C					Not Reported
_	Decau	ion [Dexamethasone]								Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020 178	883629	DIRECT	Υ		ОТ			28 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase	Remde	esivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Increased; Aspartate	Remde				S	Intravenous bolus	Other Frequency.Once,			Gilead
Aminotransferase						milavenous bolus				
Increased; Myocarditis; Respiratory Failure; Transaminases Increased	Tociliz	lescent Plasma umab			C					Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17883633	DIRECT	Υ	0	Γ			46 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Liver Funct Test Increased		desivir	Y		S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17883639	DIRECT	Υ					71 YR	Female	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Rem	desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17883645	DIRECT	Υ	Н)			50 YR	Female	USA
Preferred Term	Prod	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Blood Creatinine Increased; Hypotensio		desivir Injection			S	Intravenous (not otherwise specified)				Gilead
		comycin ofovir			C C	. ,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2020	17883718	DIRECT	Υ					59 YR	Male	USA
Preferred Term	Prod	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Condition	ase Rem	desivir 100mg	Υ		S	Intravenous (not otherwise specified)				Gilead

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FDA Received Date	Case #	Case Typ	e	Health	Prof	Outcomes	Mfr Control	#	503B Facility	Age	Sex	Country
11-Jun-2020	178377	-	ED (15-DAY)			ОТ	US-GILEAD-2 0468230			60 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Acute Kidney Injury; Inappropriate Schedule Product Administration Product Use Issue		Remdesivir				S	Unknown	Unk			G	ilead
FDA Received Date	Case #	Case Typ	<u>e</u>	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	178833	40 EXPEDITI	ED (15-DAY)			DE, OT	US-SA-2020S	A148347			Unknown	USA
Preferred Term		<u>Product</u>		Comp.	ОТС	Role	Route	Dosage	Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Covid-19; Disseminate		Lovenox				S	Subcutaneous	40 Mg	, Qd		S	anofi
Intravascular Coagulat Intra-Abdominal Haemorrhage;	ion;	Remdesivir				S	Intravenous (not otherwise specified	Unk)			N	ot Reported
Retroperitoneal		Ascorbic Acid				С		Unk			N	ot Reported
Haemorrhage; Septic Shock; Shock		Fenofibrate				С		Unk			N	ot Reported
Haemorrhagic		Heparin				С		Unk				ot Reported
		Methylprednisolone				С		Unk				ot Reported
		Nph Insulin				С		Unk			N	ot Reported
		Sodium Chloride				С		Unk			N	ot Reported
		Sitagliptin				С		Unk			N	ot Reported
		Midazolam				С		Unk			N	ot Reported
		Pantoprazole				С		Unk			N	ot Reported
		Humuline				С		Unk			N	ot Reported
FDA Received Date	Case #	Case Typ	<u>e</u>	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	178848	13 DIRECT		Υ		DE				44 YR	Female	USA

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Preferred Term		Product	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	Duration	Mf	<u>r</u>
Increased; Glomerular Filtration Rate Decrea	Itration Rate Decreased; achycardia; Tachypnoea		′		S	Intravenous (not otherwise specif		Gi	ilead	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Contr	ol# 503B Facili	<u>ty Age</u>	<u>Sex</u>	Country
11-Jun-2020	178848	18 DIRECT	Υ					69 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Hypotension		Remdesivir	Υ		S	Intravenous (not otherwise specif		5 DAY	No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u> Dutcomes</u>	Mfr Contr	ol # 503B Facili	ty Age	<u>Sex</u>	Country
11-Jun-2020	178848	25 DIRECT	Υ					57 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Glomerular Filtration F Decreased		Remdesivir Acetaminophen Azithromycin Benzonotate Bisacodyl Ceftriaxone Cyclobenzaprine Enoxaparin Famotidine Gabapentin Guafenesin Hydrocodone Acetaminopher Morphine Orphenadrine Prednisone Docusate Sennosides Sodium Chloride 0.9% Temazepam	Y		s 000000000000000000	Intravenous drip			No No No No No No No No No No No No No N	ilead of Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17884829	DIRECT	Υ		DE			77 YR	Female	e USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:1100 M Total;	g		Gilead
		min Human 5%			С					Not Reported
		ourinol			C					Not Reported
		aban			C					Not Reported
		vastatin			C C					Not Reported
	Core				C					Not Reported
		kaparin			C					Not Reported
		xetine			C C					Not Reported
		penem			C					Not Reported
	Fent				C					Not Reported
		Acid			C					Not Reported
		semide			C					Not Reported Not Reported
	Insu	roxychloroquine			CCC					Not Reported
		nylprednisolone			C					Not Reported
		coprazole			C					Not Reported
		nylephrine			C					Not Reported
		jabalin			C					Not Reported
	Prop				C					Not Reported
		asalazine			C					Not Reported
		min D			Č					Not Reported
		Sulfate			Č					Not Reported
FDA Received Date		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
11-Jun-2020	17884835	DIRECT	Υ		ОТ			36 YR	Male	USA
Preferred Term	Prod	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration F Decreased	Rate Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
	Zosy	n			S	Intravenous (not otherwise specified)				Unknown



						Dotalioa i	(opoit				
	Zosyr Vanco	omycin			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17884836	DIRECT	Υ						58 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>ext</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Alkali Phosphatase Increased	Use A	esivir Under Emergency authorization (Eua			S	Intravenous (not otherwise specific	ed)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17884843	DIRECT	Υ	(TC				41 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>ext</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Blindness; Dyspnoea; Nausea; Oxygen Saturation Decreased; Pain; Vision Blurred; Vomiting	Doxyo Methy Furos Hydro Venla Enoxo Melat Folic Panto Thian	esivir 100 Mg Vials cycline 100 Mg Po Bid reprednisolone 40 Mg Iv Bid emide 40mg Iv Bid exyzine 25 Mg Poq6h Prn faxine 37.5mg Po Daily aparin 50 Mg Sq Q12h done 50 Mg Po Qpm onin 9 Mg Po Qpm Acid 1mg Po Daily prazole 40mg Bid nine 100 Mg Iv Daily erol 2 Puffs Qid	Y		s 0000000000000	Intravenous bolus	S				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17884920	DIRECT	Υ	(OT				26 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>ext</u>	<u>Duration</u>	!	<u>Mfr</u>
Nausea; Vomiting	Pemo	esivir			S	Intravenous drip					Not Reported

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								- P			
	Acetaminophen Azithromycin Enoxaparin Hydromorphone Prochloroperazine Ceftriaxone A Received Date Case # Case Type					00000					Not Reported
FDA Received Date	Case #	<u>Ca</u>	ise Type	<u>Health</u>	Prof C	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	1788492	29 DIF	RECT	Υ	C	T			36 YR	Female	e USA
Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	ı	Remdesivir				S	Intravenous drip				Not Reported
Increased FDA Received Date	Case #		ise Type			C C C C C C C C	Mfr Control	# 503B Facility	Age	<u>Sex</u>	Not Reported Country
11-Jun-2020	1788496	65 DIF	RECT	Υ	С	E			79 YR	Male	USA
Preferred Term	1	<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia; Cardiac Arrest; Oxygen Satura Decreased		Remdesivir Use Authoriz	Under Emergency zation (Eua			S	Intravenous (not otherwise specified)	1			Gilead
FDA Received Date	Case #	<u>Ca</u>	ise Type	<u>Health</u>	Prof C	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	1788497	71 DIF	RECT	Υ	C	T			9 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased; Aspartate	ase l	Remdesivir		Υ		S	Intravenous drip		3 DAY		Gilead

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Aminotransferase Increased; Hepatic Enzyme Increased

FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	178849	76 DIRECT	Υ					63 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Dehydration; Presynco Syncope; Therapy Cessation		Remdesivir Under Emergency Use Authorization (Eua			S	Intravenous (not otherwise specified)			G	Bilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	1788498	32 DIRECT	Υ					79 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Blood Creatinine Increased; Haemodialy		Remdesivir	Y		S	Intravenous (not otherwise specified)			G	Gilead
		Piperacillin-Tazobactam			С	. ,			N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	1788499	90 DIRECT	Υ	1	НО			55 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Blood Creatinine		Remdesivir	Υ		S	Intravenous bolus			G	Silead
Increased; Glomerular Filtration Rate Increase	ed	Tocilizumab 400 Mg Iv X1 Hydroxychloroquine 200 Mg Po Bid)		C C					lot Reported lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	1788499	98 DIRECT	Υ					76 YR	Female	USA
Preferred Term		Product	Comp.	отс	Role	Route	Dosage Text	Duration	M	fr



Glomerular Filtration Ra Decreased	ate Rei	mdesivir	Υ		S	Intravenous bolus	Other Frequency:One Time;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17885006	DIRECT	Υ		ОТ			66 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury;	Rei	mdesivir Iv Solution	Υ		S	Intravenous bolus				Gilead
Azotaemia; Fluid Overload; Inflammation	1 Ato End Lis _l Hyd Noi Pro	olodipine orvastatin oxaparin pro dromorphone repinephrine opofol etaminophen			0000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17885013	DIRECT	Υ		ОТ			36 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Back Pain; Ventricular Tachycardia	Rei	mdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY		Gilead
	Aso	corbic Acid 150mg Oral			С	,				Not Reported
		oxaparin 100mg Sc			С					Not Reported
		hromax 500mg lv			С					Not Reported
		notidine 20mg lv Daily			С					Not Reported
		ocaine 5% Patch			С					Not Reported
	We Q8	thylprednisolone 125mg lv			С					Not Reported
		amine 100mg Iv Daily			С					Not Reported
		c Sulfate 220mg Po Daily			C					Not Reported
	Ace	etaminophen 650mg Oral Q6	h		Č					Not Reported
	Prn				-					
	Сус	cylcobenzaprine 10mg Oral			С					Not Reported
		Prn								•
		rphine 1mg Iv Q8h Prn			С					Not Reported

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FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	<u>#</u> 5	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17885	020	DIRECT	Υ	(OT				47 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	Mfr	:
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase	line	Remdes	sivir			S	Intravenous drip				Gi	ead
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control :	<u>#</u> 5	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17886	243	EXPEDITED (15-DAY)		(TC	US-GILEAD-20 0470876)20-		27 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	Mfr	:
Acute Kidney Injury; B Creatinine Increased	lood	Remdes	sivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd		Gi	lead
		Ascorbi	c Acid			С		Unk			No	t Reported
		Cefepin	ne			С		Unk			No	t Reported
		Choleca	alciferol			С		Unk			No	t Reported
		Enoxap	arin			С		Unk			No	t Reported
		Flucona	zole			С		Unk			No	t Reported
		Insulin (Glargine			С		Unk			No	t Reported
		Insulin L	₋ispro			С		Unk			No	t Reported
		Melaton	iin			С		Unk			No	t Reported
		Methylp	rednisolone			С		Unk				t Reported
		Pantopr	azole			С		Unk				t Reported
		Propofo	l			С		Unk				t Reported
		Fentany				С		Unk				t Reported
			Regular Hm			С		Unk				t Reported
		Norepin	•			С		Unk				t Reported
		Potassi	um Chloride			С		Unk			No	t Reported

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						Dotalioa Ito	po. c				
	Sodiu	ım Phosphate			С		Unk				Not Reported
		inylcholine amethonium Chloride]			С		Unk				Not Reported
		zolam			С		Unk				Not Reported
	Meto	prolol			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887527	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0470376)20-		77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Chills; Musculoskeleta Stiffness	al Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
	Magr Meto _l Panto Rivar Ropir Tams	pentin nesium Oxide prolol Tartrate pprazole oxaban nirole sulosin in (E.C.)			0000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887565	EXPEDITED (15-DAY)		Н	0	US-GILEAD-20 0470402)20-		66 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	ased Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Benz Amlo Dextr Enox Guaif	aminophen onatate dipine omethorphan aparin enesin			00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	Hepa	rin			С						Not Reported

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	Sodiu	ated Ringers um Chloride & Dextrose iaxone			CCC						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887576	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470407)20-		68 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration	ļ	<u>Mfr</u>
Cough; Dyspnoea; Hypertension; Malaise		desivir			S	Intravenous (not otherwise specified)	Unk, Q	d			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887628	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470406)20-		78 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	<u>Route</u>	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Transaminases Increa	ised Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887630	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470688)20-		60 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Renal Impairment	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Ur	nk			Gilead
	Unas	nox [Enoxaparin Sodium] yn [Ampicillin um;Sulbactam Sodium]			C C						Not Reported Not Reported
		semide ira anyl			C C C						Not Reported Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887633	EXPEDITED (15-DAY)			НО	US-GILEAD-20 0470433	020-	68 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17887638	EXPEDITED (15-DAY)				US-GILEAD-20 0469605	020-	43 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Product Use Issue	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg			Gilead
	Enoxa	parin			С	. ,	Unk			Not Reported
	Famot	idine			С		Unk			Not Reported
	Insulin	Glargine			С		Unk			Not Reported
	Insulin	Lispro			С		Unk			Not Reported
	Insulin	Regular Beef			С		Unk			Not Reported
	Fentar	ıyl			С		Unk			Not Reported
	Propor	fol			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888175	DIRECT	Υ		DE			79 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bilevel Positive Airway	Remde	esivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Pressure; Dysphagia; Palliative Care;	Remde	esivir			S	Intravenous bolus	1			Gilead
Respiratory Failure	Conva	lescent Plasma			С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888194	DIRECT	Υ					80 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer Increased	rase Remo	desivir			S	Intravenous (not otherwise specified)		G	Gilead
		darone astatin			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888195	DIRECT						52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Preparation E Product Preparation Is	,	desivir	Υ		S	Intravenous (not otherwise specified)		G	Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888199	DIRECT	Υ	C	T			66 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Atrial Fibrillation;	Remo	desivir			S	Intravenous drip			G	Gilead
Depression; Fear; Hypotension; Lacrima Increased	Cetiri Enox	prolol zine aparin n Detemir ormin log			00000000				N N N N N N N N N N N N N N N N N N N	Not Reported
<u> </u>	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	<u> </u>									

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Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
Aminotransferase Increased; Pneumonia; Pneumonia Pseudomonal	Precedex Meropenem Micafungin Azithromycin Vasopressin Metronidazole			C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020 17888	3215 DIRECT	Υ					44 YR	Female	e USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test ncreased; Renal Function	Remdesivir			S	Intravenous (not otherwise specified)	6 DAY		Gilead
Test Abnormal	Norepinephrine			С		,			Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020 1788	3220 DIRECT	Υ	DE	Ē			77 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased;	Remdesivir Remdesivir			s s	Intravenous bolus	Other Frequency:Once;			Gilead Gilead
Blood Pressure Decreased; Dyspnoea; Gastrointestinal Haemorrhage; Haematocrit Decreased; Haemoglobin Decreased; Hyperkalaemia; Oxygen Saturation Decreased; Thrombocytopenia	Convalenscent Plasma			C	initavenous polus				Not Reported



						Dotalloa No	, po. t			
FDA Received Date C	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020 1	7888224	DIRECT	Υ	(TC			40 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Rer Tubular Necrosis	nal Rem	desivir			S	Intravenous drip				Gilead
FDA Received Date C	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020 1	7888229	DIRECT	Υ					56 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Anxiety; Blood Pressure		desivir	Υ		S	Intravenous drip				Gilead
Systolic Increased; Ches Discomfort; Nausea	ACE	aminophen 650 Mg Tablet caine 4% Transdermal			C C	·				Not Reported Not Reported
		kaparin 30 Mg Subcutanous			С					Not Reported
	Doci Poly	usate 100 Mg Capsule ethylene Glycol 17g Powder na Tablet			C C C					Not Reported Not Reported Not Reported
FDA Received Date C	Case #	Case Type	Health	Prof (Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020 1	7888251	DIRECT	Υ	(OT			60 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Bloo Creatinine Increased;	od Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Dialysis; Pneumonia; Respiratory Failure; Sepsis	Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
opolo		aminophen Prn			С					Not Reported
		terol Inhaler			C					Not Reported
		orbic Acid (Intravenous)			С					Not Reported
		romycin (Intravenous)			С					Not Reported
		riaxone			С					Not Reported
	Eno	kaparin			С					Not Reported

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		nesin/Dextromethorphan			С						Not F	Reported
	Hydrod	ot 1 Dose) codone/Acetaminophen			С						Not F	Reported
	Orpher	s Prn (Got 1 Dose) nadrine Er Tablets Prn			С						Not F	Reported
	(Got 1 Zinc Su	Dose) ılfate Capsules			С						Not F	Reported
	Cisatra				Ċ							Reported
		yl Intravenous Drip			Č							Reported
		ant Eye Ointment			C C C							Reported
		pam Prn			C							Reported
		nephrine Intravenous Drip			C							Reported
		ol Intravenous Drip			Ċ							Reported
		ylcholine (1 Dose)			Ċ							Reported
		Tears Drops			C C C							Reported
	Veruro	nium Prn (Got 1 Dose On			C							Reported
	6/5)											
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control i	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>		Country
11-Jun-2020	17888256	DIRECT	Υ		DS, LT				75 YR	Male		USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	
Cerebrovascular Accid	lent Remde	esivir			S	Intravenous (not otherwise specified))				Not F	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>		Country
11-Jun-2020	17888259	DIRECT	Υ		DE				73 YR	Male		USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	
Respiratory Failure; Therapy Cessation	Remde	esivir			S	Intravenous (not otherwise specified))				Not F	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>		Country
11-Jun-2020	17888263	DIRECT	Υ		ОТ				70 YR	Female)	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	отс	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	

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Rash	Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
	Fluox Propo	aparin 40 Mg etine 20 Mg ifol Infusion nyl Infusion			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888265	DIRECT	Υ	Н	10			46 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreas		lesivir	Y		S	Intravenous bolus	Other Frequency:One Time;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888269	DIRECT	Υ					60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY		Gilead
Aminotransferase Increased	Remo	lesivir			S	Intravenous (not otherwise specified)		3 DAY		Gilead
	Apixa Diltiaz Metop Panto	zem Iv prolol prazole zumab rin Iv			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888273	DIRECT	Υ	C	T			54 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Aspartate Aminotransferase		ndesivir			S	Intravenous (not otherwise specifi	ed)			G	Gilead
Aminotransferase Increased; Blood Bilirub Increased; Disseminated Intravascular Coagulatic Shock	d Fen On; Nor Cisa Pro Keta Azit Ceft Epo Fan Hep Insu Peri Van	cinylcholine tanyl epinephrine atracurium cofol amine hromycin triaxone prostenol notidine trin tlin Lispro colace comycin tlin Regular Human			00000000000000000	otherwise specifi	ed)				lot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	Age	Sex	Country
11-Jun-2020	17888277	DIRECT	Υ	D	E				67 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
General Physical Health Deterioration		ndesivir Treatment Under ergency Use Authorization a)			S					Ν	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2020	17888314	DIRECT	Υ	0	Т				25 YR	Female	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransferas Increased; Aspartate Aminotransferase Increased	se Ren	ndesivir			S	Intravenous (not otherwise specifi	ed)			N	lot Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17873144	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470616	20-	71 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Bradycardia; Cardiac Arrest; Epistaxis;	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gil	ead
Hypotension; Pulseles Electrical Activity; Respiratory Arrest	ss Rivard	oxaban			С		Unk		No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17889442	DIRECT	Y		DE			62 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Cardiac Arrest; Hypoxia	Remd	esivir			S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17889551	DIRECT	Υ		НО			80 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remd	esivir			S	Intravenous (not otherwise specified)	Other Frequency:Once - Loading Dos;		Gil	ead
increased					C		-		Ge	nentech
increased	Actem Zosyn		Υ		S C					
mcreaseu	Zosyn Vanco	mycin	Υ		C C				No No	t Reported t Reported
mcreaseu	Zosyn Vanco Thiam	omycin ine	Υ		C C C				No No No	t Reported t Reported t Reported
increaseu	Zosyn Vanco Thiam Hydro Synth	omycin ine cortisone roid	Υ		0000				No No No No No	t Reported t Reported t Reported t Reported t Reported
mcreaseu	Zosyn Vanco Thiam Hydro Synthi Verse	omycin ine cortisone roid d	Υ		000000				No No No No No No	t Reported
increaseu	Zosyn Vanco Thiam Hydro Synth Verse Pepcie	omycin ine cortisone roid d	Y		0000000				No No No No No No	t Reported
mcreaseu	Zosyn Vancc Thiam Hydro Synth Verse Pepcid Insulir	omycin ine cortisone roid d d	Y		0000000				No No No No No No No	t Reported
mcreaseu	Zosyn Vancc Thiam Hydro Synth Verse Pepcid Insulir Aspirii	omycin ine cortisone roid d d	Y		0000000				No No No No No No No	t Reported

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		Heparin Fentanyl Amiodarone Epinephrine Milrinone Norepinephrine Vasopressin			0000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178895	54 DIRECT	Υ	D	E			91 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; General Physical Heal Deterioration		Remdesivir Dexamethasone 20 Mg Lv Daily Insulin Lorazepam 0.5 Mg Le1 Metoprolol 2.5 Mg Lv X1 Metoprolol 2.5 Mg Q6h Iv Nitroglycerin 0.4 Mg/Hr Patch Daily Protonix 40 Mg Lv Q12h Hydromorphone Bicarb 8.4% Continuous Infusion Morphine 1 Mg Lv Q4h Pn			%000000 0000					Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178895	80 DIRECT	Y	0	Т			68 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Ac Kidney Injury; Ischaem Hepatitis	nic	Remdesivir Selinexor Vs. Placebo Acetaminophen Furosemide Norepinephrine			8 C C C C					Gilead Not Reported Not Reported Not Reported Not Reported
				D (0			500D F!!!			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prot U	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>

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Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration		<u>Mfr</u>
Angioedema; Dyspnoe Ear Pruritus; Eye Irritat		esivir			S	Intravenous (not otherwise specified)				Gilead
Eye Pruritus; Throat	Apixal	ban			С	, ,				Not Reported
Irritation		lukast			C					Not Reported
	Guaife	enesin			С					Not Reported
	Panto	prazole			С					Not Reported
	Fluticasone-Vilanterol Acetaminophen Insulin Lispro Melatonin Zinc Sulfate Vitamin C				С					Not Reported
					С					Not Reported
					С					Not Reported
					С					Not Reported
					С					Not Reported
					С					Not Reported
	Vitam				С					Not Reported
		erol-Ipratropium			С					Not Reported
		n Glargine			С					Not Reported
	Methy	Iprednisone			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17889591	DIRECT	Υ					45 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Remd	esivir			S	Intravenous (not				Gilead
Increased; Therapy Cessation						otherwise specified)				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17889595	DIRECT	Υ					68 YR	Male	USA
Preferred Term	<u>Prod</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
							<u></u>			
Aspartate Aminotransferase Increased; Therapy Cessation	Remd	esivir			S	Intravenous (not otherwise specified)				Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17889600	DIRECT	Y					61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Administratior Error; Product Dose Omission	n Remo	desivir			S	Intravenous (not otherwise specified)		10 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17889785	DIRECT	Υ	1	ОТ			41 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer ncreased; Aspartate		desivir Iminophen			s C	Intravenous drip		1 HR		Gilead Not Reported
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased		шшорпен			C					Not Reported
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation	ion;	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u> 503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased	ion;		Health			Mfr Control a US-GILEAD-20 0471143	•	Age 60 YR	<u>Sex</u> Female	Country
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date	ion; Case #	Case Type EXPEDITED (15-DAY)	Health Comp.		<u>Outcomes</u>	US-GILEAD-20	•			Country
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation increased	Case # 17892601 Prod	Case Type EXPEDITED (15-DAY)			Outcomes OT	US-GILEAD-20 0471143	Dosage Text 200 Mg, Once	60 YR		Country USA
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation	Case # 17892601 Prod on; Remo	Case Type EXPEDITED (15-DAY) uct			Outcomes OT Role	US-GILEAD-20 0471143 Route	Dosage Text 200 Mg, Once 100 Mg, Qd	60 YR		Country USA Mfr
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation Liver Function Test ncreased; Oxygen	Case # 17892601 Prod on; Remo	Case Type EXPEDITED (15-DAY) uct desivir desivir			Outcomes OT Role S S C	US-GILEAD-20 0471143 Route Intravenous (not otherwise specified) Intravenous (not	Dosage Text 200 Mg, Once 100 Mg, Qd	60 YR		Country USA Mfr Gilead Gilead Not Reported
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation Liver Function Test ncreased; Oxygen	Case # 17892601 Prod on; Remo	Case Type EXPEDITED (15-DAY) uct desivir desivir ppion			Outcomes OT Role S S C C	US-GILEAD-20 0471143 Route Intravenous (not otherwise specified) Intravenous (not	Dosage Text 200 Mg, Once 100 Mg, Qd	60 YR		Country USA Mfr Gilead Gilead Not Reported Not Reported
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation Liver Function Test ncreased; Oxygen	Case # 17892601 Prod on; Remo	Case Type EXPEDITED (15-DAY) uct desivir desivir			Outcomes OT Role S S C C C C C	US-GILEAD-20 0471143 Route Intravenous (not otherwise specified) Intravenous (not	Dosage Text 200 Mg, Once 100 Mg, Qd	60 YR		Country USA Mfr Gilead Gilead Not Reported
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation Liver Function Test ncreased; Oxygen	case # 17892601 Prod on; Remo Remo Aceta Azithi Benzo Bisac	Case Type EXPEDITED (15-DAY) uct desivir desivir ppion uminophen romycin pcaine-Menthol odyl			Outcomes OT Role S S C C C C C C	US-GILEAD-20 0471143 Route Intravenous (not otherwise specified) Intravenous (not	Dosage Text 200 Mg, Once 100 Mg, Qd	60 YR		Country USA Mfr Gilead Gilead Not Reported
Aminotransferase ncreased; Chills; Dyspnoea; Hypertensi Dxygen Saturation Decreased FDA Received Date 12-Jun-2020 Preferred Term Endotracheal Intubation Liver Function Test ncreased; Oxygen	case # 17892601 Prod on; Remo Remo Aceta Azithi Benzo Bisac Calciu	Case Type EXPEDITED (15-DAY) uct desivir desivir ppion uminophen romycin pocaine-Menthol			Outcomes OT Role S S C C C C C	US-GILEAD-20 0471143 Route Intravenous (not otherwise specified) Intravenous (not	Dosage Text 200 Mg, Once 100 Mg, Qd	60 YR		Country USA Mfr Gilead Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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							10 0 0 0			
		Enoxaparin [Enoxaparin Sodium	1]		С					Not Reported
		Famotidine			С					Not Reported
		Fentanyl			С					Not Reported
		Guaifenesin			C C					Not Reported
		Hydromorphone			С					Not Reported
		Melatonin			C					Not Reported
		Midazolam			С					Not Reported
		Norepinephrine			C					Not Reported
		Nystatin			С					Not Reported
		Ondansetron			C C					Not Reported
		Polyethylene Glycol [Macrogol]								Not Reported
		Potassium Bicarbonate/Citric			С					Not Reported
		Acid								
		Propofol			С					Not Reported
		Senna [Senna Alexandrina]			C C					Not Reported
		Sertraline			С					Not Reported
		Temazepam			С					Not Reported
		Trazodone			С					Not Reported
DA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178926	03 EXPEDITED (15-DAY))	0	Т	US-GILEAD-20 0470917	020-	77 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Pressure Increas Endotracheal Intubatio	n;	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Heart Rate Decreased Respiratory Disorder	;	Propofol			С	Intravenous (not otherwise specified)	50-75mcg/Kg/Min			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178926	04 EXPEDITED (15-DAY))	0	Т	US-GILEAD-20 0470948)20-	62 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Bl Creatinine Increased;	ood	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Shock		Remdesivir			S	Intravenous (not otherwise specified)	100 Unk			Gilead
		Acetaminophen			С	, ,				Not Reported



							•			
	Albu Aspi Azith Ceftr D50v Eton Hydr Insul Iprat Meth Prop Rocu Sodi	caparin nidate omorphone in Lispro ropium nylprednisolone ofol uronium um Chloride			000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control :	<u>503B Fac</u>	<u>ility Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17892626	EXPEDITED (15-DAY)				US-GILEAD-20 0470372	020-	71 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Administration Error	Rem	desivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Rem	desivir			S	Intravenous (not otherwise specified)	100 Mg			Gilead
	Insul Povi Pota Simv	caparin in Glargine done Iodine ssium Chloride vastatin in Lispro			00000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	503B Fac	cility Age	<u>Sex</u>	Country
12-Jun-2020	17892627	EXPEDITED (15-DAY)		(ОТ	US-GILEAD-20 0470082)20-	59 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Creatinine Renal Clearance Decreased	Rem	desivir			S	Unknown				Gilead



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894663	DIRECT	Υ					25 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Infusion Site Erythema Infusion Site Extravasation; Infusion Site Warmth		desivir	Y		S	Intravenous (not otherwise specified)			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894689	DIRECT	Υ					63 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Product Preparation E	rror Remo	desivir	Υ		S	Intravenous (not otherwise specified)			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894693	DIRECT	Υ	0	Т			34 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>'r</u>
Rhabdomyolysis	Remo	desivir			S	Intravenous (not otherwise specified)			N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894698	DIRECT	Υ	0	Т			79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Acute Kidney Injury; Therapy Cessation	Remo	desivir			S	Intravenous (not otherwise specified)			N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894703	DIRECT	Υ	0	Т			83 YR	Male	USA

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	!
Acute Kidney Injury; Rhabdomyolysis	Remdesivir			S	Intravenous bolus	Other Frequency:Once;		Gi	lead
FDA Received Date Ca	se # Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020 17	894725 DIRECT	Υ	0	Т			43 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	[
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir			S				Ur	nknown
FDA Received Date Ca	se # Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020 17	894728 DIRECT		0	Т			46 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	<u>.</u>
Hepatotoxicity; Hypotension; Platelet	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gi	lead
Count Decreased; Pneumonia; Renal Impairment; Septic Shock	ount Decreased; eumonia; Renal Acetylcysteine Inhalation And Accorbic Acid (Intravenous)			C C C				No No No	ot Reported of Reported of Reported of Reported
	Fentanyl Drip Insulin Lispro Levalbutorol Inhalation Norepinephrine Drip			C C C				No No	ot Reported ot Reported ot Reported ot Reported
	Pantoprazole (Intraveno Propofol Drip	ous)		C				No	ot Reported ot Reported ot Reported
	Normal Saline Drip Zinc Sulfate			C C					ot Reported of Reported



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	Sex	Country
12-Jun-2020	17894732	DIRECT	Y	D		<u> </u>	<u></u>	<u>5552 : 451119</u>	52 YR	Male	USA
12-Juli-2020	17094732	DIRECT	ı	U					32 TK	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Cardiac Arrest; Hypox Pulseless Electrical Activity	ia; Rem	ndesivir			S	Intravenous (not otherwise specifie	d)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894735	DIRECT	Y						6 YR	Female	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Product Packaging Confusion; Wrong Pro Administered; Wrong Technique In Product Usage Process		desivir			S	Intravenous drip					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17894738	DIRECT	Y	D	E				56 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Peripheral Artery	Rem	desivir			S	Intravenous bolus					Gilead
Aneurysm; Retroperito Haemorrhage	Aspir Azith Carv Cefe Cotri Fam Hepa Isavi Pred Tacr	rin Ec 81 Mg rromycin 250 Mg redilol 3.125 Mg repime 2 G rimoxazole 400-80 otidine 40 Mg rarin 5000 Units uconazole 372 Mg repime 10 Mg repime 10 Mg repime 2 Mg repime 2 Mg repime 2 Mg repime 3 Mg			00000000000						Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894743	DIRECT	Υ	0	Т				17 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Blood Glucose Increas Lactic Acidosis	Conv Tocil Vand Cefta Epin	desivir valescent Covid Plasma izumab comycin azidime ephrine amine			8 C C C C C C C						Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894748	DIRECT	Υ	0	Т				77 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Rem	desivir	Υ		S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17894783	DIRECT	Υ						73 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Tocil	izumab			S	Intravenous drip			1 HR		Genentech
Increased; Aspartate Aminotransferase Increased	Hepa Cultu Losa Cefe Vand	vastatin 20 Mg arin 7500 Units urelle 1 Capsule urtan 25 Mg pime 2 G Iv comycin desivir			C C C C C S						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	17894789	DIRECT	Υ	0					82 YR		USA

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								•			
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Bilirubin Increase	ed	Remdes	ivir	Υ		S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178956	655	DIRECT	Υ	I	_T			71 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine			arin (Enoxaparin			S	Subcutaneous				Not Reported
Increased; Hypotension Melaena	Π,	40mg/0. Remdes (Eua))	ivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178957	'35	DIRECT	Υ	I	રા			70 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Erythema; Erythema Multiforme; Extravasati Peripheral Swelling; Swelling	ion;	Remdes (Eua))	ivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified	Other Frequency:Am;			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178958	354	DIRECT	Υ	I	DE			72 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Disease Progression		Remdes (Eua))	ivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	178961	69	DIRECT	Υ	ŀ	HO, RI			82 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr

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						Dotalioa It	sport.			
Hypoxia; Respiratory Failure		emdesivir (Eua) (Remdesivir ua))			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17896172	DIRECT	Υ					71 YR	Male	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Aspartate Aminotransferase Increased; Blood Crea Phosphokinase Increa Hepatic Enzyme Increased; Rhabdomyolysis	(E atine	emdesivir (Eua) (Remdesivir ua))			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2020	17896431	DIRECT	Υ	RI				70 YR	Male	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Acute Kidney Injury; B		emdesivir (Eua) (Remdesivir			S					Not Reported
Creatinine Increased; Haemodialysis; Hypotension; Nephrop Foxic; Renal Impairme Jrate Nephropathy	Re pathy (E	ua)) emdesivir (Eua) (Remdesivir ua))			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jun-2020	17894751	DIRECT	Υ	0	Γ			51 YR	Female	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
iver Function Test	Re	emdesivir			S	Intravenous drip	Other Frequency:Load;			Gilead
Increased	Ap Er La	uaifenesin/Dxm pap 650mg noxaparin 40mg Bid actobacillus evofloxacin 750mg Iv			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported

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	171.	1.00					•			
	Ns	rb/Kcitrate pime 1g			C C C				No	t Reported t Reported t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jun-2020	17894755	DIRECT	Υ					34 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	Mfr	
Glomerular Filtration R Decreased	ate Remo	desivir	Υ		S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jun-2020	17894759	DIRECT	Υ					54 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Rash Papular	Remo	lesivir	Υ		S	Intravenous drip			Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jun-2020	17894773	DIRECT	Υ					77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:200mg Then 100mg;		Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
14-Jun-2020	17894794	DIRECT	Υ	C	T			64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site		desivir			S	Intravenous drip			Gil	ead
Extravasation; Infusion Site Swelling	vitari	in D3 5000 Units			С					t Reported
C.to Cwoming		axone 1 Gm nine 100mg			C C					t Reported t Reported
		omycin 500mg			Č					t Reported

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							Detailed No	port			
		Acetamir	rin 40mg nophen 650 Mg atin 500mg ate 220			000					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	Outcome	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
14-Jun-2020	1789643	37	DIRECT	Υ		DE			70 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Respiratory Failu Treatment Failure	ıre;	Remdesi	vir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified				Gilead
		Remdesi	vir Solution 100 Mg Vial	Y		S	Intravenous (not otherwise specified)			Gilead
	(Carboxy	methylcellulose			С					Not Reported
		Chlorhex	idine			C					Not Reported
		Enoxapa	rin			С					Not Reported
		Fluconaz				C C C					Not Reported
		Furosem				С					Not Reported
		Lipid (Sn				C					Not Reported
		Meropen				С					Not Reported
			ednisolone Sodium			С					Not Reported
		Succinat				0					N (D)
		Mupiroci				С					Not Reported
		Pantopra				С					Not Reported
		Vancomy	/cın etrolatum-Mineral Oil			C C					Not Reported
		Eye Oint									Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	Outcome			<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	1781885	58	EXPEDITED (15-DAY)			HO, LT, O	T US-GILEAD-20 0468531)20-	34 YR	Male	USA
<u>Preferred Term</u>		Product		Comp.	OTO	Role Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Blister; Erythema; Rash		Remdesi	vir			S	Unknown	Unk Mg			Gilead
Macular; Rash Vesicula	ar	Remdesi	vir			S	Unknown	Unk Mg			Gilead
		Acetamir	nophen			С		Unk			Not Reported
		Morphine	•			С		Unk			Not Reported



							Detailed Ne	POIL				
		Vancon	nycin			С		Unk				Not Reported
		Potassi	um Chloride			С		Unk				Not Reported
		Tocilizu	mab			С		Unk				Not Reported
		Furoser	mide			С		Unk				Not Reported
		Famotio	dine			С		Unk				Not Reported
		Enoxap	arin			С		Unk				Not Reported
		Ceftriax				С		Unk				Not Reported
			ol [Salbutamol]			С		Unk				Not Reported
												- Tot Hopolica
FDA Received Date	Case :	<u>#</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17848	044	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469503	20-		45 YR	Male	USA
Preferred Term		Produc	<u>et</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Cardiac Arr		Remde	sivir			S	Intravenous (not otherwise specified)	200 Mg	, Once			Gilead
Glomerular Filtration R Decreased; Liver Func Test Increased;		Remde	sivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
Respiratory Failure		Norco Albutero Amioda Amiodip Aspirin Atorvas Calcium Ceftriax Chlorhec Cisatrac Dexmed Digoxin Doxycy	oine [Acetylsalicylic Acid] tatin n Carbonate n Gluconate cone exidine Gluconate alciferol curium detomidine			000000000000000000						Not Reported
		Enoxap Heparin Insulin (C						Not Reported Not Reported Not Reported



		Insulin Lispro			С					Not Reported
		Famotidine			С					Not Reported
		Fentanyl			C C					Not Reported
		Furosemide			С					Not Reported
		Losartan			C					Not Reported
		Meropenem			С					Not Reported
		Metformin			С					Not Reported
		Methylprednisolone			C C C					Not Reported
		Metoprolol			С					Not Reported
		Midazolam			С					Not Reported
		Nitroglycerin			С					Not Reported
		Norepinephrine			C C C					Not Reported
		Nortriptyline			С					Not Reported
		Phenylephrine			С					Not Reported
		Propofol			С					Not Reported
		Tocilizumab			C C C					Not Reported
		Warfarin			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	178964	56 DIRECT	Υ	D	E			61 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
<u>I Teleffed Tellii</u>		roduct	Comp.	<u>010</u>	IXOIC	<u>itoute</u>	Dosage Text	Duration		<u>IWIII</u>
Apnoeic Attack; Areflex	xia;	Remdesivir Solution 100 Mg V	′ial Y		S	Intravenous (not				Gilead
Cardiac Arrest:	,	3			_	otherwise specified)				
Electrocardiogram St		Demode di de Colodina 400 May)	(: - L \ /		0					0:1!
Segment Elevation;		Remdesivir Solution 100 Mg V	iai Y		S	Intravenous (not				Gilead
Hypotension; Pulse						otherwise specified)				
Absent; Pulseless		Acetaminophen			С					Not Reported
Electrical Activity; Sinus	IS	Albuterol Mdi			С					Not Reported
Tachycardia; Tachycar		Albuterol Neb Soln			С					Not Reported
raony caraia, raony car	dia	Aspirin Ec			C C C					Not Reported
		Chlorhexidine			C					Not Reported
		Enoxaparin								Not Reported
		Etomidate			Ċ					Not Reported
		Famotidine			C C C					Not Reported
		Fluticasone Furoate-Vilanterol			Č					Not Reported
		Furosemide			Ċ					Not Reported
		Glycopyrrolate			C C					Not Reported
		Insulin Aspart			Č					Not Reported
		Lidocaine			C					Not Reported
		Lidobalilo								140t Reported



FDA Received Date	C222 #	Tamsulo Tiotropiu Tocilizur	ephrine I Docusate Osin um mab	Health	Prof. O	C C C C C C	Mfr Control #	503B Facility	Acc	Cav	Not Reported
15-Jun-2020	Case #		Case Type EXPEDITED (15-DAY)	<u>Health</u>	<u> </u>	utcomes	US-GILEAD-20		<u>Age</u> 65 YR	<u>Sex</u> Male	<u>Country</u> USA
15-Juli-2020	176900	137	EXPEDITED (15-DAT)		O	ı	0471302	20-	00 1K	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Aspartate Aminotransferase Increased		Remdes	ivir			S	Unknown	100 Mg			Gilead
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	178967	'69	EXPEDITED (15-DAY)		Н	0	US-GILEAD-20: 0471271	20-	69 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Pressure Increase Body Temperature	,	Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Increased; Leukocytos	IS	Pantopra	azole			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Pantopra	azole			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Lactated	d Ringers			С		Unk			Not Reported
		Humalo	g			С		Unk			Not Reported
		Plasma				С	Intravenous (not otherwise specified)	Unk			Not Reported
		Acetami	nophen			С		650 Mg			Not Reported
		lbuprofe Diphenh	n ydramine			C C					Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	1789868	85 EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0469453	20-	49 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Acetaminophen			С		Unk			Not Reported
		Albuterol [Salbutamol]			С		90 Mcg			Not Reported
		Ascorbic Acid			С		500 Mg			Not Reported
		Benzonatate			С		100 Mg			Not Reported
		Dexamethasone			С		20 Mg			Not Reported
		Guaifenesin And Dextromethorphan			С		Unk			Not Reported
		Docusate			С		100 Mg			Not Reported
		Senna Plus [Docusate Sodium;Sennoside A+B]			С		50/8.6 Mg			Not Reported
		Enoxaparin			С		40 Mg			Not Reported
		Famotidine			С		20 Mg			Not Reported
		Guaifenesin			С		100/5			Not Reported
		Loperamide			С		2mg/15ml			Not Reported
		Ondansetron			С		4mg/2ml			Not Reported
		Zinc Sulfate			С		220 Mg			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	1789930	DIRECT		0	Т			83 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed	Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
		Acetaminophen 500mg Po Q6h Prn			С	ssi moo opoomou)				Not Reported
		Cefepime 1g Iv Daily			С					Not Reported

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

		onidazole 500mg lv Q12h lizumab 400mg lv Once			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899317	DIRECT	Y	Ľ	Т			41 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Pneumonia Respiratory Failure		desivir d-19 Convalescent Plasma			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899326	DIRECT	Y	C	т			91 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Erythema Infusion Site Irritation; Infusion Site Reaction; Pruritus		desivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899334	DIRECT	Υ	Н	0			56 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Creatinine Renal	Rem	desivir			S	Intravenous drip				Gilead
Clearance Increased	Vand	comycin			С	·				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899383	DIRECT	Υ	D	E			82 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Drug Ineffective Respiratory Failure	e; Rem	desivir	Υ		S	Intravenous (not otherwise specified)			Gilead

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FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	178993	94 DIRECT	Υ		ОТ			49 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration F	Rate	Remdesivir			S	Intravenous drip				Gilead
Decreased; Therapy Cessation		Azithromycin 500mg Iv Daily Ceftriaxone 2g Iv Daily Enoxaparin 40mg Subcut Q24h Methyprednisolone 40mg Iv Q8 Tocilizumab 800mg Iv Once Fentanyl Infusion Norepinephrine Infusion Propofol Infusion Vecuronium Famotidine 20mg Po Daily			0000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	178994	04 DIRECT	Υ		ОТ			78 YR	Female	e USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration F Decreased; Therapy Cessation		Remdesivir Ascorbic Acid 500mg Bid Aspirin 325mg Po Daily Azithromycin 500mg Iv Daily Ceftriaxone 1g Iv Bid Enoxaparin 40mg Subcut Bid Famotidine 40mg Po Bid Insulin Glargine 15 Units Qbedtime Insulin Lispro Sliding Scale Methylprednisolone 40mg Iv Bi Zinc Sulfate 220mg Bid	d		8 0000000 000	Intravenous drip	Other Frequency:Once;			Gilead Not Reported



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020 1	17899416	DIRECT	Υ	0	Т			62 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Bilirubin Conjugated		mdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Decreased; Hypotensior Pyrexia; Sepsis; Transaminases Increase	Kei	mdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Alb Alb Epo Mic Insi Insi Hyo Me Lind Noi Lipa Roo Pro Rej Ma	uterol Sulfate Hfa Inhaler uterol Nebulizer pprostenol-Floan dazolam ulin Regular ulin Lispro dromorphone parin prazole ropenam ezolid repinephrine ase-Protease-Amylase curonium ppofol smasol Bgk 2/3.5 placement Solution gnesium Sulfate, Potassium								Not Reported
	Chl Dia Asp Lisi	oride In Prismasate Bgk 4/2.5 lysis birin inopril dium Phosphate	5		C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020 1	17899424	DIRECT	Υ	0	т			91 YR	Femal	e USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferas	se Rei	mdesivir			S					Not Reported

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

Increased	Azi Cef Cef	corbic Acid thromycin fepime ftriaxone olecacliferol			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899429	DIRECT	Υ		OT			60 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Glomerular Filtration F Decreased; Respirato Failure	ry Alb Sol Am Cef Doc Enc Insi Mei Q12 Ser Toc Scr Var Am Dec Hep Noi	uterol-Ipratropium Inhalation ution iodarone fepime 2g Iv Bid cusate 100mg Po Bid oxaparin 40mg Subcut Bid ulin Lispro Sliding Scale thylprednisolone 40mg Iv 2h nna 8.6mg Po Daily cilizumab 400mg Once neduled ncomycin 1500mg Iv Daily iodarone Drip xmedetomidine Drip parin Drip repinephrine Drip			s c ccccc cc cccccc	Intravenous drip				Not Reported
FDA Received Date		sopressin Drip	Hoalth	Drof	C Outcomes	Mfr Control #	503B Facility	Ago		Not Reported
15-Jun-2020	Case # 17899435	Case Type DIRECT	Y	<u> </u>	OT	<u>will Control #</u>	SUSE FACILITY	<u>Age</u> 78 YR	<u>Sex</u> Female	<u>Country</u> USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Glomerular Filtration F Decreased	Rate Rer	mdesivir			S	Intravenous (not otherwise specified)				Gilead

Note: If the field is blank, there is no data.



Albuter	ol-Ipratropium			С					ot Reported
				С					ot Reported
				C					ot Reported
				C					ot Reported
				C					ot Reported
				C					ot Reported
				C					ot Reported
				C					ot Reported
	•			C					ot Reported
				C					ot Reported
				C					ot Reported
				C					ot Reported
				C					ot Reported
	razole			C					ot Reported
Zinc				C				No	ot Reported
se #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
99442	DIRECT	Υ					56 YR	Transgend	le USA
								r	
Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	Mf	r
Remde	sivir			S	Intravenous (not otherwise specified)			Gi	ilead
se #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
99447	DIRECT	Υ		DE				Male	USA
Produc	<u>21</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mf</u>	ŗ
Remde	sivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gi	llead
Amioda	rone Bolus And Infusion			С				No	ot Reported
Aspirin	Chewable 81mg Daily			Ċ					ot Reported
				Č					ot Reported
				C					ot Reported
				C					ot Reported
				С					ot Reported
				С					ot Reported
Epopro	stenol Continuous Neb								ot Reported
				С					ot Reported
3	Amlodig Ascorbi Atorvas Ceftriax Diltiaze Gabape Glimep Insulin Isosorb Methylp Metocld Pantop Zinc e # 99442 Product Remde Amioda Aspirin Atorvas Atracur Ceftriax Azithroi Dobuta Epopro	Case Type DIRECT Product Remdesivir Case Type Case Type	Amlodipine Ascorbic Acid Atorvastatin Ceftriaxone Diltiazem Gabapentin Glimeperide Insulin Glargine Insulin Lispro Isosorbide Dinitrate Methylprednisolone Metoclopramide Pantoprazole Zinc e # Case Type Health 99442 DIRECT Y Product Comp. Remdesivir E # Case Type Health 99447 DIRECT Y Product Comp. Remdesivir Amiodarone Bolus And Infusion Aspirin Chewable 81mg Daily Atorvastatin 80mg Qhs Atracurium Infusion Ceftriaxone 1g Iv Daily Dobutamine Infusion Epoprostenol Continuous Neb	Amlodipine Ascorbic Acid Atorvastatin Ceftriaxone Diltiazem Gabapentin Glimeperide Insulin Glargine Insulin Lispro Isosorbide Dinitrate Methylprednisolone Metoclopramide Pantoprazole Zinc e # Case Type Health Prof Product Comp. OTC Remdesivir Product Comp. OTC Remdesivir Product Comp. OTC Remdesivir Amiodarone Bolus And Infusion Aspirin Chewable 81mg Daily Atorvastatin 80mg Qhs Atracurium Infusion Ceftriaxone 1g Iv Daily Azithromycin 500mg Iv Daily Dobutamine Infusion Epoprostenol Continuous Neb	Amlodipine Ascorbic Acid Atorvastatin Ceftriaxone Diltiazem Ceghapentin Glimeperide Insulin Glargine Insulin Lispro Isosorbide Dinitrate Methylprednisolone Metoclopramide Pantoprazole Zinc E# Case Type Product Remdesivir Product Remdesivir Comp. OTC Role Remdesivir S Amiodarone Bolus And Infusion Aspirin Chewable 81mg Daily Atorvastatin 80mg Qhs Atracurium Infusion Cetriaxone 1g Iv Daily Azithromycin 500mg Iv Daily Dobutamine Infusion Cetriaxone CC	Amlodipine Ascorbic Acid C Ascorbic Acid C Atorvastatin C Ceftriaxone Dilitazem Gabapentin C Glimeperide Insulin Glargine Insulin Lispro Isosorbide Dinitrate Methylprednisolone Metoclopramide Pantoprazole Zinc C C E # Case Type Health Prof Product Remdesivir Product Comp. OTC Role Route Remdesivir S Intravenous (not otherwise specified) Product Remdesivir Product Comp. OTC Role Route Remdesivir S Intravenous (not otherwise specified) Product Remdesivir S Intravenous (not otherwise specified) Amiodarone Bolus And Infusion Aspirin Chewable 81 mg Daily Atorvastatin 80 mg Qhs Atracurium Infusion C Ceftriaxone 1g Iv Daily Azithromycin 500 mg Iv Daily Azithromycin 500 mg Iv Daily Azithromycin 500 mg Iv Daily Dobutamine Infusion Epoprostenol Continuous Neb C C Ceftriaxone 1G Iv Daily C Epoprostenol Continuous Neb	Aniodipine	Ascorbic Acid	Ascorbic Acid As

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						Dotanou itt	, po. c			
	Vitar	arin Infusion nin C 1500mg Iv Q6h, mine 200mg Iv Q12h			C C					ot Reported ot Reported
	Hydr Mida Nore Pher Prop Sodi	cocortisone 50mg Iv Q6h szolam Infusion spinephrine Infusion sylephrine Infusion ofol Infusion um Bicarbonate Infusion oppressin Infusion			0000000				N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899460	DIRECT	Υ	0	Т			90 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Hepatic Enzyme Increased	Rem	desivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899465	DIRECT	Υ	D	E			76 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Hypoxia; Respiratory Failure	Rem	desivir	Υ		S	Intravenous (not otherwise specified))		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899470	DIRECT	Υ					68 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Alanine Aminotransfer Increased; Ischaemic		desivir			S	Intravenous (not otherwise specified))		G	ilead
Hepatitis; Transamina Increased	Aspi Ator Dext Enox	rin vastatin romethorphan kaparin apentin			0000				N N N	ot Reported ot Reported ot Reported ot Reported ot Reported

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	Lactı Magı Com	ominophen ulose nesiun Oxide pazine tracurium			0000				N N N	ot Reported lot Reported lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17899481	DIRECT	Υ					78 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Liver Function Test Increased; Therapy Cessation	Rem	desivir			S	Intravenous drip		4 DAY	G	iilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17900464	DIRECT	Υ	D	E			65 YR	Female	USA
<u>Preferred Term</u>	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Death	Rem	desivir			S	Intravenous drip			G	iilead
		zumab ylpredisone			C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17900481	DIRECT	N	С	Т			85 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Abdominal Distension; Abdominal Infection;	; Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	ilead
Gastric Fluid Analysis Abnormal; Gastrointes Obstruction; General	stinal Rem	desivir			S	Intravenous (not otherwise specified)			G	iilead
Physical Health Deterioration	Albu Amic Amic	aminophen teral odarone odipine icillin-Sulbactam			0000				N N N	ot Reported lot Reported lot Reported lot Reported lot Reported

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		aban			С					Not Reported
	Ater				С					Not Reported
		vastatin			C					Not Reported
		cium Gluconate			C					Not Reported
		orhexidine Gluconate			C					Not Reported
		lecalciferol			C					Not Reported
		medetomidine			С					Not Reported
		trose			С					Not Reported
	Digo				С					Not Reported
		nidate			C					Not Reported
		notidine			C					Not Reported
		tanyl			C					Not Reported
		cagon			C					Not Reported
		copyrrolate			C					Not Reported
	Hep				C					Not Reported
	Insu	lin Lispro Pen			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17900482	DIRECT	Υ	0	Т			39 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Angioedema; Lip Oed	dema; Ren	ndesivir			S	Intravenous (not				Gilead
_ip Swelling; Swollen						otherwise specified)				
Tongue; Tongue Oed	0000	riaxone 2 Gm			C	outor mod opcomod)				Not Reported
		hromycin 500 Mg			C C					Not Reported
										Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900484	DIRECT	Υ	0	Т			37 YR	Male	USA
Due (T	<u>Pro</u>	<u>duct</u>	Comp.	<u>OTC</u>	<u>Role</u>	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Preferred Term					C					Gilead
	roos Dam	adaaii iir				1				
Alanine Aminotransfe	rase Ren	ndesivir			S	Intravenous (not otherwise specified)				Glieau
Alanine Aminotransfe Increased FDA Received Date		ndesivir <u>Case Type</u>	<u>Health</u>	Prof O	utcomes			<u>Age</u>	Sex	Country



Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Thrombocytopenia	Remo	desivir			S	Intravenous (not otherwise specified)			G	Silead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2020	17900494	DIRECT	Υ		DE			74 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Hepatic Failure	Remo	lesivir	Υ		S	Intravenous drip		5 DAY	G	Silead
	Propo Morpl Lover Proto Metop Zithro Ceftri Norva	nine nox nix orolol imax axone			0000000				\ \ \ \	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17900498	DIRECT	N		DE			7 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Remo	lesivir	Υ		S	Intravenous drip		2 DAY	G	Silead
	Norep Propo	nine mine m Bicarbonate binephrine			0000000				N N N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020	17900502	DIRECT	Υ		ОТ			74 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>

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Blood Creatinine Increased; Glomerular Filtration Rate Decreased	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg/D,100n g/D;	า		Gilead
	Azithromycin 500mg Iv Daily Cefepime 1g Iv Q8h Enoxaparin 40mg Subq Q24h Epoprostenol Continueous Neb Fentanyl Infusion Heparin Infusion Lantus 11 Units Qhs Insulin Lispro Sliding Scale Levothyroxine 88mcg Po Daily Midazolam Infusion Norepinephrine Infusion Pip/Tazo 4.5g Iv Q8h (Extended Infusion) Propofol Infusion Sodium Bicarbonate Infusion			000000000000000000000000000000000000000		g/D,			Not Reported
FDA Received Date Ca		Health	Prof C	Outcomes	Mfr Control #	503B Facility	Age	<u>Sex</u>	Country
15-Jun-2020 17	900505 DIRECT	Υ	C)T			80 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
nfusion Related Reaction	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
	Ceftriaxone 1g Iv Daily Azithromycin 500mg Iv Daily Convalescent Plasma Enoxaparin 40mg Subq Qhs Paroxetine 40mg Daily Zolpidem 10mg Po Qhs Prn			C C C C C	. ,				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date Ca	se # Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2020 17	900509 DIRECT	Υ	H	IO, OT			65 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase ncreased; Aspartate	Remdesivir			S	Intravenous drip	Other Frequency:One			Gilead

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Aminotransferase Time; Increased; Blood Alkaline Phosphatase Increased FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age **Sex Country** Υ USA 15-Jun-2020 17900514 DIRECT 95 YR Female **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr S Intentional Product Use Remdesivir Gilead Other Frequency:Once: Intravenous bolus Issue С Not Reported Azithromycin С Ceftriaxone Not Reported С Metoprolol Tartrate Not Reported С Piperacillin / Tazobactam Not Reported С Not Reported Magnesium FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age <u>Sex</u> Country Υ USA 15-Jun-2020 17900528 DIRECT DE 55 YR Male **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text** Duration Mfr S Gilead Death Remdesivir Υ Other Frequency:Once: Intravenous drip 1 DAY С Not Reported Norepinephrine С Sodium Bicarbnonate Not Reported С Not Reported Humalog С Not Reported Lantus С Not Reported Zosyn С Morphine Not Reported Ċ Cathflo Activase Not Reported С Atacarium Not Reported С Morphine Not Reported С Actemra Not Reported С Metoprolol Not Reported FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility <u>Age</u> Sex Country 17900534 DIRECT Υ DE 60 YR USA 15-Jun-2020 Male **Preferred Term OTC Dosage Text Product** Comp. Role Route Duration Mfr

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Death	Remdesivir	Υ		S	Intravenous drip		2 DAY		Gilead
	Norepinephrine Protonix Morphine Propofol Bicarbonate Atorvastatin Midazolam Furosemide Rocephin Zithromax Lovenox Kionex Metoprolol Calcium Gluconate Lorazepam			000000000000000					Not Reported
FDA Received Date Case		Health	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020 1781	0056 EXPEDITED (15-DAY)	[DE, HO, OT	US-GILEAD-20 0467380	20-	69 YR	Female	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased;	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 5 Mg/Ml Qd			Gilead
Death; Oliguria	Zosyn Vancomycin Potassium Chloride			S S C	,	Unk			Not Reported Not Reported Not Reported
	Etomidate			С		Unk			Not Reported
	Succinylcholine Bromide			С		Unk			Not Reported
	Fentanyl			С		Unk			Not Reported
	Naloxone			С		Unk			Not Reported
	Piperacillin/Tazobactam			С		Unk			Not Reported
	Norepinephrine			С		90 Unk			Not Reported
	Epoprostenol			С		Unk			Not Reported
	Famotidine			С		Unk			Not Reported
	Aspirin (E.C.)			С		Unk			Not Reported



							1			
	Bis	acodyl Sandoz			С		Unk			Not Reported
	Ga	bapentin			С		Unk			Not Reported
		ulin Lispro opofol			C C		Unk			Not Reported Not Reported
	Se	nna Acutifolia			С		Unk			Not Reported
		rosemide [Furosemide dium]			С	Intravenous (not otherwise specified)	40 Mg, Once			Not Reported
	Hy	droxychloroquine			С		Unk			Not Reported
	En	oxaparin			С		Unk			Not Reported
	He	parin			С		Unk			Not Reported
	Me	tolazone			С		10 Mg			Not Reported
	Va	sopressin			С					Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17837798	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0468927	20-	76 YR	Female	e USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Re	mdesivir			S	Intravenous (not otherwise specified)	300 Mg, Total			Gilead
	Ce	fepime			С		Unk			Not Reported
		oxaparin			С		Unk			Not Reported
	Fai	motidine			С		Unk			Not Reported
	Fe	ntanyl			С		Unk			Not Reported
	He	parin			С		Unk			Not Reported
	Ins	ulin Lispro			С		Unk			Not Reported
	Me	thocarbamol			С		Unk			Not Reported
	Me	thylprednisolone			С		Unk			Not Reported
					С		Unk			Not Reported
	Mic	dazolam					OTIK			
		dazolam repinephrine			С		Unk			Not Reported
	No									Not Reported Not Reported



							•				
	Van	comycin			С		Unk				Not Reported
	Vaso	opressin			С		Unk				Not Reported
	Hydi	rocortisone			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17841756	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0468849	20-		68 YR	Female	e USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Fail Covid-19	ure; Rem	ndesivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Zosy	/n			С		Unk				Not Reported
	Albu	terol [Salbutamol]			С		Unk				Not Reported
	Insu	lin Lispro			С		Unk				Not Reported
	Insu	lin Glargine			С		Unk				Not Reported
	Com	bivent			С		Unk				Not Reported
	Amlo	odipine			С		Unk				Not Reported
	Pred	edex			С		Unk				Not Reported
	Love	enox [Enoxaparin Sodium]			С		Unk				Not Reported
	Gab	apentin			С		Unk				Not Reported
	Seel	ori			С		Unk				Not Reported
	Levo	othyroxine			С		Unk				Not Reported
	Ativa	an			С		Unk				Not Reported
	Lopr	essor			С		Unk				Not Reported
	Dule	era			С		Unk				Not Reported
		cocet [Oxycodone rochloride;Paracetamol]			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17900566	DIRECT	Υ						29 YR	Male	USA

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<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	Duration	<u>N</u>	<u>Nfr</u>
Alanine Aminotransfer Increased	ase Remd	desivir			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17900583	DIRECT	Υ					54 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Infusion Site Pruritus	Remd	lesivir	Υ		S	Intravenous (not otherwise specified)	5 DAY	(Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17900630	DIRECT	Υ					72 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Skin Abrasion; Urticari	a Remd	desivir			S	Intravenous (not otherwise specified)		•	Gilead
	Potas Prinivi Aceta Enoxa	minophen Prn aparin romycin			0000000				 	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2020	17900640	DIRECT	Υ		ОТ			81 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Infusion Site Extravasa	ation Remd	desivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17901572	EXPEDITED (15-DAY)			НО	US-GILEAD-2 0471292	020-	51 YR	Male	USA

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Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Hypermagnesaemia	Remo	esivir			S	Unknown	Unk		(Gilead
	Tociliz	zumab			С	Unknown			١	Not Reported
	Сср				С				1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17901656	DIRECT	Υ	(TC			48 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury	Remo	esivir			S	Intravenous (not otherwise specifie	d)		(Gilead
	Panto Midaz	fol Infusion prazole Iv olam Infusion inephrine Infusion			C C C				1	Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17901657	DIRECT	Υ	[DE			93 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfer ncreased; Aspartate Aminotransferase ncreased; Atrial Fibrillation; Cardio-Respiratory Arrest; Glomerular Filtration Rocreased; Pulmonary Embolism	Use A	esivir Under Emergency uthorization (Eua)			S	Intravenous (not otherwise specifie	d)		C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17901658	DIRECT	Υ	[DE			60 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	отс	Role	Route	Dosage Text	Duration	M	lf <u>r</u>



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Acute Myocardial Infarction; Cardio- Respiratory Arrest	Remde	esivir			S	Intravenous bolus					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17901659	DIRECT	Υ		ОТ				29 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Route	Dosage 1	Гехt	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	Benzo Guaife Azithro Ceftria Dipher Enoxa Melato Pantop	nate nesin omycin xone nhydramine parin			» 000000000	Intravenous bolus					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u> :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17901955	EXPEDITED (15-DAY)				US-GILEAD-20 0472521	20-		27 YR	Male	USA
Preferred Term	<u>Produ</u>	ct	Comp.	OTC	Role	Route	Dosage 1	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg,	Once			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17902266	EXPEDITED (15-DAY)				US-GILEAD-20 0472466	20-		79 YR	Male	USA
Preferred Term	Produ	ct	Comp.	OTO	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>		<u>Mfr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead



									_		
FDA Received Date	Case #	Case Type	<u>Health</u>		<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17904983	EXPEDITED (15-DAY)		C	T	US-GILEAD-2 0470945	2020-		69 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration	<u>M</u>	<u>fr</u>
Hypersensitivity	Remde	sivir			S	Intravenous (not otherwise specified	100 Mg d)	g, Qd		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905097	EXPEDITED (15-DAY)		C	T	US-GILEAD-2 0470652	2020-		59 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Bradycardia	Remde	sivir			S	Intravenous (not otherwise specified	100 Mg	g, Qd		(Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905302	EXPEDITED (15-DAY)		F	Ю	US-GILEAD-2 0471308	2020-		79 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreas		sivir			S	Unknown	Unk			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905508	DIRECT	Υ	C	DΤ				45 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Renal Impairment	Remde	sivir			S	Intravenous drip	Other F	requency:Once;		١	lot Reported
	Carved Cefepir Dapton	statin 10mg Po Qbedtime ilol 12.5mg Po Bid ne 2g Iv Q12h nycin 700mg Iv Q24h Glargine 35 Units Subcut			C C C C					N N	lot Reported lot Reported lot Reported lot Reported lot Reported

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		Linezolio Nifedipir Heparin	ispro Sliding Scale d 600mg Iv Q12h ne Er 60mg Daily Drip orphone 1mg Prn			C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	179055	11	DIRECT	Υ		ОТ				69 YR	Male	USA
Preferred Term		Product	<u>t</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase		Remdes	ivir	Y		S	Intravenous (not otherwise specified)	ı				Gilead
Increased; Liver Funct Test Increased	ion	Remdes	ivir	Υ		S	Intravenous (not otherwise specified)	ı				Gilead
		Labetalo Ceftriaxo Azithrom Tamsulo Levetirao Finaster Amlodip Metronio Enoxapa Rivaroxa Albutero Lorazep	ine jum Sulfate ju			000000000000000000000000000000000000000						Not Reported
FDA Received Date		Auvii i ii	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	Age	Sex	Country
16-Jun-2020	179055	16	DIRECT	Y		ОТ			-	73 YR	Male	USA



							-			
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	esivir	Υ		S	Intravenous drip	Other Frequency:One Time;			Gilead
	Pipera Methy	omycin acillin-Tazobactam rlprednisone edetomidine fol			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905521	DIRECT	Υ	0	DE			79 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Hepatic Enzyme	Remo	esivir			S	Intravenous (not otherwise specified)			Gilead
Increased; Refusal Of Treatment By Patient; Therapy Cessation	Clinda	omycin amycin Ilprednisone			C C C		,			Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905527	DIRECT	Υ	C	DT			56 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Feeling Hot; Flushing; Rash; Rash Erythematous; Respira Disorder	Remo	esivir	Υ		S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905531	DIRECT	Υ	C	T			41 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase	ase Remo	esivir Eua			S					Not Reported

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Increased; Bilirubin Conjugated Increased; Blood Bilirubin Increased; Hepatic Enzyme Increased; Surgery; Therapy Interrupted

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905542	DIRECT	Υ	D	E			41 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Bilirubin Increas Repatic Steatosis;	,	lesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
ransaminases Increa	sed Remo	lesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Ceftri	axone			С					Not Reported
	Vanc	omycin			C					Not Reported
		log Sliding Scale			С					Not Reported
	Propo				С					Not Reported
	Esom	eprzole			С					Not Reported
	Acorb	ic Acid			С					Not Reported
		xychloroquine			С					Not Reported
		nedrol Taper Dose			С					Not Reported
		Sulfate			С					Not Reported
		anolol			С					Not Reported
	Lasix				C					Not Reported
		rin Drip			С					Not Reported
		nyl Drip			C					Not Reported
		colam Drip			С					Not Reported
		oinephrine Drip			С					Not Reported
		ronium			С					Not Reported
		propol			С					Not Reported
	Aceta	minophine			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020	17905554	DIRECT	Υ	0	Т			65 YR	Male	USA
referred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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						P			
Glomerular Filtration Rate	Remdesivir			S	Intravenous drip				Not Reported
Decreased	Ascorbic Acid 500mg Po Bid Aspirin 81mg Po Daily Enoxaparin 40mg Subcut Q24h Famotidine 20mg Po Bid Tocilizumab 800mg Iv Once Fentanyl Drip Norepinephrine Drip Propofol Drip			0000000					Not Reported
FDA Received Date Case	# Case Type	Health	Prof Ou	<u>ıtcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2020 17909	5569 DIRECT	Υ					47 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Administration Site Extravasation; Infusion	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Site Pain; Infusion Site Swelling	Sodium Chloride 0.9%			С					Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020 17820	6572 EXPEDITED (15-DAY)	07	Г	US-GILEAD-20 0467950	20-	70 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Renal Tubular Necrosis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Tocilizumab			С		400 Mg			Not Reported
	Heparin Enoxaparin Trimethobenzamide			C C C		200 Mg, Once			Not Reported Not Reported Not Reported
	Asa Insulin Lispro Acetaminophen Ondansetron Levothyroxine			C C C C		3,			Not Reported Not Reported Not Reported Not Reported Not Reported



				Dotalloa IX	орон				
Ethacrynic Acid Metoprolol			C C		Unk				Not Reported Not Reported
Tradipitant			С		Unk				Not Reported
# Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
1684 EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-2 0468502	2020-		73 YR	Male	USA
Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Remdesivir			S	Unknown	200 Mg)			Gilead
Apixaban Aspirin (E.C.) Atorvastatin Aztreonam Calcium Chloride Calcium Gluconate Ceftriaxone Chlorhexidine Benadryl 24 D Famotidine Breo Ellipta Furosemide Hydrocortisone Isosorbide Labetalol Magnesium Oxide Magnesium Sulfate Midazolam Singulair Protonix [Omeprazole] Kcl Rocuronium Verapamil Fentanyl Flolan Heparin			0000000000000000000000000						Not Reported
	# Case Type 1684 EXPEDITED (15-DAY) Product Remdesivir Acetaminophen Apixaban Aspirin (E.C.) Atorvastatin Aztreonam Calcium Chloride Calcium Gluconate Ceftriaxone Chlorhexidine Benadryl 24 D Famotidine Breo Ellipta Furosemide Hydrocortisone Isosorbide Labetalol Magnesium Oxide Magnesium Sulfate Midazolam Singulair Protonix [Omeprazole] Kcl Rocuronium Verapamil Fentanyl Flolan	# Case Type Health 1684 EXPEDITED (15-DAY) Product Comp. Remdesivir Acetaminophen Apixaban Aspirin (E.C.) Atorvastatin Aztreonam Calcium Chloride Calcium Gluconate Ceftriaxone Chlorhexidine Benadryl 24 D Famotidine Breo Ellipta Furosemide Hydrocortisone Isosorbide Labetalol Magnesium Oxide Magnesium Oxide Magnesium Sulfate Midazolam Singulair Protonix [Omeprazole] Kcl Rocuronium Verapamil Fentanyl Flolan Heparin	Metoprolol Tradipitant # Case Type Health Prof 9 1684 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Acetaminophen Apixaban Aspirin (E.C.) Atorvastatin Aztreonam Calcium Chloride Calcium Gluconate Ceftriaxone Chlorhexidine Benadryl 24 D Famotidine Breo Ellipta Furosemide Hydrocortisone Isosorbide Labetalol Magnesium Oxide Magnesium Sulfate Midazolam Singulair Protonix [Omeprazole] Kcl Rocuronium Verapamil Fentanyl Flolan Heparin	Metoprolol C Tradipitant C # Case Type Health Prof Outcomes 1684 EXPEDITED (15-DAY) DE, HO, OT Product Comp. OTC Role Remdesivir S Acetaminophen C Aojixaban C Acetaminophen C Aspirin (E.C.) C C Aspirin (E.C.) C C Aspirin (E.C.) C C C Astronomical Companies C C C C Aspirin (E.C.) C C Aspirin (E.C.) C C C Aspirin (E.C.) C C C Aspirin (E.C.) C C C C C C C C C C C C C C C C	Ethacrynic Acid Metoprolol C Tradipitant C # Case Type Health Prof Outcomes Mfr Control 1684 EXPEDITED (15-DAY) DE, HO, OT US-GILEAD-2 0468502 Product Comp. OTC Role Route Remdesivir S Unknown Acetaminophen C C Apixaban C C Aspirin (E.C.) C C Atorvastatin C C Calcium Chloride C C Calcium Gluconate C C Calcium Gluconate C C Chlorhexidine C C Enandtyl 24 D C Famotidine C C Franctidine C C Franctidine C C Benadryl 24 D C Famotidine C C Brosorbide C C Hydrocortisone C C Isosorbide C C Isosorbide C C Magnesium Oxide Magnesium Oxide Magnesium Oxide Magnesium Oxide Magnesium Oxide Magnesium Isosorbide C C Rocuronium C C C	Metoprolol Tradipitant C Unk # Case Type Health Prof DB, HO, OT US-GILEAD-2020-0468502 Product Comp. OTC Rele Remdesivir Remdesivir Acetaminophen Aspirin (E.C.) Atorvastatin Aztreonam Calcium Chloride Calcium Gluconate Ceftriaxone Chlorhexidine Benadryl 24 D Eamotidine Benadryl 24 D Famotidine Benadryl 24 D Carousemide Hydrocortisone Isosorbide Us-GILEAD-2020-0468502 Unknown 200 Mg Verapamil C C CAROURD OTC Role Route Dosage Route Dosage Route Dosage Route Dosage Route Calcium Chlorwn 200 Mg C C C C C C C C C C C C C C C C C C C	Ethacrynic Acid Metoprolol C C Unk Tradipitant C C Unk #* Case Type Health Prof Dt., Mr. Control # 503B Facility 1684 EXPEDITED (15-DAY) DE, HO, OT US-GILEAD-2020-0468502 Product Comp. OTC Role Route Dosage Text Remdesivir S Unknown 200 Mg Acetaminophen C C C C C C C C C C C C C C C C C C C	Ethacrynic Acid Metoprolol Tradipitant C C C Unk ## Case Type Health Prof DE, HO, OT US-GILEAD-2020- Froduct Comp. OTC Role Route Dosage Text Duration	Ethacrynic Acid



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17835874	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468237	020-		23 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	g, Once			Gilead
	Aceta	minophen			С	Oral	1000 M	lg Q5h			Not Reported
	Dextr	omethorphan			С	Oral	30 Mg				Not Reported
	Enox	onatate aparin in [Acetylsalicylic Acid] ofen			C C C C	Oral	400 Mg	1			Not Reported Not Reported Not Reported Not Reported
	Zinc S Hydro Predr	nin C [Ascorbic Acid] Sulfate oxychloroquine nisone erol Hfa			00000			,			Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17907183	DIRECT	Υ		HO, OT				43 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	desivir			S	Intravenous drip					Gilead
Increased; Aspartate Aminotransferase Increased; Blood Biliru Increased	Enoxa Tocili Zinc S Panto Albuta Potas Magn	ofol methasone aparin zumab Sulfate oprazole			00000000000						Not Reported Not Reported



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17-Jun-2020	17907187	DIRECT	Υ	C	T			77 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury	Remd	esivir	Υ		S	Intravenous drip			C	Gilead
	Lispro Regul Solu-I Panto Rocur Sodiu Hydra 0.5% D5 W Fenta Midaz	sate aparin tidine s Insulin l Insulin ar Insulin Medrol prazole onium m Bicarbonate lazine Normal Saline ith Sodium Bicarbonate nyl Drip olam binephrine			0000000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17907202	DIRECT	Υ	C	T			59 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; B Creatinine Increased; General Physical Heal Deterioration		lesivir Eua			S	Intravenous (not otherwise specified	l)		C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
	17907208	DIRECT	Υ	_	E			75 YR	Male	USA



Preferred Term	Prod	<u>uct</u>	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Нурохіа	Remo	desivir	Y		S	Intravenous (not otherwise specified)	r	9 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17907210	DIRECT	Υ		ОТ			43 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	desivir	Υ		S	Intravenous bolus	Other Frequency:Once;			Gilead
ncreased; Aspartate Aminotransferase	Remo	desivir	Υ		S	Intravenous drip				Gilead
Increased		desivir 200 Mg desivir 100 Mg			C C	·				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17907216	DIRECT	Υ		DE			41 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated Covid-19 Pneumonia; Diabetic Ketoacidosis; Hypoxia		desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17907224	DIRECT	Υ					68 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasation; Peripho Swelling		desivir	Υ		S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	17907227	DIRECT	Υ		DE			88 YR	Male	USA

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Preferred Term		Product Product	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>		<u>Mfr</u>
Death		Remdesivir			S						Gilead
		Amlodipine 2.5 Mg Po Daily			C						Not Reported
		Cholecalciferol Tablet 1000			Ċ						Not Reported
		Units Po Daily			Ū						riot rioportou
		Cyanocobalamin 1000 Mcg Po			С						Not Reported
		Daily			Ü						Hot Roportou
		Dexamethasone 10 Mg Lv Daily	.,		С						Not Reported
		Enoxapan'N 40 Mg Iv Q12h	y		Č						Not Reported
		Levothyroxine 112 Mcg Po Dail	V		Č						Not Reported
		Hydromorphone Pca	У		Č						Not Reported
EDA Deserte al Deser		,	11141	D ()		Mr. O		500D E	•		•
FDA Received Date	Case #	Case Type	Health		<u>Dutcomes</u>	Mfr Contro	<u>) #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	1790723	32 DIRECT	Y	(DT				39 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase	Remdesivir			S						Gilead
Increased; Aspartate		Aspirin 81 Mg Po Daily			С						Not Reported
Aminotransferase		Cettriaxone 19 lv Daily			С						Not Reported
ncreased		Chlorhexidine 0.12% Mouthwas 15ml	sh		С						Not Reported
		Dexamethasone 6 Mg Lv Daily			С						Not Reported
		Famotidine 20 Mg Po Bid			C						Not Reported
		Furosemide 20 Mg Iv Q8h			С						Not Reported
		Metoclopramide 5 Mg Iv Q8h			C						Not Reported
		Mvi			Č						Not Reported
		Senna Docusate Po Bid			Č						Not Reported
		Vancomycin Lv			Č						Not Reported
		Artificial Tears			Č						Not Reported
		Dexmedetomidine Lv Cont			Č						Not Reported
		Infusion			Ū						not reported
		Fentanyl Continuous Infusion			С						Not Reported
		Heparin Continue Infusion			Č						Not Reported
		Insulin Continuous Infusion			Č						Not Reported
		Midazolam Continuous Infusion	1		Č						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country



						2014110411				
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Remo Capto Furos				S C C					Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	1# <u>503B Fa</u>	<u>acility</u> <u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17907768	DIRECT	Υ		ОТ			77 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir 0.7 Mg/Ml	Υ		S	Intravenous drip				Gilead
	Remo	lesivir 0.7 Mg/Ml	Υ		S	Intravenous drip				Gilead
	Docus Enoxa Famo Lantu Lispro Regul Solu-I Panto Rocur Sodiu Hydra 0.5% D5 W Fenta Midaz	aparin tidine s Insulin n Insulin ar Insulin Medrol prazole onium m Bicarbonate Ilazine Normal Saline ith Sodium Bicarbonate nyl Drip			00000000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	1# <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
17-Jun-2020	17908452	EXPEDITED (15-DAY)		1	ОТ	US-GILEAD-: 0472502	2020-	37 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Hepatic Enzyme Increased	Remo	lesivir			S	Intravenous (not otherwise specifie	Unk, Qd d)			Gilead
	Propo	fol			С		Unk			Not Reported

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	Hydro	morphone			С		Unk				Not Reported
	Norep	pinephrine			С		Unk				Not Reported
	Docus	sate;Senna			С		Unk				Not Reported
	Enoxa	aparin			С		Unk				Not Reported
	Panto	prazole			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17908465	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0472503)20-		38 YR	Female	e USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	Duration		<u>Mfr</u>
Abnormal Dreams; Hallucination; Suicidal	Remo	lesivir			S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead
Ideation	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Uı	nk			Gilead
	Benzo	onatate			С		Unk				Not Reported
	Dextr	omethorphan			С		Unk				Not Reported
	Ceftri	axone			С		Unk				Not Reported
	Doxyo	cycline			С		Unk				Not Reported
	Aceta	minophen			С		Unk				Not Reported
	Chlori	nexidine			С	Oral	Unk				Not Reported
	Enoxa	aparin			С		Unk				Not Reported
	Labet	alol			С		Unk				Not Reported
	Guaife	enesin			С		Unk				Not Reported
	Nifedi	pine			С		Unk				Not Reported
	Norco	•			С		Unk				Not Reported
	Нера	rin			С		Unk				Not Reported
	Onda	nsetron			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17908535	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0472755)20-		68 YR	Male	USA

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Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury	Remde	esivir			S	Unknown	Unk			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17908548	EXPEDITED (15-DAY)		C	DΤ	US-GILEAI 0472764	D-2020-			Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>M</u> :	<u>fr</u>
Blood Alkaline Phosphatase Increase	Remde d	esivir			S	Unknown				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17908571	EXPEDITED (15-DAY)		C	DΤ	US-GILEAI 0472816	D-2020-		73 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>M</u> :	<u>fr</u>
Renal Replacement Therapy	Remde	esivir			S	Unknown				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910859	DIRECT	Υ	C	T				66 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remde	esivir			S	Intravenous drip				G	iilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910866	DIRECT	Y	C)S				40 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	<u>Role</u>	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury;	Remde	esivir	Υ		S	Intravenous drip				G	iilead
Haemodialysis	Doxyc Azithro	ycline omycin			C C						ot Reported ot Reported

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					Detailed IX	eport			
	Cefepime Enoxaparin Furosemide Vancomycin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020 1791	0870 DIRECT	Υ					57 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Liver Function Test Increased; Therapy Cessation	Remdesivir Methylprednisolone Enoxaparin			S C C	Intravenous bolus		1 DAY		Gilead Not Reported Not Reported
FDA Received Date Case	# Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020 1791	0874 DIRECT		0	Т			29 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase ncreased; Aspartate Aminotransferase ncreased; Liver Function Test Increased	Remdesivir			S	Intravenous drip				Gilead
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020 1791	0893 DIRECT	Υ	0	Т			67 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Haemodialysis; Hypotension; Renal	Remdesivir 5mg/MI Injection - Eua			S	Intravenous drip	Other Frequency:Once;			Gilead
Impairment; Septic Shock	Remdesivir 5mg/MI Injection - Eua			S	Intravenous drip				Gilead
	Ceftriaxone 1g lv Daily Gabapentin 100mg Po Daily Propofol Continuous lv			C C C					Not Reported Not Reported Not Reported

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							1			
	Midaz Aspiri Insulii Aceta Famo Fenta Furos	yephrine Continuous Iv colam Continuous Iv in 81mg Oral Daily in Lispro Sq Per Protocol iminophen 1g Iv Q6h Prn bitidine 20mg Iv Daily inyl Continuous Iv itemide 40mg Iv X 1 inin 25% 25g Iv X 1			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910897	DIRECT	Υ		ОТ			29 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
	Tocili	zumab			С	,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910903	DIRECT	Υ		ОТ			39 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	Remo	desivir			S	Intravenous bolus				Gilead
Increased	Azithr Zofral Fenta Proto Lover Methy Robu	axone romycin n ınyl nix			0000000000					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910907	DIRECT	Υ					47 YR	Unknov	vn USA

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Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>Mfr</u>	
Blood Creatinine Increased	Remd	esivir			S	Intravenous (not otherwise specified)	Other Frequency: Dose;	X 1	Gilead	
	Conva	alescent Plasma			С				Not Repo	rted
	Colace	e 100 Mg Po Daily			С				Not Repo	rted
		etine 60 Mg Po Daily			С				Not Repo	
	Hepar Hours	rin 5000 Units Subq Q 8			С				Not Repo	rted
	Cultur	elle 1 Po Daily			С				Not Repo	rted
	Zosyn	2.25 G Q 6 Hours			С				Not Repo	rted
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Fac	cility Age	Sex Cou	<u>ıntry</u>
17-Jun-2020	17910919	DIRECT	Υ	0	Т			39 YR	Male USA	4
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Remd	esivir			S				Gilead	
Critical Illness	Acetai	minophen			С				Not Repo	rted
	Enoxa				С				Not Repo	
	Albute				С				Not Repo	
	Ascorl	bic Acid			С				Not Repo	
	Cisatra	acurium			С				Not Repo	rted
	Vanco	omycin			С				Not Repo	rted
		onium			С				Not Repo	
	Propo	fol			С				Not Repo	
	Pipera	acillin/Tazobactam			С				Not Repo	
		prazole			С				Not Repo	
	Norep	pinephrine			С				Not Repo	rted
	Midaz	.olam			С				Not Repo	rted
	Metop	rolol			С				Not Repo	rted
	Methy	/lprednisolone			С				Not Repo	
	Loraze	•			С				Not Repo	rted
		loxacin			С				Not Repo	
	Hydro	morphone			С				Not Repo	
	Fentai				С				Not Repo	
	Famot	tidine			С				Not Repo	
	Cefep	ime			С				Not Repo	
	Δzithr	omycin			С				Not Repo	rtod



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910922	DIRECT	Υ	DS	S			61 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury;	Rem	ndesivir	Υ		S	Intravenous drip				Gilead
Haemodialysis	Cefe	xpapain epime comycin			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910926	DIRECT	Υ					81 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		Mfr
Renal Impairment	Rem	ndesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Rem	ndesivir			S	Intravenous drip				Gilead
	Una Cefe Digo Etor Furc Line Meto Meto Meto Mida Pota Suc Mor Clini Diltia	azem Drip arin Drip epinephrine Drip			0000000000000000000					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910931	1 DIRECT	Υ	l	_T, OT			59 YR	Male	USA
Preferred Term	<u>P</u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Acute Kidney Injury; Continuous Haemodiafiltration; Therapy Cessation	R	emdesivir	Υ		S	Intravenous (not otherwise specified))		G	iilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17910936	5 DIRECT	Υ	[OS, HO, OT			55 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Acute Kidney Injury; Anuria; Therapy Cess	ation A A D E F M N P R	emdesivir mpicillin-Sulbactam Iv zithromycin Iv exmedetomidine Infusion noxaparin entanyl Infusion lidazolam Infusion orepinephrine Infusion ropofol Infusion ocuronium Injection ocilizumab Injection ancomycin Injection	Y		8 00000000000	Intravenous bolus			N N N N N N N	illead lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jun-2020	17911462	2 DIRECT	Υ	I	DE			52 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Death; Pulse Absent; Ventricular Tachycard		emdesivir Eua			S	Intravenous (not otherwise specified))	2 HR	G	iilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	1# <u>503B F</u>	acility Age	<u>Sex</u>	Country
17-Jun-2020	17911526	DIRECT	Y	0	Т			77 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransfer Increased	Atorva Docus Enoxa Famo Lantus Lispro Regul Solu-N Panto Rocur Sodiu Hydra 0.5% D5 Wi Fenta Midaz	sate sparin tidine s Insulin ar Insulin Medrol prazole onium m Bicarbonate lazine Normal Saline th Sodium Bicarbonate nyl Drip	Y		» 000000000000000000000000000000000000	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u> 503B Fa</u>	acility Age	<u>Sex</u>	Country
18-Jun-2020	17805184	EXPEDITED (15-DAY)		D O	E, DS, HC T	, LT, US-GILEAD- 0466961	2020-	48 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>1</u>	<u>Mfr</u>
Blood Creatinine Increased; Hepatic Function Abnormal	Remd Metfor Atorva Atropi Ceftaz Chlort Dextro Midaz Morph	rmin astatin ne zidime nexidine ose olam			8 0000000	Intravenous (not otherwise specifie	200 Mg, Qd d)			Gilead Not Reported



						Dotalloa No	ρυ				
	Nalox	cone			С						Not Reported
	Neos	tigmine			С						Not Reported
	Nore	pinephrine			C C C C C						Not Reported
	Panto	oprazole			С						Not Reported
		ronium			С						Not Reported
		omycin			С						Not Reported
		pressin									Not Reported
	Hydro	ocortisone			С	Intravenous (not otherwise specified)	100 Mg				Not Reported
		ephrine			С	. ,					Not Reported
		anyl Abz			C						Not Reported
		repam			C						Not Reported
	Propo				С						Not Reported
	Fluma	azenil			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>503</u>	BB Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17835872	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0468272	20-		46 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>tt</u>	<u>Duration</u>	<u> </u>	<u>VIfr</u>
Seizure	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qo	d			Gilead
	Tocili	zumab			С		Unk				Not Reported
	Zinc				С		Unk				Not Reported
	Queti	apine			С		Unk				Not Reported
	Methy	ylprednisolone			С		Unk				Not Reported
	Melat	tonin			С		Unk				Not Reported
	Atorv	astatin			С		Unk				Not Reported
	Asco	rbic Acid			С		Unk				Not Reported
		aparin			С						Not Reported
		otidine			С						Not Reported
	Insuli				С						Not Reported
	Potas				С						Not Reported
	Fenta Midaz				C C						Not Reported
					C						Not Reported
	ivore	pinephrine			C						Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	<u>!</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17842534	EXPEDITED (15-DAY)		(DΤ	US-GILEAD-20 0468511	20-		54 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	Aceta Albute Hypro Benzo Bisac Ceter Docus Enoxa Guaife	minophen erol Hfa smellose ocaine onatate odyl ezol sate aparin enesin			s 000000000000000000000000000000000000	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead Not Reported
	Hydrocodone Bitartrate And Acetaminophen Albuterol;Ipratropium Melatonin Morphine Ondansetron Pantoprazole Simethicone Sodium Chloride Tramadol				00000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17844495	EXPEDITED (15-DAY)		(TC	US-GILEAD-20 0468824	20-		26 YR	Femal	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Liver Function Test Increased	Remo	lesivir			S	Intravenous (not otherwise specified)		g, Once			Gilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Remo	lesivir			S	Intravenous (not	200 Mg	g, Once			Gilead



						otherwise specified)				
	Remo	desivir			S	Intravenous (not otherwise specified	100 M	lg, Qd		(Gilead
	Cova	llescent Plasma			С		Unk			1	Not Reported
	Tocili	izumab			С		Unk			1	Not Reported
	Olanz Panto Potas Aceta Hyalu	rhexidine zapine oprazole ssium Chloride aminophen uronidase um Phosphate			0000000					1 1 1 1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17848043	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0469167	020-		61 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Respiratory Arrest	Remo	desivir			S	Intravenous (not otherwise specified		lg, Once		(Gilead
	Conv	alescent Plasma			С		Unk			1	Not Reported
	Amlo	dipine			С		Unk			1	Not Reported
	Atorv	rastatin			С		Unk			1	Not Reported
	Azith	romycin			С		Unk			1	Not Reported
	Ceftri	iaxone			С		Unk			1	Not Reported
	Enox	aparin			С		Unk			1	Not Reported
	Escita	alopram			С		Unk			1	Not Reported
	Folic	Acid			С		Unk			1	Not Reported
	Furos	semide			С		Unk				Not Reported
	Insuli	in Lispro			С		Unk			1	Not Reported
	Losai	rtan			С		Unk				Not Reported
	Panto	oprazole			С		Unk			1	Not Reported
	Polyc	carbophil			С		Unk			1	Not Reported



	Apata	minanhan					<u> </u>				Not Deported
		minophen			С		Unk				Not Reported
		minophen			С						Not Reported
	Alpraz	zoiam			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17868205	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469507)20-		69 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Pyrexia; Ventricular Tachycardia	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg	g, Qd			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Aceta	minophen			С		Unk				Not Reported
	Atorva Benzt Carve Divalp Donep Famo Furos Guaife Insulir Ipratro Albute	ban n (E.C.) astatin ropine [Benzatropine] dilol broex bezil tidine emide enesin n Glargine n Regular Hm brium Bromide And erol Sulfate			000000000000000000000000000000000000000						Not Reported
	Lorata Methy Succi	Iprednisolone Sodium			C C						Not Reported Not Reported
	Ibrutin	prazole apine ulosin			000000						Not Reported
	Zosyn				č						Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17873038	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469296)20-		59 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Remde	esivir			S	Intravenous (not otherwise specified)	Unk			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17910335	EXPEDITED (15-DAY)			OT	US-GILEAD-20 0472813)20-		79 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; B Creatinine Increased	lood Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd		Gil	ead
	Pipera	cillin & Tazobactam			С	. ,	Unk			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17910451	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0473164)20-		56 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Creatinine Renal Clearance Increased	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17910487	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0473079)20-		90 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration	<u>Mfr</u>	
Hepatic Enzyme Increased	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd		Gil	ead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17912038	DIRECT	Y						Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Hepatic Enzyme Increased	Remo	desivir			S				Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17912045	DIRECT	Υ					62 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Incorrect D Administered		desivir	Y		S	Intravenous drip	Other Frequency:Once;		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17912177	DIRECT	Υ	0	Γ			59 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified	d)		Gil	ead
	Albute Amloo Atorva Cefep	dipine astatin bime nedetomidine idate anyl rin Jlin N			000000000000				No No No No No No No	t Reported

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	Nore _l Onda Propo	zolam pinephrine ansetron ofol omycin			C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17912699	EXPEDITED (15-DAY)		(ОТ	US-GILEAD- 0473172	2020-		80 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Infusion Related React	on Related Reaction Remdesivir Ceftriaxone				S	Intravenous (not otherwise specifie	100 M d)	g, Qd			Gilead
	Azithi Conv Enox	romycin alescent Plasma aparin xetine			0 0 0 0 0						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17913269	EXPEDITED (15-DAY)		(ОТ	US-GILEAD- 0473152	2020-		40 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	Duration		Mfr
Chills; Dyspnoea; Hypotension; Hypoxia		desivir aminophen			s C	Unknown	Unk				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	I #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17913808	EXPEDITED (15-DAY)				US-GILEAD- 0471183	2020-		29 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Device Malfunction	Remo	desivir			S	Intravenous (not otherwise specifie	100 M d)	g, Qd			Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914120	EXPEDITED (15-DAY)				US-GILEAD-20 0468293)20-		58 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTO	Role	Route	Dosage 1	<u>'ext</u>	Duration		<u>Mfr</u>
Product Storage Error	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg				Gilead
	Aceta	minophen			С		650 Mg,	Prn			Not Reported
	Aqua	ohor Healing			С	Topical	Unk				Not Reported
	Chole	calciferol			С	Oral	1000 U				Not Reported
	Citalo	pram			С		15 Mg, C	Qhs			Not Reported
	Citalo Albute	pram erol Hfa			C	Respiratory (inhalation)	2 Puffs				Not Reported Not Reported
	Trazo	done			С	Oral	25 Mg				Not Reported
	Dextro	ose & Sodium Chloride			С	Intravenous (not otherwise specified)	1000 MI				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914752	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0472809)20-		61 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage 1	<u>'ext</u>	Duration		<u>Mfr</u>
Cardiac Arrest; Death; Electrocardiogram St	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg,	Once			Gilead
Segment Elevation; Hypotension; Pulseles: Electrical Activity; Shoo		lesivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead
Sinus Tachycardia;		minophen			С		Unk				Not Reported
Tachycardia	Albute	erol [Salbutamol]			С		Unk				Not Reported
	Aspiri	n Ec			С		Unk				Not Reported
	Chlori	hexidine			С		Unk				Not Reported
	Chlori	Chlorhexidine			С		Unk				Not Reported
				С						Not Reported	

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							- 10				
	Er	noxaparin			С		50 Unl	(Not Reported
	Er	noxaparin			С		100 U	nk			Not Reported
	Et	omidate			С		Unk				Not Reported
	Fa	amotidine			С		Unk				Not Reported
	Fl	uticasone Furoate			С		Unk				Not Reported
	Fu	ırosemide			С		Unk				Not Reported
	GI	ycopyrrolate [Glycopyrronium]			С		Unk				Not Reported
	In	sulin Aspart			С		Unk				Not Reported
	Lic	docaine			С		Unk				Not Reported
	M	upirocin			С		Unk				Not Reported
	No	prepinephrine			С		Unk				Not Reported
	Pr	opofol			С		Unk				Not Reported
	Se	enna [Senna Alexandrina]			С		Unk				Not Reported
	Ta	amsulosin			С		Unk				Not Reported
	Tie	otropium			С		Unk				Not Reported
	To	ocilizumab			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914772	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0473016	020-		33 YR	Female	USA
Preferred Term	<u>Pı</u>	roduct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Angioedema; Eye Irritation; Pruritus	Re	emdesivir			S	Intravenous (not otherwise specified	100 M	g, Qd			Gilead
	Ap	pixaban			С	•	Unk				Not Reported
	Me	ontelukast			С		Unk				Not Reported
		uaifenesin antoprazole			C C		Unk				Not Reported Not Reported
	Fl	uticasone;Vilanterol			С		Unk				Not Reported
	Ac	cetaminophen			С		Unk				Not Reported
	In	sulin Lispro			С		Unk				Not Reported



							P • · · ·				
	Melato	nin			С		Unk			No	t Reported
	Zinc S	ulfate			С		Unk			No	t Reported
	Vitami	n C [Ascorbic Acid]			С		Unk			No	t Reported
	Vitami	n D [Colecalciferol]			С		Unk			No	t Reported
	Albute	rol;Ipratropium			С		Unk			No	t Reported
	Insulin	Glargine			С		Unk			No	t Reported
	Methyl	prednisolone			С		Unk			No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914891	EXPEDITED (15-DAY)		(OT	US-GILEAD-20 0473119)20-		57 YR	Male	USA
Preferred Term	Produ	ct	Comp.	<u>otc</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Alanine Aminotransfer Increased	e Aminotransferase Remdesivir sed				S	Intravenous (not otherwise specified)	200 M	g, Qd		Gil	ead
	ased Remdesivir				S	Intravenous (not otherwise specified)	100 M	g, Qd		Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914932	EXPEDITED (15-DAY)				US-GILEAD-20 0472409)20-		37 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>otc</u>	Role	Route	Dosage	e Text	Duration	Mfr	
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914935	EXPEDITED (15-DAY)				US-GILEAD-20 0472420)20-		43 YR	Female	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Preparation E					S	Intravenous (not otherwise specified)	100 M	g, Qd		Gil	ead



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

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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control :	# <u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914942	EXPEDITED (15-DAY)				US-GILEAD-20 0472425	020-		47 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>t</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd)	I		C	Bilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u> <u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914944	EXPEDITED (15-DAY)				US-GILEAD-20 0472430	020-		76 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>t</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg, Qd)	I		C	Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Unk)			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control :	<u>#</u> <u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914946	EXPEDITED (15-DAY)				US-GILEAD-20 0472433	020-		42 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>t</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd)	I		C	Silead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u> <u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914950	EXPEDITED (15-DAY)				US-GILEAD-20 0472462	020-		65 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>t</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
		a ivir			S	Intravenous (not	200 Mg, Qd	I		G	Silead
Product Preparation E	Frror Remde	SIVII				otherwise specified)					

Note: If the field is blank, there is no data.



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914962	EXPEDITED (15-DAY)				US-GILEAD-20 0472474	020-	60 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified	100 Mg, Qd)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914964	EXPEDITED (15-DAY)				US-GILEAD-20 0472486	020-	69 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified	200 Mg, Qd			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified	100 Mg, Qd)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914965	EXPEDITED (15-DAY)				US-GILEAD-20 0472480	020-	70 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		Mfr
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified	200 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
18-Jun-2020	17914967	EXPEDITED (15-DAY)				US-GILEAD-20 0472504	020-	61 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified	100 Mg, Qd)			Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>1 #</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17914972	EXPEDITED (15-DAY)				US-GILEAD- 0472507	2020-		55 YR	Female	e USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTO	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Product Preparation E	rror Remd	esivir			S	Intravenous (not otherwise specifie	200 Mg, Q	ld			Gilead
	Remd	esivir		S		Intravenous (not otherwise specifie	100 Unk d)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>1#</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17915858	DIRECT	Υ						69 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remd	esivir			S	Intravenous (not otherwise specifie	d)				Gilead
		omycin			С	·	,				Not Reported
	Cresto				C C						Not Reported
		omycin acurium			C						Not Reported Not Reported
	Propo				Č						Not Reported
	Teraz				С						Not Reported
	Cefep	ime			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>1 #</u> 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17915865	DIRECT	Y		ОТ				46 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>
Chest Pain; Dyspnoea Hypersensitivity; Thera		esivir			S	Intravenous (not otherwise specifie	d)				Gilead
Cessation	Doxycycline				С						Not Reported
	Enoxaparin				С						Not Reported
	Ceftria Azithr	axone omycin			C C						Not Reported Not Reported
		minophen			C						Not Reported

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17915873	DIRECT	Υ					42 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Bradycardia		lesivir Under Emergency authorization (Eua)	Υ		S				1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17915881	DIRECT	Υ					41 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Dyspnoea; Throat Tightness	Remo	lesivir			S	Intravenous (not otherwise specified)			(Gilead
	Doxyo	cycline			С	, , , , , , , , , , , , , , , , , , ,			1	Not Reported
	Enoxa	parin			С					Not Reported
		/ptiline etamine-			C C					Not Reported Not Reported
		etamine- pamphetamine			C				'	чот керопеа
	Citalo				С				ı	Not Reported
		zepam			C					Not Reported
	Monte	elukast			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17915886	DIRECT	Υ					36 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfer Increased	rase Remo	esivir	Υ		S	Intravenous bolus			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17915949	DIRECT	Υ					66 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>

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Blood Creatine Increased;	Remd	esivir	Υ		S	Intravenous drip				Gilead
Dialysis	Ns	pril fol nyl aparin			000000000					Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020 179	15955	DIRECT	Υ	DE				84 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Azotaemia; Hypotension; Lung Consolidation;	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Paralysis	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Perce Fental Midaz Norep Propo Rocur Huma Esomi Ascob Seleni Zinc Tpn	onium log Sliding Scale eprazole iic Acid iun			0000000000000					Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020 179	15963	DIRECT	Υ	DE				68 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>



Acute Kidney Injury; Acut Respiratory Failure;	te Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Condition Aggravated; Dialysis; Hypoxia; Lung Consolidation; Multiple	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Organ Dysfunction	Apixa	bn			С					Not Reported
Syndrome; Pseudomona					C					Not Reported
Test Positive; Respirator	-				C					Not Reported
Acidosis		log Sliding Scale			C					Not Reported
10.000.0		penem			С					Not Reported
	Seroq				С					Not Reported
		omycin			C					Not Reported
		Sulfate			C					Not Reported
		oic Acid			C					Not Reported
	Fenta				C					Not Reported
	Propo				C					Not Reported
	Ativar				C					Not Reported
	Selen				C					Not Reported
	Verse	d			C					Not Reported
	Noren	ineohrine			Č					Not Reported
		onium			C					Not Reported
	Cefep	ime			C					Not Reported
	Vitam				С					Not Reported
FDA Received Date C	ase #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020 1	7915988	DIRECT	Υ					43 YR	Male	USA
Preferred Term	<u>Prod</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Rash Macular	Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
	Ceftria Doxyo	axone cycline			C C					Not Reported Not Reported
FDA Received Date C	ase #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020 1	7915997	DIRECT	Y					65 YR	Male	USA
Preferred Term	<u>Prod</u> ı	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Adverse Drug Reaction;	Remd	esivir	Υ		S	Intravenous drip				Gilead

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Glomerular Filtration Rate Decreased; Renal Impairment; Respiratory Failure; Septic Shock

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control:	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2020	17916329	DIRECT	Υ	C)T				80 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remd	esivir Injection 100 Mg/Vial	Υ		S	Intravenous (not otherwise specified))				Gilead
	Remd	esivir Injection 100 Mg/Vial	Υ		S	Intravenous (not otherwise specified))				Gilead
	Atorva Azithro Brimon Enoxa Famon Hydro Lantus	omycin nidine uparin tidine xychloroquine s Insulin log Insulin oprost Medrol amivir			00000000000000000						Not Reported
FDA Received Date	Hydra Case #	lazine <u>Case Type</u>	Health	Prof C	C Outcomes	Mfr Control		503B Facility	<u>Age</u>	Sex	Not Reported Country
19-Jun-2020	17847986	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469172	_		92 YR	Female	-
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Li Function Test Increase					s C	Unknown	Unk				Gilead Not Reported

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		Morphine Glycopyrrolate [Glyco Bromide]			C					Not Reported Not Reported	
		Hydromorphone Unasyn Im/Iv Haldol Decan Heparin				C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17868	197 EXPEDITED	(15-DAY)			ОТ	US-GILEAD-20 0469457	20-	49 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	OTO	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
lanine Aminotransferase ncreased; Dehydration; lypotension; Syncope		Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Hypotension; Syncope	9	Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Albuterol Hfa				С		Unk			Not Reported
		Ascorbic Acid				С		Unk			Not Reported
		Enoxaparin				С		Unk			Not Reported
		Tussionex [Hydrocodone;Phenyl	toloxamine			С					Not Reported
		Solu-Medrol				С		Unk			Not Reported
		Sodium Chloride 0.9% Thiamine	6			C C		Unk			Not Reported Not Reported
		Zinc Sulfate [Zinc Sulf Monohydrate]	fate			С		Unk			Not Reported
		Chlorhexidine				С		Unk			Not Reported
		Famotidine				С		Unk			Not Reported
		Mupirocin				С		Unk			Not Reported
		Morphine				С		Unk			Not Reported
		Acetaminophen				С		Unk			Not Reported



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17901688	EXPEDITED (15-DAY)			НО	US-GILEAD-20 0471284)20-		74 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Hypermagnesaemia	Remo	desivir			S	Unknown	Unk				Gilead
	Lasix Ccp	desivir [Furosemide Sodium] zumab Recombinant			S C C C						Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17916163	DIRECT	Υ		НО				68 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Liver Funct Test Increased		desivir (Eua) (Remdesivir)			S		Other F	Route:Iv			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	Sex	Country
19-Jun-2020	17916168	DIRECT	Υ		НО				51 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Urea Increased; Hepatic Enzyme Increased; Respiratory	(Eua)	desivir (Eua) (Remdesivir)			S		Other F	Route:Iv			Not Reported
Disorder					0	Mfr Control	<u>.</u>	503B Facility	۸۵۵	Sex	Country
	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	WIII CONTROL	<u>#</u>	SUSB FACILITY	<u>Age</u>	<u>Sex</u>	<u>Country</u>

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Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	N	<u>lfr</u>
Dyspepsia; Nausea	Rer (Eu	mdesivir (Eua) (Remdesivir ia))			S	Intravenous (not otherwise specifi	ed)			ļ	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17916363	DIRECT	Υ						59 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatinine Increased; Renal Disor		mdesivir (Eua) (Remdesivir aa))			S	Intravenous (not otherwise specifi	ed)			1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17916633	DIRECT	Υ						54 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Transaminases Increas	sed Rei	mdesivir	Υ		S	Intravenous drip				(Gilead
		etaminophen			C						Not Reported
		uterol Hfa			С						Not Reported
		corbic Acid 500 Mg nzonatate 100 Mg			C C						Not Reported Not Reported
		xtromethorphan-Guaifenesin			C						Not Reported
	10-	100									·
		oxaparin 40 Mg			С						Not Reported
		tformin 1000 Mg			С						Not Reported
		cilizumab 400 Mg ulin Lispro			C C						Not Reported Not Reported
		vothyroxine 75 Mcg			C						Not Reported
		ymetazoline Nasal Spray			C						Not Reported
		c Sulfate 220 Mg			Č						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17917085	EXPEDITED (15-DAY))	(ЭТ	US-GILEAD 0473734)-2020-		62 YR	Male	USA
Preferred Term		oduct	Comp.	OTC	Role	Route	Dosag	_	Duration		<u>lfr</u>



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Acute Kidney Injury; Bilirubin Conjugated	Remde	esivir			S	Intravenous (not otherwise specified)	200 M	g, Qd		Gi	lead
ncreased	Remde	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd		Gi	lead
	Sodiur	n Phosphate			С					No	t Reported
	Lisinor	oril .			С					No	t Reported
	Aspirin	ı (E.C.)			С					No	t Reported
	Magne Chloric	esium Sulfate;Potassium de			С					No	ot Reported
	Prisma	asol			С						ot Reported
	Rocur	onium			С						t Reported
	Propof	fol			С						t Reported
	Lipase				С						ot Reported
		nephrine			С						ot Reported
	Linezo				C C						ot Reported
	Merop				С						ot Reported
	Ompra				C						ot Reported
	Hepari				С						ot Reported
		morphone			C C						ot Reported
	Insulin				C						ot Reported
		Regular Beef			Ċ						ot Reported
	Midazo				С						ot Reported
	Epopro Sodiur	ostenol [Epoprostenol			С					No	ot Reported
		rol Sulfate Hfa			С					No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17918257	EXPEDITED (15-DAY)				US-GILEAD-20 0472481)20-		47 YR	Female	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>e Text</u>	Duration	<u>Mfı</u>	[
Product Preparation E	rror Remde	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd		Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17918557	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468535)20-		59 YR	Female	USA



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Remarkance Re	Aspartate Aminotransferase		desivir		S	Intravenous (not otherwise specified)	200 N	lg, Once			Gilead
Hydromorphone	Haemorrhage;	Remo	desivir		S		100 M	lg, Qd			Gilead
Acetaminophen C		Hydro	omorphone		С						Not Reported
Zofran [Ondansetron] C					С						
Seroque					С						
Seroque					С						
Seroque		Titrala	ac [Calcium Carbonate]		С						Not Reported
Calcium Gluconate C					С						Not Reported
Miralax		Calciu	um Gluconate		С						Not Reported
Miralax		Lasix	[Furosemide]		С						
Magnesium Sulfate											
Magnesium Sulfate		Mirala	ax		С						
Magnesium Sulfate		Bena	dryl		С						Not Reported
Potassium Chloride					С						
Propofol					С						
Propofol					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Protonix [Omeprazole] C					С						
Flagyl [Metronidazole] C Not Reported Rocephin [Ceftriaxone] C Not Reported Vancomycin C Not Reported Prilosec [Omeprazole] C Not Reported Potassium Bicarbonate C Not Reported Zemuron C Not Reported Zemuron C Not Reported Vancomycin C Vancomycin Vancomychill Vancomycin Vanc					С						
Vancomycin Zenpep C Prilosec [Omeprazole] Potassium Bicarbonate Zemuron C C Not Reported Not Rep					C						Not Reported
Vancomycin Zenpep C Prilosec [Omeprazole] Potassium Bicarbonate Zemuron C C Not Reported Not Rep					C						
Zenpep C C Not Reported Prilosec [Omeprazole] C Not Reported C Not Reported Potassium Bicarbonate C Not Reported Potassium Bicarbonate C Not Reported Zemuron C Not Reported Convalescent Plasma C Unk Not Reported Not Reported Convalescent Plasma C Not Reported Plasma C Not Reported Not Repor					C						
Prilosec [Omeprazole] C Not Reported Potassium Bicarbonate C Not Reported Not Reported Not Reported Zemuron C Not Reported Convalescent Plasma C Unk Not Reported					C						
Potassium Bicarbonate C Not Reported Not Rep					C						
Zemuron C C Unk Not Reported No					C						
Convalescent Plasma C Unk Not Reported Levaquin C Not Reported Levaquin C Not Reported					C						
Levaquin C Not Reported FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 19-Jun-2020 17919219 EXPEDITED (15-DAY) DE, OT US-GILEAD-2020- 76 YR Female USA											
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 19-Jun-2020 17919219 EXPEDITED (15-DAY) DE, OT US-GILEAD-2020- 76 YR Female USA		Conv	alescent Plasma		C		Unk				Not Reported
19-Jun-2020 17919219 EXPEDITED (15-DAY) DE, OT US-GILEAD-2020- 76 YR Female USA		Levad	quin		С						Not Reported
19-Jun-2020 17919219 EXPEDITED (15-DAY) DE, OT US-GILEAD-2020- 76 YR Female USA 0473354	FDA Received Date	Case #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
	19-Jun-2020	17919219	EXPEDITED (15-DAY)		DE, OT		20-		76 YR	Female	USA

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							-			
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Creatinine Renal Clearance Decreased; Death; Renal Failure	Remde	sivir			S	Unknown			Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17919225	EXPEDITED (15-DAY)				US-GILEAD-2 0473117	2020-	63 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mfr	:
Product Preparation E	rror Remde	sivir			S	Intravenous (not otherwise specified	100 Mg, Qd d)		Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17919515	EXPEDITED (15-DAY)				US-GILEAD-2 0473064	2020-	5 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mfr	:
Incorrect Product Dosa Form Administered; Of Label Use		sivir			S	Intravenous (not otherwise specified	2.5 Mg/Kg, Qd d)		Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17919730	EXPEDITED (15-DAY)		(ТС	US-GILEAD-2 0473961	2020-	64 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	<u>.</u>
Bradycardia	Remde	sivir			S	Intravenous (not otherwise specified	100 Mg, Qd d)		Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17919777	EXPEDITED (15-DAY)		(ТС	US-GILEAD-2 0473916	2020-	48 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mfr	:
Alanine Aminotransfera	ase Remde	sivir			S	Intravenous (not	200 Mg, Qd		Gi	lead

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						otherwise specified)				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17919795	EXPEDITED (15-DAY)			ОТ	US-GILEAD-202 0473915	20-	41 YR	Male	USA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>N</u>	<u>lfr</u>
Alanine Aminotransfera	ase Re	mdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		(Gilead
	Re	emdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921943	DIRECT	Υ		НО			27 YR	Female	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Foetal Exposure Durin Pregnancy; Liver Func Test Increased; Materi Exposure During Pregnancy; Transaminases Increa	otion Pip nal	emdesivir Via Eua peracillin-Tazobactam			S C	Intravenous bolus				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921949	DIRECT	Υ		DE			53 YR	Female	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; Thrombocytopenia	Re	mdesivir			S	Intravenous (not otherwise specified)			(Gilead
		ncomycon nnipaque 350 Mg			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921951	DIRECT	Υ		ОТ			35 YR	Male	USA

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Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Therapy Cessation; Transaminases Increas		desivir methasone			S C					lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921956	DIRECT	Υ	DE	Ī			81 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	M	<u>fr</u>
Palliative Care	Remo	desivir	Υ		S	Intravenous (not otherwise specified	3)		C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921960	DIRECT	Υ	DE	Ī			61 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	M	<u>fr</u>
Acute Kidney Injury; General Physical Healt		desivir			S	Intravenous (not otherwise specified	Other Frequency:1 Time		C	Silead
Deterioration; Rhabdomyolysis	Remo	desivir			S	Intravenous (not otherwise specified	d)		C	Silead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921964	DIRECT	Υ	0	Γ			67 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Hepatotoxicity; Liver		desivir			S	Intravenous bolus			C	Silead
Function Test Increase	Atorv	astatin			C C					Not Reported
		ecalciferol aparin			C					Not Reported Not Reported
		otidine			Č					lot Reported
		ocortisone			С					Not Reported
		acillin/Tazobactam			С				N	Not Reported
	Valpr	oic Acid			С				N	Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921966	DIRECT	Υ		ОТ			37 YR	Male	USA
Preferred Term	Pre	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Palpitations; Ventricula Tachycardia		mdesivir For Emergency Use thorization			S	Intravenous drip		2 DAY	C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921972	DIRECT	Υ		DE			71 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Re	mdesivir			S	Intravenous (not otherwise specified))		C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921986	DIRECT	Υ		DE			95 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Re	mdesivir			S	Intravenous (not otherwise specified))		C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17921992	DIRECT	Υ		ОТ			51 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Infusion Related Reac Pruritus; Rash	·	mdesivir aifenesin			s C	Intravenous drip	Other Frequency:Once;	5 DAY		Gilead Not Reported
	En	oxaparin nvalescent Plasma			C C				N	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17922004	DIRECT	Υ		OT			38 YR	Male	USA

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Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	N	<u>Afr</u>
Liver Function Test Increased		Remdesivir Clonazepam Dexmedetomidine Epoprostenol Famotidine Fentanyl Heparin Methylprednisolone Midazolam Tocilizumab Vecuronium			s c c c c c c c c c c c c					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	1792201	13 DIRECT	Υ	(DΤ			65 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Faeces Discoloured		Remdesivir			S	Intravenous (not otherwise specified	1)		(Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	1792203	39 DIRECT	Υ	Γ	DE			94 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Death		Remdesivir			S	Intravenous (not otherwise specified	d)			Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	1792204	DIRECT	Υ	(TO			77 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer	ase	Remdesivir	Υ		S	Intravenous bolus	Other Frequency:Once;			Gilead
Increased; Aspartate Aminotransferase Increased; Blood		Enoxaparin 110mg Sc Q12h Famotidine 20mg Iv Bid			C C		, , ,			Not Reported Not Reported

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Creatinine Increased	H <u>i</u> No Pi Pi	entanyl Infusion ydroxychloroquine orepinephrine Infusion peracillin-Tazobactam ropofol Infusion ancomycin Iv			00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control:	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17922077	DIRECT	Υ		OT				37 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase R	emdesivir	Υ		S	Intravenous bolus					Gilead
Increased	Ci Ci Pi Ei H <u>i</u> Di O	cetaminophen eftriaxone 1g lvpb olchicine 0.6mg robenacid 500mg noxaparin 40mg ydrocortisone 50mg uoneb ndansetron 4mg romethazine 12.5mg			00000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17922091	DIRECT	Υ						21 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase R	emdesivir	Υ		S	Intravenous drip					Not Reported
Increased; Aspartate Aminotransferase Increased	FI O G Se	noxaparin ovent Hfa ndansetron uiafenesin enna-Docusate buterol Hfa			00000	·					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17922096	DIRECT							68 YR	Fema	le USA



Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>		Mfr
Infusion Site Extravasa		desivir desivir			S C						Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17922100	DIRECT	Υ	C	DT				52 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Methy Enox Ceftri Losar Doxyo	axone			800000						Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2020	17922121	DIRECT		C	T					Unkno	wn USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remo	desivir	Υ		S				7 DAY		Gilead
Increased	Vanco Cefep	omycin oime			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2020	17922104	DIRECT		C	DT				66 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Liver Funct Test Increased		desivir			S						Not Reported



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jun-2020	17922192	DIRECT	Υ	C	T			38 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Infusion Site Extravasa	ation Remo	desivir			S	Intravenous (not otherwise specified)		Ν	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2020	17922080	DIRECT	Υ					37 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Neutropenia	Remo	desivir Eua Solution			S	Intravenous drip			G	Silead
	Filgas Topir	aparin 40 Mg Sq Daily stim 480 Mcg Once amate 50 Mg Qday Sulfate 220 Mg Qday			C C C				N N	lot Reported lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2020	17922087	DIRECT	Y				-	92 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury	Remo	desivir Eua Solution			S	Intravenous drip			G	Gilead
	Atorv Carve Enox Furos Panto	in 81 Mg Daily astatin 80 Mg edilol 6.25 Mg aparin 40 Mg Sq semide 40 Mg X 1 oprazole 40 Mg Daily acillin/Tazobactam 2.25g			000000				N N N	lot Reported
	Potas	ssium Chloride 40 Meq Q4h omycin 1 Gm X 1			C C					lot Reported lot Reported



Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17922109	DIRECT	Υ		НО			53 YR	Male	USA
<u>Prod</u>	<u>uct</u>	Comp.	ото	Role Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Remo	lesivir Eua Solution			S	Intravenous drip				Gilead
Gabaj Hepar Midod Pipera	pentin 300 Mg Qpm rin Sq Tid drine 10 Mg Tid			0000	а.толово сп.,р				Not Reported Not Reported Not Reported Not Reported Not Reported
	omycin 1.25g Bid			С					Not Reported
Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17922134	DIRECT	Υ		ОТ			78 YR	Male	USA
Prod	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
sed; Remd	desivir	Y		S	Intravenous (not otherwise specified)				Not Reported
Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17922135	DIRECT	Υ		DE			76 YR	Male	USA
Prod	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Remd	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once, Then 100mg;			Gilead
				C	. ,	Ç.			Not Reported Not Reported
				С					Not Reported
				C					Not Reported
				C					Not Reported
	•			C					Not Reported
Lopre: Oxyco				C C					Not Reported Not Reported
>	Production of the control of the con	Product Remdesivir Eua Solution Baclofen 5 Mg Ttid Gabapentin 300 Mg Qpm Heparin Sq Tid Midodrine 10 Mg Tid Piperacillin/Tazobactam 3.375g Q8h Vancomycin 1.25g Bid Case # Case Type 17922134 DIRECT Product ed; Remdesivir Case Type	Product Remdesivir Eua Solution Baclofen 5 Mg Ttid Gabapentin 300 Mg Qpm Heparin Sq Tid Midodrine 10 Mg Tid Piperacillin/Tazobactam 3.375g Q8h Vancomycin 1.25g Bid Case # Case Type Health 17922134 DIRECT Y Product Comp. ed; Remdesivir Y Case # Case Type Health 17922135 DIRECT Y Product Comp. Remdesivir Albuterol Ceftriaxone Aspirin Lovenox Finasteride	Product Comp. OTC Remdesivir Eua Solution Baclofen 5 Mg Ttid Gabapentin 300 Mg Qpm Heparin Sq Tid Midodrine 10 Mg Tid Piperacillin/Tazobactam 3.375g Q8h Vancomycin 1.25g Bid Case # Case Type Health Prof 17922134 DIRECT Y Product Comp. OTC ed; Remdesivir Y Case # Case Type Health Prof 17922135 DIRECT Y Product Comp. OTC Remdesivir Albuterol Ceftriaxone Aspirin Lovenox Finasteride	Product	Product Comp. OTC Role Remdesivir Eua Solution Baclofen 5 Mg Titid Gabapentin 300 Mg Qpm Heparin Sq Tid Midodrine 10 Mg Tid Piperacillin/Tazobactam 3.375g Q8h Vancomycin 1.25g Bid Case # Case Type Health Prof Outcomes Product Comp. OTC Role Remdesivir Product Comp. OTC Role Route Case # Case Type Health Prof Outcomes Mfr Control # 17922135 DIRECT Product Comp. OTC Role Route Comp. OTC Role Route Remdesivir Y DE Product Comp. OTC Role Route Comp. OTC Role Route Remdesivir Y DE Product Comp. OTC Role Route Case # Case Type Health Prof Outcomes Mfr Control # Intravenous (not otherwise specified) Albuterol Ceftriaxone Aspirin Lovenox Finasteride Insulin Lispro	Product Comp. OTC Role Route Dosage Text	17922109 DIRECT Y	17922109 DIRECT Y

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2020	17922138	DIRECT	Υ					42 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cholestasis; Exposure During Pregnancy; Foe		mdesivir	Υ		S	Intravenous (not otherwise specified)	1			Gilead
Heart Rate Abnormal; Gestational Diabetes; I Risk Pregnancy;	High Re	mdesivir	Υ		S	Intravenous (not otherwise specified)	1			Gilead
Premature Labour	Ro Lov Ins Lal Pre	nmax cephin venox uin Sliding Scale cetadol enatal Vitamin sodiol			000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2020	17922140	DIRECT	Υ		ОТ			36 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Thrombocytopenia	Re	mdesivir			S	Intravenous bolus	Other Frequency:One Time;			Not Reported
		venox ftriaxone			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17892600	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470905	020-	74 YR	Female	USA
Preferred Term	Pre	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Burning Sensation; Generalised Oedema	Re	mdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		nethicone parin			C C	. ,				Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	1792225	59 DIRECT	Υ					71 YR	Male	USA
Preferred Term	1	<u>Product</u>	Comp.	OTC		Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Incorrect Dose Administered; Injection Site Extravasation		Remdesivir			S	Intravenous drip	Other Frequency:Once;	5 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	1792311	4 EXPEDITED (15-DAY	()		ОТ	US-GILEAD-20 0473800	20-	76 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>N</u>	<u>Afr</u>
Acute Kidney Injury; Alanine Aminotransfer		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Increased	I	Docusate			С		Unk			Not Reported
	I	Enoxaparin			С		Unk			Not Reported
	I	Famotidine			С		Unk			Not Reported
	I	Lantus			С		Unk			Not Reported
	ı	Lispro Insulin			С		Unk			Not Reported
	I	nsulin Regular Hm			С		Unk			Not Reported
	;	Solu-Medrol			С		Unk			Not Reported
	ı	Pantoprazole			С		Unk			Not Reported
	ı	Rocuronium			С		Unk			Not Reported
	;	Sodium Bicarbonate			С		Unk			Not Reported
	ı	Hydralazine			С		Unk			Not Reported
	i	Normal Saline			С		Unk			Not Reported
	ı	D5 With Sodium Bicarbonate			С		Unk			Not Reported
	ı	Fentanyl			С		Unk			Not Reported
	ı	Midazolam			С		Unk			Not Reported
		Norepinephrine			С		Unk			Not Reported

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	Propo	ofol			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17923759	DIRECT	Υ	I	DE			67 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remo	desivir	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
22-Jun-2020	17923785	DIRECT	Υ					53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified	d)			Not Reported
		erol Hfa			С		,			Not Reported
		minophen ussin Ac			C C					Not Reported Not Reported
	Lover				C					Not Reported
		nedrol			C C					Not Reported
	Lasix			-			" Tool T !!!			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>		<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17923803	DIRECT	Υ	(TC			79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia	Remo	lesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Doxy	cycline			С		1. 1. 1, 1. 100,			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17923809	DIRECT	Υ	(ОТ			71 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Nausea	Remo	desivir	Y		S					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17923814	DIRECT	Υ		ОТ			61 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Haemodial	ysis;	emdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Initial Dose;			Not Reported
Urine Output Decreas	ed Re	emdesivir			S	Intravenous (not otherwise specified)	1			Not Reported
	Az	ithromycin Iv			С					Not Reported
	Ce	eftriaxone Iv			С					Not Reported
		orvostatin Oral			С					Not Reported
	Fe	nobirate Oral			С					Not Reported
		examethasone lv			С					Not Reported
		repinephrine lv Infusion			C					Not Reported
		dazolam Iv Infusion			С					Not Reported
		dromorphone Iv Infusion			C C					Not Reported
		ocuronium Iv Infusion			С					Not Reported
		ntanyl Iv			С					Not Reported
		opofol Infusion			C					Not Reported
		motidine lv			С					Not Reported
		etaminophen Tablet			С					Not Reported
		nenobarbital Inj Iv			С					Not Reported
	Ta	tassium Bicarb-Citric Acid blet			С					Not Reported
	Ins	sulin Regular Infusion			С					Not Reported
		omidate Iv			С					Not Reported
	As	pirin Tablet			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17923823	DIRECT	Υ		DE			52 YR	Femal	e USA
<u>Preferred Term</u>	<u>Pr</u>	oduct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Disease	Re	emdesivir	Υ		S	Intravenous bolus				Gilead
Progression	Az	ithromycin			С					Not Reported
		iproprion			Ċ					Not Reported
		ispirone			C					Not Reported



	Fenta Hydro Panto Propo	ocortisone oprazole			00000					N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17923855	DIRECT	Υ	ОТ					34 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>M</u> :	<u>ir</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase Rem	desivir	Υ		S	Intravenous (not otherwise specified))			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17924892	EXPEDITED (15-DAY)		ОТ		US-GILEAD-20 0474386)20-		54 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u> :	<u>ir</u>
Transaminases Increa	ased Rem	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd		G	ilead
	Aceta	aminophen			С		Unk			N	ot Reported
	Asco Benz Dexti	erol Hfa rbic Acid onatate romethorphan Hbr &			C C C					N N	ot Reported ot Reported ot Reported ot Reported
	Enox Metfo Tocili Insuli Levo Oxyn	fenesin aparin ormin izumab in Lispro thyroxine netazoline Sulfate			000000					N N N N	ot Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17925092	EXPEDITED (15-DAY)		I	НО	US-GILEAD-20 0473804	20-	69 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Metroi Vanco	nidazole omycin			C C		Unk			Not Reported Not Reported
	Hydro	ridine [Pethidine chloride]			С		Unk			Not Reported
	Magne	esium Sulfate			С		Unk			Not Reported
	Labeta				С		Unk			Not Reported
	Ceftria	axone			С		Unk			Not Reported
	Azithro	omycin			С		Unk			Not Reported
	Tamsı	ulosin			С		Unk			Not Reported
	Leveti	racetam			С		Unk			Not Reported
	Finast	teride			С		Unk			Not Reported
	Amlod	dipine			С		Unk			Not Reported
	Metro	nidazole			С		Unk			Not Reported
	Enoxa	aparin			С		Unk			Not Reported
	Rivard	oxaban			С		Unk			Not Reported
	Albute	erol [Salbutamol Sulfate]			С		Unk			Not Reported
	Loraze	epam			С		Unk			Not Reported
	Cyclob	benzaprine			С		Unk			Not Reported
	Trazo	done			С		Unk			Not Reported
	Multiv	itamin [Vitamins Nos]			С		Unk			Not Reported
	Acetai	minophen			С		Unk			Not Reported
		Pm [Diphenhydramine e;lbuprofen]			С		Unk			Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17925342	EXPEDITED (15-DAY)		(T	US-GILE 0474408	AD-2020-		38 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Liver Function Test	Remo	lesivir			S	Unknown	Unk				Gilead
Increased	Clona	zepam			С		Unk				Not Reported
	Dexm	edetomidine			С		Unk				Not Reported
	Epop	rostenol			С		Unk				Not Reported
	Famo	tidine			С		Unk				Not Reported
	Fenta	nyl			С		Unk				Not Reported
	Нера	rin			С		Unk				Not Reported
	Methy	/lprednisolone			С		Unk				Not Reported
	Midaz	colam			С		Unk				Not Reported
	Tocili	zumab			С		Unk				Not Reported
	Vecui	onium			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17928219	DIRECT	Υ	(T				40 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Lacta Dehydrogenase Increased; Liver Funct Test Increased	ate	lesivir	Υ		S	Intravenous (n otherwise spec					Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17928222	DIRECT		[DΕ				68 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>

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Acute Kidney Injury; Cardiogenic Shock	Remo	desivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17928224	DIRECT	Υ		ОТ			53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remo	desivir	Υ		S	Intravenous (not otherwise specified)				Not Reported
		axone romycin			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17928230	DIRECT	Υ		HO, LT			86 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea		desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Increased	Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
		semide 80mg Po Qam opril 40mg Po Qam			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17928233	DIRECT	Υ		НО			50 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>]	<u>Wfr</u>
Bradycardia	Dexa	desivir methasone 6mg Once			S C					Gilead Not Reported
	Daily Cefe _l Iv	pime 1gm Every 24 Hours			С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Fa	acility Age	<u>Sex</u>	Country
22-Jun-2020	17928237	DIRECT	Υ					48 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	lesivir	Υ		S	Intravenous bolus				Not Reported
Increased; Therapy Interrupted	Insulii Tociliz Enoxa	vastatin n Glargine zumab aparin emide orolol			00000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Fa	acility Age	<u>Sex</u>	Country
22-Jun-2020	17928253	DIRECT	Υ	Н	0			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Culture Positive Candida Test Positive		lesivir			S	Intravenous (not otherwise specified)				Gilead
	Tociliz	zumab			S	Intravenous (not otherwise specified)				Genentech
		zumab methasone 10mg			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Fa	acility Age	<u>Sex</u>	Country
22-Jun-2020	17928265	DIRECT						67 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Liver Funct Test Increased		lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control #	503B Fa	acility Age	<u>Sex</u>	Country
22-Jun-2020	17928273	DIRECT	Υ	0	-			47 YR	Male	USA

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					Dotalloa 110	Port			
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased	Remdesivir Atorvastatin 40 Mg Ascorbic Acid 1000 Mg Po Bid Azithromycin 500 Mg Daily Ceftriaxone Enoxaparin 40 Mg Daily Iohexol Acetaminophen 650 Mg X1 Dose			8000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date Case :	<u>Case Type</u>	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020 17928	290 DIRECT	Υ	0	Т			64 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Blood	Amiodarone			С	. ,				Not Reported
Creatinine Increased;	Apixiban Piperacillin/Tazobactam			C					Not Reported Not Reported
Glomerular Filtration Rate	Fuorsemide			C					Not Reported
Decreased; Pulmonary Function Test Decreased;	Propofol			С					Not Reported
Shock	Cisatricurium			С					Not Reported
	Fentanyl Midazolam			C C					Not Reported Not Reported
	Phenylephrine			Č					Not Reported
	Dexamethasone			С					Not Reported
	Vasopressin			C C					Not Reported
	Vancomycin								Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020 17928	301 DIRECT	Υ					70 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased	Remdesivir Albuterol Nebulizer			S C					Gilead Not Reported
	Azithromycin			С					Not Reported

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							<u> </u>				
	Cefepi				С						Not Reported
	Ceftria				С						Not Reported
		nethasone			C						Not Reported
		a-Lyte-A			С						Not Reported
	Enoxa				C C						Not Reported
	Finaste				C						Not Reported
		(Long Acting, Short			С						Not Reported
		, And Infusion)									N . 5
	Linezo				С						Not Reported
	Loraze				С						Not Reported
	Olanza				C						Not Reported
	Pantop				C C						Not Reported
		/Docusate			C						Not Reported
	Tamsu				С						Not Reported
	Potass	sium Chloride			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control:	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2020	17928545	DIRECT	Υ		RI				44 YR	Male	USA
Preferred Term	Produ	ct	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	<u> </u>	Лfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remde	esivir 100 Mg			S	Intravenous bolus					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17842544	EXPEDITED (15-DAY)		1	ОТ	US-GILEAD-20 0468274)20-		34 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	<u>n</u>	<u>Mfr</u>
Anxiety; Blood Pressu Increased; Erythema; Heart Rate Increased; Hyperhidrosis; Nausea Oxygen Saturation Decreased; Respirator Rate Increased	a;	esivir			S	Intravenous (not otherwise specified)	200 Mg	, Once			Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17857266	EXPEDITED (15-DAY)				US-G 04685	LEAD-2020- 44		79 YR	Female	e USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Product Preparation Is	sue Remd	esivir			S	Unknown					Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr C	Control #	503B Facility	<u>Age</u>	Sex	Country
23-Jun-2020	17872272	EXPEDITED (15-DAY)			НО	US-G 04693	LEAD-2020- 02		46 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	Text	Duration		<u>Mfr</u>
Alanine Aminotransfer	ase Remd	esivir			S	Unknown	200 Mg	g			Gilead
Increased	Remd	esivir			S	Unknown	100 Mg	_			Gilead
	Aceta	minophen			С		Unk				Not Reported
	Albute	erol [Salbutamol]			С		Unk				Not Reported
	Azithro	omycin			С		Unk				Not Reported
	Ceftria	axone			С		Unk				Not Reported
	Dexm	edetomidine			С		Unk				Not Reported
	Dopar	mine			С		Unk				Not Reported
	Enoxa	parin			С		Unk				Not Reported
	Lanso	prazole			С		Unk				Not Reported
	Propo	fol			С		Unk				Not Reported
	Hydro	morphone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17896650	EXPEDITED (15-DAY)			DE, HO, LT,	OT US-G 04721	LEAD-2020- 97		63 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u>Text</u>	Duration		<u>Mfr</u>
Acute Kidney Injury; A Myocardial Infarction; Acute Respiratory Dist		esivir			S	Intravenous otherwise s		g, Once			Gilead

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Syndrome; Acute		rin [Acetylsalicylic			С	Unknown	81 Mg]			Not Reported
Respiratory Failure; Arrhythmia;	Peni	;Ascorbic Acid] cillin [Benzylpenicillin			С						Not Reported
Cardiomyopathy; Deat Ischaemic Hepatitis;		ssium] odarone			С	Intravenous bolus	Unk				Not Reported
Respiratory Distress	Ator	vastatin			С		Unk				Not Reported
	Atra	curium			С		Unk				Not Reported
	Cefti	riaxone			С		Unk				Not Reported
	Azith	nromycin			С		Unk				Not Reported
	Dob	utamine			С		Unk				Not Reported
	Epop	prostenol			С		Unk				Not Reported
	Fent	anyl			С		Unk				Not Reported
	Нера	arin			С		Unk				Not Reported
	Vitar	nin C [Ascorbic Acid]			С		Unk				Not Reported
	Hydr	ocortisone			С		Unk				Not Reported
	Mida	zolam			С		Unk				Not Reported
	Nore	pinephrine			С		Unk				Not Reported
	Pher	nylephrine			С		Unk				Not Reported
	Prop	ofol			С		Unk				Not Reported
	Sodi	um Bicarbonate			С		Unk				Not Reported
	Vaso	pressin			С		Unk				Not Reported
	Fam	otidine			С		Unk				Not Reported
	Thia	mine			С		Unk				Not Reported
	Insul	lin Lispro			С		Unk				Not Reported
	Meto	prolol Tartrate			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17930765	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-: 0474819	2020-		76 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Rem	desivir			S	Intravenous (not	200 N	lg, Once			Gilead

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						otherwise specified)				
	Cef	triaxone			С		Unk				Not Reported
	Asp	pirin [Acetylsalicylic Acid]			С		Unk				Not Reported
	Lov	renox [Enoxaparin Sodium]			С		Unk				Not Reported
	Fin	asteride			С		Unk				Not Reported
	Ins	ulin Lispro			С		Unk				Not Reported
	Lop	pressor			С		Unk				Not Reported
	Oxy	ycodone			С		Unk				Not Reported
	Tar	nsulosin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17930918 EXPEDITED (15-DAY) Product				DE, OT	US-GILEAD-2 0474713	020-		79 YR	Female	e USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Covid-19; Hepatic Enz	Remdesivir me				S	Intravenous (not otherwise specified		lg, Qd			Gilead
Increased; Respiratory Disorder	′ Var	ncomycin			С	·	Unk				Not Reported
Disorder	Clir	ndamycin			С		Unk				Not Reported
	Me	thylprednisolone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17930929	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0472715	020-		40 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Rei	mdesivir			S	Intravenous (not otherwise specified	Unk)				Gilead
	Lasix [Furosemide] Tocilizumab Solu-Medrol Cefepime Vancomycin Montelukast				000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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							1			
	Azii Zind End	rvastatin thromycin c Sulfate oxaparin malog			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
		ntoprazole ropenem			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control i	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17931108	EXPEDITED (15-DAY)		НС)	US-GILEAD-20 0474396	20-	27 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Maternal Exposure Du Pregnancy;	J	mdesivir			S	Intravenous (not otherwise specified)	Unk, Qd			Gilead
Transaminases Increa	Piperaciilin & razobactam				S	Unknown	Unk			Not Reported
FDA Received Date			<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	<u>Case #</u> <u>Case Type</u> 17933002 EXPEDITED (15-DAY)			DE	, OT	US-GILEAD-20 0474849	20-	67 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Death	Rer	mdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		silizumab sma			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control i	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17933440	EXPEDITED (15-DAY)		DE	•	US-GILEAD-20 0474844	20-	52 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19; Oxygen Therapy	Oxygen Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Azi	thromycin			С		Unk			Not Reported
	Bupropion				С		Unk			Not Reported



Alanine Aminotransfer Increased	ase Remo	lesivir			S						Gilead
<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>		<u>Mfr</u>
23-Jun-2020	17934307	DIRECT	Υ						46 YR	Male	USA
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
Blood Creatine Phosphokinase Increa Renal Impairment	Remo	lesivir			S						Not Reported
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>		Mfr
23-Jun-2020	17934303	DIRECT	Υ	0	Γ				73 YR	Male	USA
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Renal Impairment	Remo	lesivir			S						Not Reported
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosag	<u>le Text</u>	<u>Duration</u>		Mfr
23-Jun-2020	17934300	DIRECT	Υ	0	Γ				65 YR	Male	USA
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	Warfa Predn Albute Levac	isone erol [Salbutamol]			C C C						Not Reported Not Reported Not Reported Not Reported
	Norep	inephrine			С		Unk				Not Reported
	Propo	fol			С		Unk				Not Reported
	•	prazole			С		Unk				Not Reported
		cortisone			С		Unk Unk				Not Reported
	Fenta	axone			C C		Unk				Not Reported Not Reported
	Buspi				С		Unk				Not Reported



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	Sex	Country
23-Jun-2020	17934311	DIRECT	Y	0					69 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dos	age Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Therapy Cessation; Transaminases Increa		desivir	Υ		S	Intravenous drip)			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17934317	DIRECT	Υ	Н	0				24 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dos	age Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Cough; Dyspnoea; Live Function Test Increase		desivir, 100 Mg			S	Intravenous (no otherwise specif				1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17934320	DIRECT	Υ	D	E				81 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dos	age Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; Respiratory Acidosis	Amlo Omer Epoe Cinac Sodic Vento Allopi Azithi Ceftri Acter Norm Conv Apres Atrov	om Bicarbonate olin urinol romycin axone nra al Saline Ivf alescent Plasma soline	Y		% 000000000000000	Intravenous boli	JS			1 1 1 1 1 1 1 1 1 1	Gilead Not Reported

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ADIVI	INISTRA	1101				Detailed R	eport			
		r			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17934326	DIRECT	Υ					54 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Dialysis; Respiratory Failure	Chlori Omep Aceta Fenta Midaz Hepa Propo	colam rin fol oinephrine			800000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17934330	DIRECT	Υ	DE				73 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hospice Care	Cefep Chlori Famo Hepa Insulii Metro Mupir Potas Vanco Norep	hexidine Topical tidine	Y		s	Intravenous bolus	Other Frequency:Once;			Gilead Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	1793433	5 DIRECT	Y					52 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Therapy Interrupted; Transaminases Increa		Remdesivir Injection	Y		S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	1793434	0 DIRECT	Υ	1	ОТ			74 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer Increased; Aspartate	ase	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg	ιX	Gil	ead
Aminotransferase ncreased; Blood Biliru	ihin	Acetaminophen 650mg Po Q Prn	6h		С	. ,	, , ,		No	t Reported
ncreased; Blood Creatinine Increased;		Albumin 5% 12.5g Iv Once			С					t Reported
Device Occlusion; Fac		Amlodipine 10mg Po Daily			С					t Reported
Dedema; Haemodialy:	oio.	Aspirin Chew 81mg Po Daily Atorvastatin 20mg Po Qhs			C C					t Reported t Reported
nternational Normalis	ea	Azithromycin 500mg Iv Daily			C					t Reported
Ratio Increased; Oxyg		Cefepime 1g Iv Q24h			Č					t Reported
Saturation Abnormal;		Dexamethasone 6mg lv Q24l	า		C					t Reported
enal Impairment; herapy Interrupted		Enoxaparin 30mg Subq Q12h			С					t Reported
nerapy interrupted		Enoxaparin 40mg Subq Q24h	1		С					t Reported
		Fentanyl Infusion			С					t Reported
		Furosemide 40mg And 80mg	IV		С					t Reported
		Heparin 7500 Units Q8h Hydrochlorothiazide 12.5mg	20		C C					t Reported t Reported
		ajurochiorothiazide iz.amg i Daily	U		C				INO	rivehorien
		_antus Subq Qhs			С				No	t Reported
		nsulin Lispro Sliding Scale			Č					t Reported
		5x/Day			•					. 5
		_evothyroxine 88mcg Po Dail	У		С				No	t Reported



							Detailed Ne	port			
		Propofol Ir Midazolam Norepinep Pip/Tazo				C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	179343	69 E	DIRECT	Y	0	Γ			29 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Hepatic	rase	Remdesiv	ir			S	Intravenous (not otherwise specified))			Gilead
Enzyme Increased; Therapy Interrupted			e 2 Grams Q24 ne 100 Mg Bid			C C	,	,			Not Reported Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	179343	375 E	DIRECT	Υ					26 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted		Remdesiv	ir Injection			S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	9	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	179343	91 [DIRECT	Y					56 YR	Male	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase		Remdesiv	ir	Υ		S	Intravenous (not otherwise specified))	2 DAY		Gilead
Increased; Blood Crea Increased; Dyspnoea; Glomerular Filtration F Decreased; Sars-Cov- Test Positive; Septic Shock	Rate	Atracurium Senna/Col Enoxapari Famotidine Lispro Insu Oxycodon Piperacillir Vancomyo	lace n e ulin e n/Tazobactam			00000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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	Midaz Norep Propo	omorphone colam oinephrine			C C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17934397	DIRECT	Υ	I	DE			72 YR	Fema	le USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia; Disease Progression; Pneumonia; Respiratory Failure; Respiratory Failure; Sars-Cov-2 To Positive	•	lesivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17934404	DIRECT	Υ	(ТС			46 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cough; Sedation;	Remo	lesivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Wheezing	Remo	lesivir			S	Intravenous bolus				Gilead
	Famo Azithr Ceftri Dexa Piper Aceta	omycin axone methasone acillin-Tazobactam minophen enhydramine ofol			000000000000000000000000000000000000000					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# <u>503B Faci</u>	lity Age	<u>Sex</u>	Country
23-Jun-2020	17934408	DIRECT	Υ	0	Т			71 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Rash	Remo	desivir Injection			S	Intravenous (not otherwise specifie	d)			Gilead
	Enoxi Panto Prepa Tocili Vanco	cillin-Sulbactam aparin oprazole aration H Cream zumab omycin ssium Chloride			000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# <u>503B Faci</u>	lity Age	<u>Sex</u>	Country
23-Jun-2020	17934411	DIRECT	Υ	DI	Ε			80 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Refusal Of Treatment Patient; Refusal Of Treatment By Relative	Ceflri	desivir axone cycli Ne			S C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# <u>503B Faci</u>	lity Age	<u>Sex</u>	Country
23-Jun-2020	17934416	DIRECT	Υ	DI	Ε			78 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	desivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u> 503B Faci</u>	<u>lity</u> <u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	17934422	DIRECT	Υ	0	Т			71 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir			S					Not Reported

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FDA Received Date	Case #	<u>Case Type</u>	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	179344	50 DIRECT	Υ	0	Т			83 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation		Remdesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	179344	68 DIRECT	Υ	D	E			66 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Death; Sars-Cov-2 Tes Positive	st	Remdesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2020	179344	75 DIRECT	Υ	D	E			84 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Bradycardia; Cardio- Respiratory Arrest;		Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Haemodynamic Instab Pulseless Electrical Activity	oility;	Convalescent Plasma Hydroxychloroquine 400 Mg Po Azithromycin 500 Mg Iv X 1 Azithromycin 250 Mg Po Once			C C C	outor wide appointed)				Not Reported Not Reported Not Reported Not Reported
		Daily Ceftriaxone 1 Gm Iv Once Dail Methyprednisolone 40 Mg Iv Q12hr	y		C C					Not Reported Not Reported
		Thiamine 100 Mg Po Bid Zinc Sulfate 220 Mg Po Once Daily			C C					Not Reported Not Reported
		Vasopressin Iv 20 Units/MI Enoxaparin 70 Mg Sq Q12hr Enoxaparin 70 Mg Sq Once Daily			C C C					Not Reported Not Reported Not Reported

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	Asc	epime 1 Gm Iv orbic Acid 1500 Mg Iv Q6hr orbic Acid 1500 Po Once			CCC						Not Reported Not Reported Not Reported
	Dail	y rvastatin 80 Mg Po Once			С						Not Reported
	Ami Ami	odarone 450 Mg Iv Infusion odarone 200 Mg Po Once			C C						Not Reported Not Reported
	B-1: Dilti	y irin 81 Mg Po Once Daily 2 1000 Mcg Sq Once Daily azem 100 Mg Iv Infusion azem 30 Mg Po Q8hr			C C C						Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17848032	EXPEDITED (15-DAY)			ОТ	US-GILE/ 0468530	ND-2020-		57 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Bilirubin Conjugated		ndesivir			S	Unknown	Unk				Gilead
Increased; Transamina Increased	Enc Fen Gab Hyd Insu Insu Keta Lora Nor Oxy Pan Poly	cusate exaparin exaparin exaparin exapentin exapentin exapentin exitorial substitution examine			000000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17873054	EXPEDITED (15-DAY)			DE, OT	US-GILE/ 0470425	ND-2020-		45 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration		Mfr

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Blood Creatinine

Remdesivir

Intravenous (not otherwise specified)

S

100 Mg, Qd

Gilead

Increased; Cardiac Arrest; Hypoxia; Respiratory Failure; Vomiting

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17881349	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0470063	20-	60 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Ren	ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Preparation Error	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Ace	taminophen			С		Unk			Not Reported
	Bisa	acodyl			С		Unk			Not Reported
	Chlo	orhexidine			С	Oral	Unk, Bid			Not Reported
	Rob	itussin Dm			С		Unk			Not Reported
	Hep	parin			С		Unk			Not Reported
	Mela	atonin			С		Unk			Not Reported
	Mer	nthol [Levomenthol]			С		Unk			Not Reported
	Met	hocarbamol			С		Unk			Not Reported
	Sali	gay [Menthol;Methyl cylate]			С		Unk			Not Reported
		u-Medrol			С		Unk			Not Reported
		troban [Mupirocin]			С		Unk			Not Reported
	Zofr	an [Ondansetron]			С		Unk			Not Reported
	Pan	toprazole			С		Unk			Not Reported
	Mira	alax			С		Unk			Not Reported
	Ns				С		Unk			Not Reported
		papentin cycycline			C C		Unk			Not Reported Not Reported
	Ceff	triaxone			С		Unk			Not Reported



						Detailed No	port				
	Potass	ium Chloride			С		Unk				Not Reported
	Conval	escent Plasma			С		Unk				Not Reported
	Cymbalta Neurontin Robaxin Lasix [Furosemide] Eliquis				C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17890267	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0470430	020-		50 YR	Female	e USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Device Connection Iss Drug Monitoring Procedure Incorrectly Performed	ue; Remde	sivir			S	Intravenous (not otherwise specified	100 M)	g, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17892602	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0470906	020-		74 YR	Male	USA
Preferred Term	Produ	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Mouth	Remde	sivir			S	Intravenous (not otherwise specified		g, Once			Gilead
Haemorrhage; Respira Failure; Urine Output Decreased	^{itory} Remde	sivir			S	Intravenous (not otherwise specified	100 M)	g, Qd			Gilead
	Remde Plasma				S C		Unk				Gilead Not Reported
	Tocilizu	ımab			С		Unk				Not Reported
	Heparii	ı			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17914726	EXPEDITED (15-DAY)		0	т	US-GILEAD-20 0473031	020-		54 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		Mfr

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Acute Kidney Injury; Aspartate	Rem	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Aminotransferase	Rem	desivir			S	,				Gilead
ncreased; Blood Bilirubi	n Succ	inylcholine Bromide			Č					Not Reported
Increased; Disseminated	j Fent				Č					Not Reported
Intravascular Coagulatio		pinephrine			Č					Not Reported
Shock		racurium			Č					Not Reported
	Prop				Č					Not Reported
	Keta				Č					Not Reported
		romycin			C					Not Reported
		iaxone			C					Not Reported
		rostenol			C					Not Reported
		otidine			C					
					C					Not Reported
	Hepa				С					Not Reported
		in Lispro			С					Not Reported
		omycin			С					Not Reported
		in Regular Hm			С					Not Reported
	Mida	zolam			С		Unk			Not Reported
FDA Received Date (Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020 1	7932085	EXPEDITED (15-DAY)		0	Т	US-GILEAD-202 0472177	20-		Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Chills; Dyspnoea; Hypertension; Oxygen Saturation Decreased; Respiratory Distress	Rem	desivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
FDA Received Date (Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020 1	7935081	DIRECT	Υ	Н	0			21 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferas Increased	se Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
	Dexa	ımethasone			С	,				Not Reported
		fenesin			Č					Not Reported



	Hydro	codone-Chlorpheniramine			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17935114	DIRECT	Υ					52 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Extra Dose Administer	ed Remd	esivir Injection			S	Intravenous drip		30 MIN		Gilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17935120	DIRECT	Y	ОТ	-			55 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
	Das18	1			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17936231	DIRECT	Y	DE				72 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Hypoxia; Respiratory Failure	Remd	esivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17936237	DIRECT	Y	ТО	-			53 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remd	esivir			S	Intravenous (not otherwise specified)		9 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	itcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17936244	DIRECT	Υ					48 YR	Male	USA

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Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Bilirubin Increase	ed Ren	ndesivir	Υ		S	Intravenous (not otherwise specified	Other Frequency:Once;			Gilead
	Ren	ndesivir	Υ		S	Intravenous (not otherwise specified)			Gilead
	Chlo Dex Fam Furc Hep Insu Met Ocu Fen Noro Prop Roc	ilin oprolol lar Lubricant (Artificial Te tanyl epinephrine pofol uronium	ars)		0000000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control	# 503B Facility	Age	Sex	Not Reported Country
	17936250	DIRECT	Y	ŀ	Ю		-	79 YR	Male	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Cefe Line Dex	ndesivir 100 Mg/20ml epime 1000 Mg ezolid 600 Mg amethasone 20 Mg ilizumab 600 Mg	Y		S C C C	Intravenous drip				Gilead Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17936256	DIRECT	Υ					88 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ise Ren	ndesivir			S	Intravenous (not otherwise specified)			Not Reported

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						Dotalloa IX	оролс				
Aminotransferase Increased	Pip Fei	ncomycin eracillin/Tazobactam ntanyl xamethasone			C C C						Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17936262	DIRECT	Υ						64 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; E Creatinine Increased; Glomerular Filtration F Increased; Haemodial Respiratory Failure	Rate Atr lysis; Far He Lis Po Se Hy No	mdesivir acurium oxaparin motidine parin pro yethylene Glycol nna-Docusate dromorphone repinephrine opofol etaminophen	Y		\$ 0000000000	Intravenous bolus			8 DAY		Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17938926	EXPEDITED (15-DAY	")		ОТ	US-GILEAD-2 0472220	2020-		70 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	Duration		Mfr
Hypotension; Hypotension; Supraventricular Extrasystoles; Ventric Tachycardia		mdesivir			S	Unknown	Unk				Gilead
	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	Case #	<u>oasc rypc</u>									
FDA Received Date 24-Jun-2020	17940295	EXPEDITED (15-DAY	T)		НО	US-GILEAD-2 0474225	2020-		29 YR	Male	USA



Alanine Aminotransfera	ase Remo	desivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u># 5031</u>	B Facility Ag	<u>e</u>	<u>Sex</u>	Country
24-Jun-2020	17940954	DIRECT	Υ	(ТС			81	YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Du</u>	<u>ration</u>	!	Mfr_
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased	Inject Amlo Azith Ceftr Doxy Hepa Insuli Insuli Latar Metro Piper Polye	dipine romycin axone cycline	Y <u>Health</u>	Prof (S C C C C C C C C C	Intravenous bolus	# <u>503</u> 1	B Facility Ag	<u>e</u>		Gilead Not Reported Country
24-Jun-2020	17940981	DIRECT	Υ	I	DE			82	YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Du</u>	<u>ration</u>]	<u>Mfr</u>
Death		desivir			S	Intravenous (not otherwise specified)				Gilead
		alescent Plasma methasone			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u># 5031</u>	B Facility Ag	<u>e</u>	<u>Sex</u>	Country
24-Jun-2020	17940998	DIRECT	Υ	I	DE			36	YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Du</u>	<u>ration</u>]	<u>Mfr</u>
Cardiac Arrest; Hypoxi Respiratory Acidosis	ia; Remo	desivir			S	Intravenous (not otherwise specified)				Gilead

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25 YR Duration Age 36 YR	Male Sex Female	Mfr Gilead Not Reported
		Mfr Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
		Mfr Gilead Not Reported Not Reported
		<u>Mfr</u>
25 YR	Male	USA
<u>Age</u>	<u>Sex</u>	Country
		Not Reported Not Reported
		Not Reported
		Not Reported
		Not Reported Not Reported
		Not Reported
		Not Reported
		Not Reported Not Reported
		Not Reported
		Not Reported
		Not Reported Not Reported
		Not Reported
		Not Reported
		Not Reported
		Not Reported
		Not Reported Not Reported
	Age	Age <u>Sex</u>

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Dyspnoea; Platelet Co Increased	unt Re	mdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;			Gilead
		etaminophen 325mg Po Q6h	า		С					Not Reported
		in 1-3, Fever nzonatate 100-200mg Po Q	3h		С					Not Reported
		oxaparin 30mg Subq Q12h			С					Not Reported
	Ke 4-6	torolac 15mg Iv Q6h Prn Pai	in		С					Not Reported
		elatonin 6mg Po Qhs Prn			С					Not Reported
		thylprednisolone 30mg lv			С					Not Reported
		thylprednisolone 30mg lv			С					Not Reported
		2h omethazine-Codeine 25/10/5ml Po Q4h Prn			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941055	DIRECT		C	T			69 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed Re	mdesivir			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941061	DIRECT	Υ	(T			24 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Re	mdesivir			S	Intravenous (not otherwise specified)				Gilead
	То	ciluzumab			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941070	DIRECT	Υ	(T			77 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



						Dotalloa 110	port			
Alanine Aminotransferas ncreased; Aspartate	se l	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase	ı	Doxycycline			С	ou.o.moo opoomou)				Not Reported
ncreased		Amlopine			C					Not Reported
		Carvedilol			C					Not Reported
		Famsulosin			C					
					C					Not Reported
		Aspirin			C					Not Reported Not Reported
		Enoxaparin			C					
		Methylprednisolone Prednisone			C					Not Reported
	-									Not Reported
		Atorvastatin			C C					Not Reported
		Quetiapine								Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	1794108	0 DIRECT	Y		LT			55 YR	Male	USA
Preferred Term	ļ	Product	Comp.	<u>отс</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Oxygen	ı	Remdesivir			S	Intravenous bolus				Gilead
Saturation Decreased		Buspirone Midazolam			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	1794108	8 DIRECT	Υ		DE, LT			56 YR	Male	USA
Preferred Term	!	<u>Product</u>	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Distre	ess l	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;			Gilead
Creatinine Increased;	. /	Acetaminophen 325mg Pr Q4h	า		С					Not Reported
Slomerular Filtration Ra	ite	Albumin 25g Iv Q6h			С					Not Reported
creased; Hypotension	;	Azithromycin 500mg Iv Q24h			С					Not Reported
lypoxia; Right Ventricul		Senokot-S 8.6/50mg 2 Tabs Q	hs		С					Not Reported
ailure		Ceftriaxone 1g ly Daily			С					Not Reported
	(Cisatracurium 10mg Iv Q1h Pr /ent Synchrony	n		Ċ					Not Reported
	1	Enoxaparin 30mg Subq Q12h			С					Not Reported
	1	Epinephrine Infusion			С					Not Reported
	I	Epoprostenol Continuous Neb			С					Not Reported



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

		Folic Ad Heparir Duonek Linezol Midazo Mvi Wit Norepir Pantop Phenyk Pip/Taz	id 600mg Iv Q12h Iam Infusion In Minerals Dephrine Infusion Prazole 40mg Iv Q24h Dephrine Infusion			000000000000					Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	179410	097	DIRECT	Υ	(T			69 YR	Male	USA
Preferred Term		Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Covid-19; Fibrin D Dimer Increas Hypercalcaemia; Hypercalcaemia; Pneumo Renal Failure; Tachycardia; Tachypn	sed; oxia; onia;	Aspirin Atorvas Azithro Ceftriax Carved Dexam Preced Enoxap Famotic Fentan Insulin 4x/Day Midazo Nicardi Norepir Propofo Amioda	n 12.5-25 Grams Iv Ec 81mg Daily statin 40mg Qhs mycin 500mg Iv Q24h cone 1g Iv Daily ilol 6.25mg Po Bid ethasone 6mg Iv Daily ex Infusion parin 40mg Daily dine 20mg Iv Q12h yl Infusion Lispro Sliding Scale			s 000000000000 000000	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;			Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	179411	08 DIRECT	Υ		ОТ			54 YR	Female	USA
Preferred Term		Product	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Platelet Count Increas	sed	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;			Gilead
		Acetaminophen 650mg Po Q6h Pain 1-3, Fever			С	, ,	, , ,			Not Reported
		Azithromycin 500mg Iv Daily Ceftriaxone 1g Iv Daily Dexamethasone 6mg Po Daily Enoxaparin 40mg Qhs And			C C C					Not Reported Not Reported Not Reported Not Reported
		30mg Bid Robitussin Dm 5ml Po Q4h Prn			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	179411	15 DIRECT	Υ		НО			30 YR	Female	USA
Preferred Term		Product	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased;		Remdesivir Injection 100mg/20ml (5mg/Ml)	Υ		S	Intravenous drip	Other Frequency:Once;	1 DAY		Unknown
Nephropathy Toxic; Ro Impairment		Tocilizumab Injections	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY		Not Reported
		Mucomyst 20%			С					Not Reported
		Maalox Plus Abscorbic Acid 500mg Tablet			C C					Not Reported Not Reported
		Aspirin 81mg			Č					Not Reported
		Atorvastatin 40mg Tablet			Ċ					Not Reported
		Chlorhexidine Oral Rinse			С					Not Reported
		Dexamethasone 5mg lv			С					Not Reported
		Enoxparin 35mg Sq Etomidate 16mg Iv			C C					Not Reported Not Reported
		Famotidine 20mg Iv			C					Not Reported
		Melatonin 10mg Po			Č					Not Reported
		Zosyn 3.75mg lv			С					Not Reported
		Rocuronium 70mg Iv			С					Not Reported
		Vancomycin 1250mg Iv			С					Not Reported



		Zinc 220mg Tocilizumab Injections			C S					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	179411	56 DIRECT	Y		ОТ			60 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Respiratory Fail		Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;			Gilead
Increased; Hypoxia; Oxygen Saturation		Acetaminophen 325mg Po Q6h Prn Pain 1-3			С	,	, , ,			Not Reported
Decreased; Pneumoni Sars-Cov-2 Test Positi		Azithromycin 500mg Iv Daily			С					Not Reported
Odi 3 OOV 2 103(1 03)(1		Ceftriaxone 1g lv Daily			С					Not Reported
		Dexamethasone 6mg lv/Po Daily	1		C C					Not Reported
		Precedex Infusion Diltiazem Infusion			C					Not Reported Not Reported
		Enoxaparin 30mg Q12h Or			C					Not Reported
		40mg Q24h Famotidine 20mg Iv Q12h			С					Not Reported
		Fentanyl Infusion			C C					Not Reported
		Furosemide			C					Not Reported
		Hydralazine 20mg Iv Q4h Prn Lantus Qhs			C					Not Reported
		Insulin Lispro Sliding Scale 4x/D								Not Reported Not Reported
		Norepinephrine Infusion			C C					Not Reported
		Pip/Tazo			C					Not Reported
		Propofol Infusion			Č					Not Reported
		Tocilizumab 400mg Iv Once			Č					Not Reported
		Vecuronium 10mg Iv Q1h Prn Vent Dyssynchrony			Ċ					Not Reported
		Verit Dyssynchrony Vit C 1500mg Q6h, B1 200mg Iv Q12h			С					Not Reported
		Zinc Sulfate 220mg Po Daily			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	179412	56 DIRECT	Υ		DE			61 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



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Hypotension; Oxygen Saturation Decreased;		ndesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg D1, 100mg/D;			Gilead
Pulse Absent		aminophen 650mg Po Q4h Pain 1-3, Fever			С	, ,				Not Reported
		rin Ec 81mg Daily			С					Not Reported
		vastatin 20mg Qhs			Č					Not Reported
		nromycin 500mg Iv Q24h			Č					Not Reported
		pime 1g Iv Q6h			C C					Not Reported
		riaxone 1g Iv Q24h			С					Not Reported
		amethasone 6mg Po Daily			С					Not Reported
	Pred	edex Infusion			С					Not Reported
	Eno	xaparin 40mg Subq Daily			С					Not Reported
		ephrine Infusion			С					Not Reported
		prostenol Continuous Neb			С					Not Reported
		otidine 20mg Iv Q12h			C C					Not Reported
		us 25-30 Units Qhs			C					Not Reported
		lin Lispro Sliding Scale 4x/D			С					Not Reported
		oclopramide 10mg +			С					Not Reported
	Meto	enhydramine 25mg Iv Q6h oprolol 5mg Iv Q4h Prn Sbp 0 Or Hr>100			С					Not Reported
	Toci Vitar	lizumab 400mg Iv Once min C 1g Q12h, Zinc Omg Po Q12h			C C					Not Reported Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941265	DIRECT	Υ		ОТ			42 YR	Female	USA
Preferred Term	Prod	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Heart Rate Decreased Hypotension	l; Rem	ndesivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941275	DIRECT	Υ		ОТ			72 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Rem	ndesivir	Υ		S	Intravenous drip				Gilead



FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941286	DIRECT	Υ		ОТ			59 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Re	mdesivir	Y		S	Intravenous bolus	Other Frequency:200 Once,100x4days;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2020	17941803	DIRECT	Υ		ОТ			50 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Re	mdesivir 100mg			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17818496	EXPEDITED (15-DAY)			DE, LT, OT	US-GILEAD-20 0468321	20-	72 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	Duration		Mfr
Acidosis; Acute Kidney Injury; Acute Respirato	ory	mdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Distress Syndrome; Co 19 Pneumonia; Hypernatraemia; Rena	Ke	mdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Impairment	End	oxaparin [Enoxaparin Sodium]	1		С		100 Mg			Not Reported
	Ins	ulin			С		Unk			Not Reported
	Me	thylprednisolone			С		Unk			Not Reported
	Lor	razepam			С		Unk			Not Reported
	Lev	ophed .			С		Unk			Not Reported
	Do	pamine			С		Unk			Not Reported
	Epi	inephrine Hydrochloride			С		Unk			Not Reported

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	Phe	enylephrine			С		Unk			Not Reported
	Epo	prostenol			С		Unk			Not Reported
	Var	ncomycin			С		Unk			Not Reported
	Pip	eracillin/Tazobactam			С		Unk			Not Reported
	Нер	parin			С		Unk			Not Reported
	Am	iodarone			С		Unk			Not Reported
		amine [Ketamine drochloride]			С		Unk			Not Reported
	Moi	rphine			С		Unk			Not Reported
	Roo	curonium			С		Unk			Not Reported
	Too	cilizumab			С	Intravenous (not otherwise specified)	800 Mg			Not Reported
	Soc	dium Bicarbonate			С		Unk			Not Reported
	Vas	sopressin			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
							ooob i domey			
	17881950	EXPEDITED (15-DAY)			E, OT	US-GILEAD-20: 0470915	_	70 YR	Male	USA
25-Jun-2020	17881950		Comp.			US-GILEAD-202 0470915	_			-
25-Jun-2020 Preferred Term	17881950	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-202 0470915	20-	70 YR		USA
25-Jun-2020 Preferred Term	17881950 Pro	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-202 0470915 Route Intravenous (not	20- Dosage Text	70 YR		USA Mfr
25-Jun-2020 Preferred Term	17881950 Pro	EXPEDITED (15-DAY) oduct mdesivir razolam		D	Role S	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd	70 YR		USA Mfr Gilead
25-Jun-2020 Preferred Term	17881950 Pro rest Rer Alp	EXPEDITED (15-DAY) oduct mdesivir razolam		D	Role S C	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd Unk	70 YR		USA Mfr Gilead Not Reported
25-Jun-2020 Preferred Term	17881950 Protest Rer Alpi	EXPEDITED (15-DAY) oduct mdesivir razolam ulin		D	Role S C C	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd Unk Unk	70 YR		USA Mfr Gilead Not Reported Not Reported
25-Jun-2020 Preferred Term	17881950 Pro rest Rer Alpi Insu Cef Vita	EXPEDITED (15-DAY) Deduct modesivir razolam ulin ftriaxone		D	Role S C C C	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd Unk Unk Unk Unk	70 YR		USA Mfr Gilead Not Reported Not Reported Not Reported
25-Jun-2020 Preferred Term	17881950 Protest Rer Alpi Insu Cef Vita Ond	EXPEDITED (15-DAY) coduct mdesivir razolam ulin triaxone amin E [Tocopherol]		D	Role S C C C C	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd Unk Unk Unk Unk Unk Unk	70 YR		USA Mfr Gilead Not Reported Not Reported Not Reported Not Reported Not Reported
25-Jun-2020 Preferred Term	17881950 Pro rest Rer Alpi Insu Cef Vita Onc Azit	EXPEDITED (15-DAY) oduct mdesivir razolam ulin triaxone amin E [Tocopherol] dansetron		D	Role S C C C C	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd Unk Unk Unk Unk Unk Unk Unk Un	70 YR		USA Mfr Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
25-Jun-2020 Preferred Term Cardio-Respiratory Ari	17881950 Pro rest Rer Alpi Insu Cef Vita Onc Azit	EXPEDITED (15-DAY) Deduct modesivir razolam ulin triaxone amin E [Tocopherol] dansetron thromycin sscar		D	Role S C C C C C	US-GILEAD-202 0470915 Route Intravenous (not	Dosage Text 200 Mg, Qd Unk Unk Unk Unk Unk Unk Unk Un	70 YR		USA Mfr Gilead Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17882692	EXPEDITED (15-DAY)		C	T	US-GILEAD-20 0469672)20-	54 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Ro	emdesivir			S	Intravenous (not otherwise specified	200 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17892599	EXPEDITED (15-DAY)		C	T	US-GILEAD-20 0470904	020-	72 YR	Female	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased;		emdesivir			S	Intravenous (not otherwise specified	200 Mg, Once			Gilead
Cerebrovascular Accid	dent; Ro	emdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd			Gilead
Consciousness; Hemiparesis		emdesivir asma			S C	Carlot mod opcomod	Unk			Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17923215	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0473789	020-	68 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased; Death	ase Ro	emdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd			Gilead
	At De Er	spirin (E.C.) torvastatin extromethorphan noxaparin			0000					Not Reported Not Reported Not Reported Not Reported
	Ad La	abapentin cetaminophen actulose agnesium Oxide			C C C					Not Reported Not Reported Not Reported Not Reported
	Co	ompazine [Prochlorperazine aleate]			Ċ					Not Reported

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	Cisa	atracurium			С				No	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17925226	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0473427)20-	74 YR	Female	USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Blood Creatinine Increased; Death;		ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gi	lead
Glomerular Filtration R Decreased	Rate Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gi	lead
FDA Received Date	Cefe Eno Epo Fen Hep Lan Insu Leve Mida Nore Pipe Proj Sod	ulin Lispro othyroxine azolam epinephrine eracillin/Tazobactam pofol lium Bicarbonate Case Type	Health		C C C C C C C C C C C	Mfr Control a		Age	No No No No No No No No No No No No No N	ot Reported
25-Jun-2020	17940248	EXPEDITED (15-DAY)			T, OT	US-SA-2020S <i>A</i>			Unknown	USA
Preferred Term	<u>Pro</u>	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfı	
Acute Kidney Injury;		enox			S	Subcutaneous	80 Mg			nofi
Bradycardia; Cytokine Storm; Disseminated	Ren	ndesivir			S	Unknown	Unk		No	ot Reported
Intravascular Coagulat	· - ,	tanyl			С		Unk		No	ot Reported
Haemoglobin Decreas Hyperglycaemia;	sed; Dulo	oxetine			С		Unk		No	ot Reported
Hyperkalaemia;	Gab	papentin			С		Unk		No	ot Reported
Hypotension; Iron Deficiency; Lactic	Met	oprolol			С		Unk		No	ot Reported

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Acidosis; Liver Injury;	N	/lidazolam			С		Unk				Not Reported
Pneumonia;		evetiracetam			С		Unk				Not Reported
Retroperitoneal Haematoma; Septic		Pantoprazole			С		Unk				Not Reported
Shock; Shock	P	Propofol			С		Unk				Not Reported
Haemorrhagic; Swellin	าต	Otezla			С		Unk				Not Reported
		ocilizumab			С		Unk				Not Reported
	V	/ancomycin			С		Unk				Not Reported
		urosemide			С		Unk				Not Reported
	C	Ceftriaxone			С		Unk				Not Reported
	F	errous Sulfate			С		Unk				Not Reported
	N	Methylprednisolone			С		Unk				Not Reported
	F	Polyethylene Glycol [Macrogol]			С		Unk				Not Reported
	C	Cefepime			С		Unk				Not Reported
	Д	ativan			С		Unk				Not Reported
		Oocusate;Senna			С		Unk				Not Reported
	L	actulose			С		Unk				Not Reported
	N	licotine			С		Unk				Not Reported
		Duoneb			С		Unk				Not Reported
	S	Suboxone			С		Unk				Not Reported
	C	Chlorhexidine			С		Unk				Not Reported
	А	zithromycin			С		Unk				Not Reported
	Д	cetaminophen			С		Unk				Not Reported
		Dextromethorphan			С		Unk				Not Reported
	N	Meropenem			С						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	1794264	6 DIRECT	Υ	С	T				85 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	rase R	Remdesivir			S	Intravenous (not					Not Reported

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Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased;

otherwise specified)

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17942947	DIRECT	Υ	(DΤ			58 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Li Function Test Increase Therapy Cessation		lesivir			S				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17942953	DIRECT	Υ	(TO			81 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dyspnoea; Therapy Cessation	Remo	lesivir	Y		S	Intravenous bolus	Other Frequency:One Time;		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u> Dutcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17942965	DIRECT	Υ					64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Remo	lesivir Injection	Υ		S				Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17942969	DIRECT	Υ	L	T, OT			76 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	

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Disease Progression; Hepatic Function		desivir			S	Intravenous (not otherwise specified)			Gilead
Abnormal; Hypotension	n; Aceta	minophen			С	•				Not Reported
Multiple Organ	Δlhut	•			Č					Not Reported
Dysfunction Syndrome	, Amio	darone			С					Not Reported
Renal Impairment;	Aspir				С					Not Reported
Tachycardia		astatin			С					Not Reported
	Azith	romycin			С					Not Reported
		sate Sodium			С					Not Reported
	Ephir	ephrine			С					Not Reported
	Famo	otidine			С					Not Reported
	Fenta	nyl			С					Not Reported
		semide			С					Not Reported
	Guaif	enesin			С					Not Reported
	Hepa	rin			С					Not Reported
	Humi	ılin N			С					Not Reported
	Humi	ılin R			C C					Not Reported
	Atrov	ent Hfa			С					Not Reported
	Lactu	lose			С					Not Reported
	Melat	onin			С					Not Reported
		penem			С					Not Reported
	Meth	ylprednisolone			С					Not Reported
	Mida	zolam			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17942976	DIRECT	Υ	0	Γ			72 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypertension; Rash	Remo	desivir	Υ		S	Intravenous drip	Other Frequency:Once;			Not Reported
Erythematous; Rash Papular; Tachycardia	Effex Mirta	romycin 250 Mg or 150 Mg zapine 45 Mg axone 2g			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17943053	DIRECT	Υ	H)			47 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



Intestinal Perforation	Remd	esivir			S	Intravenous (not otherwise specifie	ed)				Gilead
	Tociliz	zumab			S	Intravenous (not otherwise specifie		Frequency:Once;			Genentech
	Ceftria	axone			С	•	,				Not Reported
		omycin			С						Not Reported
		/lprednisolone			C C						Not Reported Not Reported
	Enoxa	•									·
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17946669	EXPEDITED (15-DAY)			DE, OT	US-GILEAD- 0475647	-2020-		68 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTO	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Unknown	200 N	∕lg, Qd			Gilead
	Remd	esivir			S	Unknown	100 L	•			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17946844	EXPEDITED (15-DAY)			DE, OT	US-GILEAD- 0475654	-2020-		51 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Unknown	200 N	/lg, Qd			Gilead
	Remd	esivir			S	Unknown	100 N	/lg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17946943	EXPEDITED (15-DAY)			DE, OT	US-GILEAD- 0475655	-2020-		47 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Unknown	200 N	∕lg, Qd			Gilead
	Remd	esivir			S	Unknown		/lg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro		503B Facility	Age	<u>Sex</u>	Country
25-Jun-2020	17947072	DIRECT	Υ		DE				85 YR	Female	USA
20 0011 2020	11071012	DINEOT	•		D_L				00 110	i ciliale	JUA

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Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Hypotension; Respirato	ry Ren	ndesivir			S	Intravenous drip				Gilead
Rate Increased		amethasone notidine			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17947079	DIRECT	Υ		ОТ			89 YR	Female	e USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	se Ren	ndesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Aminotransferase Increased; Therapy Cessation	Azit	vastatin 40 Mg hromycin 500 Mg Iv			C C					Not Reported Not Reported
Cessation		lecalciferol 4000 lu amethasone 5 Mg Iv			C C					Not Reported Not Reported
		c Acid 1 Mg			C					Not Reported
		osemide 40 Mg Iv Once			Č					Not Reported
		toprazole 40 Mg Iv			C					Not Reported
		eracillin-Tazobactam 2.25 G			С					Not Reported
	Sele	enium 200 Mcg			С					Not Reported
	Thia	amine 250 Mg			С					Not Reported
		min E 1000 lu			С					Not Reported
		Sulfate			С					Not Reported
		medetomidine Infusion 400 100 MI			С					Not Reported
	Hep 500	arin Infusion 25000 Units/			С					Not Reported
		epinephrine Infusion 16 Mg/			С					Not Reported
	Asc	orbic Acid 1000 Mg irin 81 Mg			C C					Not Reported Not Reported
							" TOOD T !!!!			·
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17947091	DIRECT	Υ		ОТ			86 YR	Male	USA
Preferred Term	Pro	duct	Comp.	отс	Role	Route	Dosage Text	Duration		Mfr

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							I			
Alanine Aminotransfera Increased; Aspartate	ase I	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Aminotransferase	(Ceftriaxone			С	,				Not Reported
ncreased; Therapy Cessation		Amiodarone			С					Not Reported
Cessalion		Apixaban			С					Not Reported
		Dexamethasone			Ç					Not Reported
	,	Azithromycin			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	1794713	6 DIRECT	Υ		ОТ			85 YR	Female	e USA
Preferred Term	1	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Neutrophil Count Decreased; Platelet Co	ount	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Decreased; White Bloo Cell Count Decreased	,	Atorvastatin			С					Not Reported
Cell Count Decreased		Carvedilol			С					Not Reported
		Citalopram			C					Not Reported
		Dexamethasone 6mg			С					Not Reported
		Diltiazem			С					Not Reported
		Doxycycline			С					Not Reported
		nsulin Glargine Enoxaparin			C C					Not Reported Not Reported
		nsulin Lispro			C					Not Reported
		Pantoprazole			C					Not Reported
		Narfarin			Č					Not Reported
		Acetaminophen			Č					Not Reported
		Ondansetron			č					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	1794714	7 DIRECT	Υ		DE			71 YR	Male	USA
Preferred Term	1	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	I	Remdesivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	1794715	4 DIRECT	Υ		DE			51 YR	Male	USA

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						Dotalioa i	(opoit				
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		Mfr
Death	Remd	esivir			S	Intravenous bolu	S				Gilead
	Aspirii Atorva Cefep Dexar Famoi Flucor Metroi	darone 150 Mg Iv n 81 Mg astatin 80 Mg ime 2 Gm Iv nethasone 10 Mg Iv tidine 20 Mg Iv nazole 200 Mg Iv nidazole 500 Mg Iv pic Acid 500 Mg Iv			00000000	maronodo bola					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
		omycin 1000 Mg Iv			C						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17947164	DIRECT	Υ						49 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Dialysis; Renal Failure	Remd	esivir			S	Intravenous bolu	S				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2020	17948215	DIRECT	Υ	(TC				61 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remd	esivir			S						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17835873	EXPEDITED (15-DAY)		(TC	US-GILEAD 0468468)-2020-		75 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation	Remd	esivir			S	Intravenous (not otherwise specifi		lg, Qd			Gilead
	Aceta	minophen			С	Oral	650 N	1g			Not Reported

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	An	nlodipine			С	Oral		10 Mg				Not Reported
	Ар	ixaban			С	Oral		2.5 Mg				Not Reported
	Do	oxazosin			С	Oral		4 Mg				Not Reported
	Ну	dralazine			С			Unk				Not Reported
	Lo	razepam			С			Unk				Not Reported
	Co	mbivent Respimat			С			Unk				Not Reported
	As	corbic Acid			С	Oral		500 Mg				Not Reported
	Ch	olecalciferol			С	Oral		2000 lu				Not Reported
	Le	vothyroxine			С			Unk				Not Reported
	Zir	nc Sulfate			С			Unk				Not Reported
	Ту	lenol			С							Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>		Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17835882	EXPEDITED (15-DAY)			ОТ		US-GILEAD-2020 0468290	0-		67 YR	Female	e USA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Rout	<u>e</u> <u>C</u>	Oosage 1	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Dysphagia; Swelling;	Re	emdesivir			S	Unkno	own	200 Mg				Gilead
Throat Irritation	Alk	outerol Hfa			С			Unk				Not Reported
	Ny	estatin			С			Unk				Not Reported
		rcocet [Oxycodone drochloride;Paracetamol]			С			Unk				Not Reported
		ntoprazole			С			Unk				Not Reported
	Zir	nc			С			Unk				Not Reported
	Vit	amin D [Colecalciferol]			С			Unk				Not Reported
	Vit	amin C [Ascorbic Acid]			С			Unk				Not Reported
	As	pirin [Acetylsalicylic Acid]			С			Unk				Not Reported
	Me	ethylprednisolone			С			Unk				Not Reported
	Dip	oridamole			С			Unk				Not Reported
	Ins	sulin Lispro			С			Unk				Not Reported
	Le	trozole			С			Unk				Not Reported



							-			
	Amlo	odipine			С		Unk			Not Reported
	Lisir	opril			С		Unk			Not Reported
	Sita	gliptin			С		Unk			Not Reported
	Metf	ormin			С		Unk			Not Reported
	Emp	agliflozin			С		Unk			Not Reported
	Diph	enhydramine			С	Intravenous (not otherwise specified)	Unk, Prn			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17877950	EXPEDITED (15-DAY)		I	DE, HO, OT	US-GILEAD-20 0470603	20-	63 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Acute Kidney Injury; A Respiratory Distress	cute Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Syndrome	Doc Eno Fam Furd	nromycin usate;Senna xaparin otidine osemide comycin			C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17892305	EXPEDITED (15-DAY)		I	HO, OT	US-GILEAD-20 0469665	20-	73 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Rem	ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Dex	amethasone			С	Oral	20 Mg			Not Reported
	Eno	xaparin			С	Subcutaneous	30 Mg			Not Reported
	Eton	nidate			С	Intravenous (not otherwise specified)	20 Mg			Not Reported

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	Famo	otidine			С	Intravenous (not otherwise specified)	20 Mg			Not Reported
	Tocili	zumab			С	Intravenous (not otherwise specified)	400 Mg			Not Reported
	Propo	ofol			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Midaz	zolam			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Nore	pinephrine			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Vanc	omycin			С	Intravenous (not otherwise specified)	2500 Mg			Not Reported
	Azithi	romycin			С	Intravenous (not otherwise specified)	500 Mg			Not Reported
	Cefep	oime			С	Intravenous (not otherwise specified)	2 G			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17948303	DIRECT	Υ	Ľ	Т			74 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Albut Guaif Allopi Aspiri Enox Huma Levot Omep	desivir erol Mdi Q6hr Prn enesin 600 Mg Q12h urinol 300 Mg Bid in 81 Mg Qd aparin 40 Mg Qhs alog Ssi thyroxine 137mcg Qd prazole 20 Qd tonin 5mg Qhs			%000000000					Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17948310	DIRECT	Υ	0	·Τ			59 YR	Male	USA
Preferred Term	Prod	uot.	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr

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Rash; Rash Erythematous; Red Ma Syndrome		Remdesivir 0.9% Sodium Chloride 1I			S C	Intravenous bolus	Other Fre	quency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	1794840	03 DIRECT	Υ		НО				45 YR	Male	USA
Preferred Term	1	Product	Comp.	OTO	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase l	Remdesivir			S	Intravenous (not otherwise specified)					Gilead
) 	Dexamethasone Azithromycin Enoxaparin Ascorbic Acid Zinc Sulfate Melatonin			00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	1794917	9 EXPEDITED (15-DA	Y)		DE, OT	US-GILEAD-20 0475738	20-		56 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	<u>Route</u>	Dosage Te	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Death	I	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, 0	Qd			Gilead
		Albumin (Human)			С	, ,					Not Reported
		Azithromycin			С						Not Reported
		Senokot-S			C C						Not Reported
		Ceftriaxone Sodium			C						Not Reported
		Cisatracurium -			Ċ						Not Reported
		Enoxaparin			С						Not Reported
		Epinephrine			С						Not Reported
		Epoprostenol [Epoprostenol Sodium]			С						Not Reported
		Fentanyl			С						Not Reported
		Folic Acid			С						Not Reported
		Heparin			С						Not Reported
		Duoneb			С						Not Reported
	l	Linezolid			С						Not Reported
		Midazolam			С						Not Reported

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	Nore Pant Phei	ivitamins;Minerals epinephrine toprazole nylephrine rracillin & Tazobactam oofol			000000		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17949182	DIRECT	Υ					37 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Extra Dose Administer	ed Rem	ndesivir			S	Intravenous (not otherwise specified)				Gilead
	Enox Insu Insu Labe Furo Con	riaxone xaparin lin Glargine lin Lispro etalol esemide valescent Plasma otidine			0000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949291	DIRECT	Y		HO, OT			79 YR	Female	USA
Preferred Term	Prod	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bundle Branch Block Right; Heart Rate	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Decreased; Nodal Rhythm; Therapy	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Cessation		nromycin 500mg Po Qam ansetron 4mg Iv X1 At 2052 5/20			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17949624	DIRECT	Υ					70 YR	Male	USA

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransferase	Remde	esivir	Υ		S	Intravenous bolus				Gilead
Increased	Atorvas Amlodi Fiorice Enoxap Zetia Robitus Mag-O Niacin Zinc	pine t parin ssin x 400			000000000					Not Reported
FDA Received Date Case	<u>e #</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020 1794	19632	DIRECT	Υ		DE			73 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Agonal Rhythm; Gastrointestinal Haemorrhage; Hypotension; Respiratory	Remde Conval	esivir escent Plasma			s C	Intravenous (not otherwise specified)			Gilead Not Reported
Distress										
FDA Received Date Case	<u>e #</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020 1794	19709	DIRECT	Υ		DS			53 YR	Female	e USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cerebrovascular Accident; Hemiparesis	Remde Hepari				s s	Intravenous bolus				Gilead Not Reported
FDA Received Date Case	e #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020 1795	50233	DIRECT	Υ		DE			87 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Oxygen Saturation Decreased	Remde	esivir			S	Intravenous drip				Gilead

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							•			
	Hydro	zumab ocortisone methasone			CCC					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17950264	DIRECT	Υ	D	E			84 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation;		desivir			S	Intravenous bolus				Gilead
Hypotension; Respirate Distress	Levoi Ceftri	zumab floxacin axone romycin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17950269	DIRECT	Υ	Lī	Γ			67 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatine Phosphokinase Increa Rhabdomyolysis		desivir			S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17950326	DIRECT	Υ	0	Т			75 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17950382	DIRECT	Υ					49 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Pyrexia	5	desivir			S					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17951103	EXPEDITED (15-DAY)			ОТ	US-GILEAD- 0475616	2020-		57 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Glomerular Filtration R Decreased	tate Remd	esivir			S	Intravenous (not otherwise specifie	100 Mg	g, Qd		(Gilead
	Benzo Bisaco Ceftria Cyclol Enoxa Famo Gabaj Guaife Hydro Aceta Morph Orphe Predn Docus Sodiu	exone benzaprine aparin tidine bentin enesin codone Bitartrate And minophen nine enadrine isone									Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17951358	EXPEDITED (15-DAY)		1	ОТ	US-GILEAD- 0475730	2020-		63 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Renal Impairment	Remd	esivir			S	Intravenous (not otherwise specifie		g, Once		(Gilead
	Ceftria	axone			С	-	Unk			I	Not Reported
	Azithr	omycin			С		Unk			I	Not Reported
	Atorva	astatin			С		Unk			I	Not Reported
	Asa				С		Unk			I	Not Reported
	Vitam	in D3			С		Unk			1	Not Reported

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	Fnox	aparin			С		Unk			Not Reported
		semide			С					Not Reported
							Unk			•
		enesin			С		Unk			Not Reported
	Methy	/lprednisolone			С		Unk			Not Reported
	Panto	prazole			С		Unk			Not Reported
	Dexm	nedetomidine			С		Unk			Not Reported
	Propo	ofol			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17952105	EXPEDITED (15-DAY)		Е	E, OT	US-GILEAD-20 0475740)20-	61 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Death	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		ıminophen			С					Not Reported
	Aspiri				С					Not Reported
		astatin			C					Not Reported
		romycin			C					Not Reported
	Cefer	axone			C					Not Reported Not Reported
		methasone			C					Not Reported
	Prece				C					Not Reported
		aparin			C					Not Reported
		phrine			Č					Not Reported
		rostenol			C					Not Reported
	Famo	tidine			С					Not Reported
	Lantu				С					Not Reported
		n Lispro			С					Not Reported
		clopramide			С					Not Reported
	Metor				С					Not Reported
		zumab			C					Not Reported
		in C [Ascorbic Acid]			000000000000000000000000000000000000000					Not Reported
		al Saline			C					Not Reported
	Clopic	dogrel			<u> </u>					Not Reported



						•				
				С						Not Reported
Insulii Metfo Metop	n rmin orolol Tartrate			C C C C						Not Reported Not Reported Not Reported Not Reported
Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17952320	EXPEDITED (15-DAY)		DE	E, OT	US-GILEAD- 0476715	2020-		59 YR	Male	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	Duration	<u>N</u>	<u>//fr</u>
Remo	lesivir			S	Unknown					Gilead
Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17952476	EXPEDITED (15-DAY)		DE	E, OT	US-GILEAD- 0476711	2020-		60 YR	Male	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	Duration	<u>N</u>	<u>Afr</u>
Remo	lesivir			S	Unknown					Gilead
Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17952547	EXPEDITED (15-DAY)		Н)	US-GILEAD- 0476372	2020-		36 YR	Female	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	Duration	<u>N</u>	<u>//fr</u>
	lesivir			S	Intravenous (not otherwise specifie		Mg, Qd			Gilead
ose Omission Remdesivir				S	Intravenous (not	100 [Mg, Qd			Gilead
Benzo	onatate			С		,				Not Reported
				С						Not Reported
				С						Not Reported
				C						Not Reported Not Reported
				C						Not Reported Not Reported
[Codeine				J						Not Reported
	Hydro Insulin Metfo Metop Raniti Metfo Metop Raniti Metfo Metop Raniti Metop Raniti Metop Raniti Metop Raniti Metop Raniti Metop Raniti Metop Prome [Code	Product Remdesivir Case # Case Type 17952476 EXPEDITED (15-DAY) Product Remdesivir Case # Case Type 17952476 EXPEDITED (15-DAY) Product Remdesivir Case # Case Type 17952547 EXPEDITED (15-DAY) Product ed; Remdesivir Remdesivir Remdesivir Benzonatate Enoxaparin Ketorolac Melatonin Methylprednisolone Promethazine - Codeine	Hydrochloride] Insulin Metformin Metoprolol Tartrate Ranitidine Case # Case Type Health 17952320 EXPEDITED (15-DAY) Product Remdesivir Case # Case Type Health 17952476 EXPEDITED (15-DAY) Product Remdesivir Case # Case Type Health 17952547 EXPEDITED (15-DAY) Product Remdesivir Case # Case Type Health 17952547 EXPEDITED (15-DAY) Product Remdesivir Benzonatate Enoxaparin Ketorolac Melatonin Methylprednisolone Promethazine - Codeine [Codeine	Hydrochloride] Insulin Metformin Metoprolol Tartrate Ranitidine Case # Case Type Health Prof Off 17952320 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Case # Case Type Health Prof Off 17952476 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Case # Case Type Health Prof Off 17952547 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Case # Case Type Health Prof Off 17952547 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Benzonatate Enoxaparin Ketorolac Melatonin Methylprednisolone Promethazine - Codeine [Codeine	Hydrochloride Insulin	Hydrochloride Insulin	Hydrochloride Insulin	Hydrochloride Insulin	Hydrochloride Insulin Metrormin Metrormin Metrormin Metrormin Metrormin C	Hydrochloride on



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		ochloride] aminophen		(0					Not Reported
FDA Received Date	Case #	Case Type	Health P	rof Outc	<u>omes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17952601	EXPEDITED (15-DAY)		DE, C	T	US-GILEAD-202 0475755	20-	83 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Pulseless Electrical Activity	Remo	desivir		\$	6	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Plasn Hydro	na oxychloroquine					Unk			Not Reported Not Reported
	Azithı	romycin		(Intravenous (not otherwise specified)	500 Mg, Once			Not Reported
	Azithı	romycin		(2	Oral	250 Mg, Qd			Not Reported
	Ceftri	axone		(2		Unk			Not Reported
	Methy	ylprednisolone		(2		Unk			Not Reported
	Thian	nine		(2		Unk			Not Reported
	Zinc S	Sulfate		(2		Unk			Not Reported
	Vaso _l	pressin		(2		Unk			Not Reported
	Enox	aparin		(2	Subcutaneous	70 Mg, Bid			Not Reported
	Enox	aparin		(2	Subcutaneous	70 Mg, Qd			Not Reported
	Cefep	oime		(2		Unk			Not Reported
	Ascor	rbic Acid		(Intravenous (not otherwise specified)	1500 Mg, Q6h			Not Reported
	Ascor	rbic Acid		(0	Oral	1500 Mg, Qd			Not Reported
	Atorv	astatin		(0	Oral	80 Mg, Qd			Not Reported
	Amio	darone		(0	Intravenous (not otherwise specified)	450 Mg			Not Reported
	Amio	darone		(0	Oral	200 Mg, Qd			Not Reported
FDA Received Date	Case #	Case Type	Health P	rof Outc	<u>omes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
26-Jun-2020	17952608	EXPEDITED (15-DAY)		DE, C	T	US-GILEAD-202 0476714	20-	61 YR	Male	USA

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remo	esivir			S	Unknown					Gilead
	Remo	esivir			S		Unk				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17952610	EXPEDITED (15-DAY)			НО	US-GILEAD-20 0476284	020-		60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		Mfr
Alanine Aminotransfera	ase Remo	esivir			S	Intravenous (not otherwise specified)	200 Mg	ı, Qd			Gilead
	Remo	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
		omycin Fumarate			С						Not Reported
		axone			C						Not Reported
		methasone			С						Not Reported
	Prece				C C						Not Reported
	Diltiaz				C						Not Reported
		aparin			С						Not Reported
	Famo				С						Not Reported
	Fenta				С						Not Reported
		emide 			С						Not Reported
		lazine			С						Not Reported
	Lantu				С						Not Reported
		Lispro Dci			С						Not Reported
		inephrine Bitartrate			С						Not Reported
		acillin & Tazobactam			С						Not Reported
	Propo				С						Not Reported
		onium			С						Not Reported
	Vitam Zinc	in C [Ascorbic Acid]			C C						Not Reported Not Reported
											Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17952624	EXPEDITED (15-DAY)		1	ОТ	US-GILEAD-20 0476289	020-		69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	Duration		Mfr



Blood Bilirubin Increas	ed Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Aspiri	n (E.C.)			С						Not Reported
		astatin [′]			С						Not Reported
	Azithr	omycin			С						Not Reported
	Ceftri	axone			С						Not Reported
	Carve	edilol			С						Not Reported
	Dexa	methasone			С						Not Reported
	Prece	edex			С						Not Reported
	Enox				С						Not Reported
	Famo	tidine			С						Not Reported
	Fenta				С						Not Reported
		n Lispro			С						Not Reported
	Midaz				С						Not Reported
	Nicar				С						Not Reported
		pinephrine			С						Not Reported
	Propo				С						Not Reported
	Amio	darone			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17952666	EXPEDITED (15-DAY)				US-GILEAD-20 0476262	20-		58 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	Duration	<u>I</u>	<u>VIfr</u>
Product Use Issue	Remo	desivir			S	Unknown					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17952676	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0476716	20-		52 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	<u>1</u>	<u>Vlfr</u>
Death	Remo	desivir			S	Unknown					Gilead
			Llaalth	Drof	Outcomes	Mfr Control #	ŧ	503B Facility	<u>Age</u>	Sex	Country
FDA Received Date	Case #	Case Type	пеан	<u> </u>	<u>Outoonico</u>	MIT CONTROL II	<u>-</u>		90	oox	<u>oountry</u>

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Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Bradycardia; Therapy Interrupted	Remo	lesivir			S				٨	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17955109	DIRECT	Υ		ÞΕ			80 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury; Cardiac Arrest; Pancytopenia; Pulsele Electrical Activity; Sep		lesivir			S	Intravenous bolus			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	I# 503B Facilit	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17955112	DIRECT	Υ		ÞΕ			91 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Remo	lesivir			S	Intravenous (not otherwise specifie	d)		G	Gilead
		loxacin omycin axone			C C C		- ,		N	lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17955114	DIRECT	Υ					45 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Atrial Fibrillation; Hear Rate Decreased; Sinu Bradycardia		lesivir			S				٨	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17955116	DIRECT	Υ	г	E			66 YR	Male	USA

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						2010111001110	Port			
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Bradycardia		Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Cardiac Arrest; Condition Aggravated; Pulseless Electrical Activity; Rena Impairment		Convalescent Plasma Tocilizumab			C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	1795512	24 DIRECT	Y					33 YR	Female	e USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Contraindicated Product Administered; Transcription Medicatic Error	an l	Remdesivir Ketorolac Albuterol	Y		S C C	Intravenous drip	Other Frequency:Once;			Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	1795512	27 DIRECT	Y					59 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Extra Dose Administere	ed	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Daily;	1 DAY		Gilead
		Remdesivir	Υ		S	Intravenous (not otherwise specified)		1 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	1795513	B6 DIRECT	Υ					67 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Oxygen Saturation		Remdesivir	Υ		S	Intravenous drip				Gilead
Decreased		Odefsey Lisinopril Ceftriaxone			C C C	·				Not Reported Not Reported Not Reported

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						Detailed Re	- port			
		Azithromycin Atorvastatin Asa			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>Case Type</u>	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2020	17955	138 DIRECT	Υ	D	S			17 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Appendicitis; Pneuma Intestinalis; Respirator Failure		Remdesivir Famotidine 20 Mg Iv Qd Morphine 2mg Iv Prn Q2h Dexamethasone 6mg Iv Qd Ondansetron 4mg Iv Prn Q8hr Morphine Drip 0.025mg/Hour Dexmedetomidine Iv Drip Insulin Drip Metronidazole 500mg Iv Q 8 Hr Cefepime 2g Iv Q 12h Lorazepam 2mg Q4hprn Enoxaparin 40mg Sq Melatonin 3mg Hs Azithromycin Oral	Y		» 0000000000000	Intravenous bolus		4 DAY		Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2020	17955	143 DIRECT	Υ	L1	Ī			32 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	rase	Remdesivir			S	Intravenous drip				Gilead
Increased; Aspartate Aminotransferase		Centrum Multivitamin Oral Solution			С	р				Not Reported
Increased; Hypotensic	on;	Enoxaparin 40 Mg Injection			С					Not Reported
Ischaemic Hepatitis; Transaminases Increa	ased	Phytonadione 5 Mg Tablet Potassium Phosphate 30 Mmol			C C					Not Reported Not Reported
		Injection Acetaminophen 650 Mg Oral			С					Not Reported
		Liquid Cefepime 2g Injection			С					Not Reported
		Dexmedetomidine Continuous			Č					Not Reported

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							P			
	Fa Fe Hy In: Pe Ni Pc	fusion amotidine 20 Mg Injection entanyl Continuous Infusion ydrocortisone 50 Mg Injection sulin Aspart eptamen Continuous Enteral utrition olyethylene Glycol 17g Packet			C C C C C C C C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2020	17955146	DIRECT	Υ	ОТ	-			67 YR	Female	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	Mfr .
Liver Function Test Increased	Re	emdesivir			S	Intravenous (not otherwise specified)				Not Reported
		zithromycin eftriaxone			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955074	DIRECT		ОТ	-			79 YR	Female	USA
Preferred Term	<u>P</u> i	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
International Normalise Ratio Increased; Thera Change		arfarin emdesivir			S S					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955085	DIRECT	Υ	ОТ	<u>-</u>			85 YR	Female	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chest Pain; Dyspnoea Infusion Related Reac Therapy Cessation		emdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955147	DIRECT	Υ					76 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatine Increas General Physical Heal	th	desivir	Υ		S	Intravenous bolus		2 DAY		Gilead
Deterioration	Atrace Busp Docu Famo Furo Mem Meto Polyce Senr Venla Epop Hydr Mida Nore Prop	otidine semide antine prolol ethylene Glycol abalin na afaxine orostenol omorphone zolam pinephrine			00000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955173	DIRECT	Υ					53 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasa	ation Rem	desivir	Y		S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955174	DIRECT	Υ	DE	Ē			51 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Multiple Organ	Rem	desivir			S	Intravenous bolus				Gilead

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Dysfunction Syndrome	1									
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955178	DIRECT	Y		LT			68 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfera Increased; Ammonia Increased; Aspartate Aminotransferase Increased; Internationa Normalised Ratio Increased; Prothrombir Time Prolonged; Sars- Cov-2 Test Positive	Rei Am al	mdesivir Lyophilized Powder mdesivir Lyophilized Powder iiodarone Continuous Infusion			S S C	Intravenous bolus Intravenous bolus	Other Frequency:Once;		Gil	ead ead t Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955182	DIRECT	Υ		ОТ			82 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension	Rei	mdesivir	Υ		S	Intravenous drip	Other Frequency:Once;		Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2020	17955186	DIRECT	Υ		ОТ			62 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Sinus Bradycardia		mdesivir etiapine			s C	Intravenous drip				ead t Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17818878	EXPEDITED (15-DAY)			DS, HO, LT,	OT US-GILEAD-20: 0468569	20-	60 YR	Male	USA
Preferred Term	D.,	oduct	Comp.	отс	Role	Route	Dosage Text	Duration	Mfr	



Cerebrovascular Accident	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Remdesivir Acetaminophen			S C		Unk			Gilead Not Reported
	Aspirin [Acetylsalicylic Acid]			С		Unk			Not Reported
	Azithromycin			С		Unk			Not Reported
	Ceftriaxone			С		Unk			Not Reported
	Furosemide			С		Unk			Not Reported
	Hydroxychloroquine			С		Unk			Not Reported
	Magnesium Sulfate			С		Unk			Not Reported
	Potassium Bicarbonate			С		Unk			Not Reported
	Enoxaparin			С		Unk			Not Reported
FDA Received Date Case	# Case Type	Health P	rof Ou	ıtcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020 1783	5865 EXPEDITED (15-DAY)		ОТ	-	US-GILEAD-202 0468246	20-	70 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Aminotransferase Abnormal; Hepatic	Atorvastatin			С	Oral	20 Mg			Not Reported
Enzyme Increased	Propofol			С		Unk			Not Reported
	Chlorhexidine			С	Oral	15 MI, Bid			Not Reported
	Dexamethasone			С	Intravenous (not otherwise specified)	10 Mg, Qd			Not Reported
	Enoxaparin			С	Subcutaneous	70 Mg, Bid			Not Reported
	Famotidine			С	Intravenous (not otherwise specified)	20 Mg, Qd			Not Reported
	Insulin Aspart			С	Subcutaneous	Unk			Not Reported
	Insulin Detemir			С	Subcutaneous	10 Units			Not Reported
	Piperacillin/Tazobactam			С	Intravenous (not otherwise specified)	3.375 G, Tid			Not Reported



	,	Acetaminophen			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	1784803	7 EXPEDITED (15-DAY)		ОТ	US-GILEAD-20 0468536	20-	55 YR	Male	USA
Preferred Term]	Product	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Hypotension; Infusion Related Reaction	ſ	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	ŀ	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	1788277	6 EXPEDITED (15-DAY)		ОТ	US-GILEAD-20 0469674	20-	77 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased;		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Glomerular Filtration F Decreased	Rate I	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk			Gilead
	i i	Enoxaparin			С		Unk			Not Reported
	i	amotidine			С		Unk			Not Reported
	l	∟orazepam			С		Unk			Not Reported
	ŀ	Hydromorphone			С		Unk			Not Reported
	ı	Metoclopramide			С		Unk			Not Reported
	(Ceftriaxone			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	1795517	7 EXPEDITED (15-DAY)		НО	IT-MYLANLAB 2020M1059286		64 YR	Male	ITA
Preferred Term	<u> </u>	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>I</u>	<u>Mfr</u>
Erythema; Hypersensitivity; Off L		Piperacillin/Tazobactam			S	Intravenous drip	13 Gram, Qd			Not Reported

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Use; Rash Maculo- Papular		Remdes	sivir /chloroquine Sulfate			S C	Intravenous drip Oral	100 Milligram, Qd 400 Milligram			Mylan Mylan
FDA Received Date	Case #	<u> </u>	Case Type	Health	Prof C	Outcomes	Mfr Control #		Age	Sex	Country
29-Jun-2020	179568	363	DIRECT	Υ	C	DΤ			61 YR	Male	USA
Preferred Term		Produc	t	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase	Remdes	sivir	Υ		S	Intravenous (not otherwise specified)	1			Gilead
Aminotransferase Increased; Covid-19 Pneumonia; Respirato Failure	ory	Dexame	one 2 Gm Ivpb Daily ethasone 6 Mg Ivp Daily cline 100 Mg Po Twice			C C	outerwise specimes)	,			Not Reported Not Reported Not Reported
		Enoxap Daily	arin 70 Mg Sq Twice (Omnipaque) 90 Ml Iv X			C C					Not Reported Not Reported
		Multivita Daily	amin With Minerals Po			С					Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	179568	364	DIRECT	Υ	C	T			44 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase	Remdes	sivir			S					Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof C	Outcomes	Mfr Control #	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	179568	365	DIRECT	Υ	C	T			74 YR	Female	e USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Failure		Remdes	sivir			S	Intravenous drip				Gilead
		Cefepin Amioda Doxycyc	rone			C C C	· 				Not Reported Not Reported Not Reported

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	Fentan Vecuro Propofe Levoph Levoth Decadi	nium bl ned yroxine			00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control:	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956866	DIRECT	Υ		ОТ				79 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Disease Progression; Liver Function Test Increased; Therapy Interrupted	Remde Fenofik				S C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956881	DIRECT	Υ		ОТ				68 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>		Mfr
Liver Function Test Increased	Remde	esivir	Υ		S	Intravenous (not otherwise specified))		4 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956925	EXPEDITED (15-DAY)			HO, LT, OT	NL-AUROBINE APL-2020-031				Male	NLD
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Furose	mide			S	Unknown	Unk				Aurobindo
	Remde	esivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Parace	tamol			С	Oral	Unk				Not Reported
	Norepi	nephrine			С	Intravenous (not otherwise specified)	Unk				Not Reported

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	F	Remifentanil			С	Intravenous (not otherwise specified)	Unk				Not Reported
	C	Ceftriaxon			С	Intravenous (not otherwise specified)	Unk				Not Reported
	N	Movicolon			С	Oral	Unk				Not Reported
	N	ladroparin			С	Subcutaneous	Unk				Not Reported
	C	cisatracurium			С	Intravenous (not otherwise specified)	Unk				Not Reported
	P	Propofol Propofol			С	Intravenous (not otherwise specified)	Unk				Not Reported
	S	Supradyn			С	Oral	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	1795696	8 DIRECT	Υ		DE				60 YR	Male	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Wrong Technique In		Remdesivir	Υ		S	Intravenous drip					Gilead
Product Usage Proces	A A A A A A B C C C C C C C C C C C C C	Offirmev Iv Accetaminophen Sol 325mg/10m Accetylcysteine Sol 20% Albuterol Inh Amiodarone Iv Atorvastatin 10mg Benzonatate 100mg Calcium Gluconate Iv Ceftriaxone 1g Dexamethasone 6mg Iv Dexamedetomidine Doxycycline Enoxaparin Epinephrine Drip Tamotidine 20mg Iv Desulin Glargine Lorepinephrine Drip	ıl		00000000000000000						Not Reported



	Vasop	oressin			С				ı	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956974	DIRECT	Υ	0	Т			58 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Anxiety; Feeling Abnor	mal Remd	esivir			S	Intravenous bolus			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956980	DIRECT	Υ	0	Т			58 YR	Male	USA
<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Heart Rate Increased; Liver Function Test Increased	Remd Propo Norep Fenta	fol inephrine			S C C C	Intravenous bolus			1	Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956985	DIRECT	Υ	0	Т			44 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfer	ase Remd	esivir			S	Intravenous drip			(Gilead
Increased	Dexar Trama Zinc S Aceta Enoxa	Sulfate minophen			000000				! ! ! !	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956992	DIRECT	Υ					46 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>

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							•			
Therapy Interrupted	Remo	lesivir			S	Intravenous (not otherwise specified)			Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956994	DIRECT	Υ					32 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Intentional Product Use Issue	e Remo	lesivir			S	Intravenous (not otherwise specified)		5 DAY	Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17956998	DIRECT	Υ					33 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	ŗ
Intentional Product Use Issue	e Remo	lesivir			S	Intravenous (not otherwise specified)			Gi	lead
	Dexa	methasone			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17957001	DIRECT	Υ					34 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	ŗ
Alanine Aminotransfera Increased	ase Remo	lesivir	Y		S	Intravenous drip		1 DAY	Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17957034	DIRECT	Υ	C	T			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mf</u> ı	r
Blood Creatinine Increased; Covid-19;		lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY	Gi	lead
Glomerular Filtration R Decreased	tate Remo	lesivir			S	Intravenous (not		2 DAY	Gi	lead

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						otherwise specific	ed)				
		zumab 600mg Iv X1 an 1000 Mg/100 MI			C C	outerwise specific	ou)				ot Reported ot Reported
		inephrine 16mg/250 MI			С					N	ot Reported
	Sodiu	m Bicarbonate 150 Meq/ MI Swi			С					N	ot Reported
		oressin 40 Unit/100 MI Ns			С					N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>ıtcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17957040	DIRECT	Υ						27 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Hepatic Enzyme Increased; Therapy Interrupted	Remo	lesivir			S					N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>ıtcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17957735	EXPEDITED (15-DAY)		DE	E, OT	US-GILEAD 0476718)-2020-		77 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Death; Glomerular Filtration Rate Decrea	Remo	esivir			S	Unknown				G	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>ıtcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17957740	EXPEDITED (15-DAY)				US-GILEAD 0476394)-2020-		25 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Product Use Issue	Remo	esivir			S	Intravenous (not otherwise specific		g, Qd		G	lead
	Vanco	omycin			С	·	Unk			N	ot Reported
	Cefaz	olin			С		Unk			N	ot Reported
					С					N	



							10 0 0 0				
		Dexamethasone			С		Unk				Not Reported
		Enoxaparin			С		Unk				Not Reported
		Methadone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	179577	73 EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0476697)20-		52 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Death		Remdesivir			S	Unknown					Gilead
		Remdesivir			S	Unknown					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	179582	17 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0476315)20-		54 YR	Female	USA
Preferred Term		Product	Comp.	OTO	Role Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Platelet Count Increas	ed	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
		Azithromycin Ceftriaxone Dexamethasone Enoxaparin [Enoxaparin Sodium] Robitussin Dm Acetaminophen]		00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	179607	73 DIRECT	Υ		ОТ				28 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OT(</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase	ase	Remdesivir Benzocain-Menthol Lozenge			S C						Not Reported Not Reported



Increased; Therapy

Cessation										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17960783	DIRECT	Υ	D	DΕ			52 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Cardiac Arrest; Condit Aggravated; Metabolic Acidosis		esivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17960861	DIRECT	Υ					43 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
ntercepted Product Dispensing Error; Prod Preparation Error	Remd duct	esivir	Y		S	Intravenous drip	Other Frequency:Once;	1 DAY	G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17960869	DIRECT	Υ	C	T			77 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	r
Blood Pressure	Remd	esivir			S	Intravenous bolus		5 DAY	G	ilead
nadequately Controlle Blood Pressure Systol Increased; Hypertension	ic Azithro on Carve Ceftria	omycin dilol			00000				Ni Ni Ni	ot Reported ot Reported ot Reported ot Reported ot Reported ot Reported

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						Dotalloa No	, po			
	Haldo Hydra Effer-l Citric	minophen Ι lazine Κ (Potassium Bicarb -			00000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17960883	DIRECT	Υ	Н	0			79 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Dose Omissic Transcription Medicati Error		esivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17960897	DIRECT	Υ					24 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase Remd	esivir	Y		S	Intravenous bolus		5 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17960951	DIRECT	Υ	Н	0			51 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dizziness; Nausea; Peripheral Swelling;	Remd	esivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;			Gilead
Swelling Face	Cefdir Ascor	bic Acid nethasone			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported



						2010111001110	- PO: 1			
		motidine nc Sulfate			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17961055	DIRECT	Υ					50 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransfera	ase Re	mdesivir			S	Intravenous (not otherwise specified)				Gilead
		nvalescent Plasma cilizumab			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17961069	DIRECT	Υ	Н	0			54 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Kidney Injury; Cardio-Respiratory Arr Heart Rate Decreased Hepatic Enzyme Increased; Ischaemic Hepatitis; Pulseless Electrical Activity; Ren Tubular Necrosis	rest; I;	mdesivir	Y		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17961119	DIRECT	Υ	0	Т			72 YR	Female	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Glomerular Filtration R	Rate Re	mdesivir			S	Intravenous bolus				Not Reported
Decreased; Hepatic Enzyme Increased; Re	enal Alb	outerol/Ipratropium Nebulizer			С					Not Reported
Impairment; Therapy Cessation	As	corbic Acid 500mg Po Daily			C					Not Reported
Cosalion		ithromycin 500mg Iv Daily ftriaxone 2g Iv Daily			C C					Not Reported Not Reported
		olecalciferol 1000 Unit Po			C					Not Reported

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Note: If the field is blank, there is no data.

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							- 1			
	Doo	ly kamethasone 6mg Iv Daily cusate/Senna 50-8.6mg 2 p Po Qhs			C C					ot Reported ot Reported
	Нер	parin 5000 Unit Q8h ulin Glargine 30 Unit Subq			C C					ot Reported ot Reported
		ulin Lispro Sliding Scale Subo	I		С				No	ot Reported
		ntoprazole 40mg Iv Daily c 220mg Po Q12h			C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	l# 503B Facility	<u>/ Age</u>	<u>Sex</u>	Country
29-Jun-2020	17961135	DIRECT	Υ	0	Т			31 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>:</u>
Alanine Aminotransfel Increased; Aspartate Aminotransferase Increased; Maternal Exposure During Pregnancy; Sars-Cov- Test Positive		ndesivir			S	Intravenous drip			Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>/ Age</u>	<u>Sex</u>	Country
29-Jun-2020	17961246	DIRECT	Υ					36 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	[
Product Dose Omission	on Rer	mdesivir			S	Intravenous (not otherwise specifie	d)		Gi	lead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2020	17961537	DIRECT	Υ	D	E			71 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	[
Acute Kidney Injury;	D	ndesivir 100mg Vial			S	Intravenous (not			0.	lead

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Bacteraemia; General Physical Health Deterioration; Hepatic Failure; Hypernatraemia;	Remdesivir 100mg Vial			s C	otherwise specified) Intravenous (not otherwise specified)	Other Frequency:9 Dose	s;		Gilead Not Reported
Multiple Organ	Doxycycline Enoxaparin			C					Not Reported
Dysfunction Syndrome; Septic Shock; Toxic	Piperacillin-Tazobactam			C					Not Reported
Encephalopathy;	Pantoprazole			Ċ					Not Reported
Unresponsive To Stimuli	Vancomycin			Č					Not Reported
Sinosponoivo to Sanian	Furosemide			С					Not Reported
	Insulin			С					Not Reported
	Fentanyle			С					Not Reported
	Norepinephrine			С					Not Reported
	Propofol			С					Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020 17835	876 EXPEDITED (15-DAY)			LT, OT	US-GILEAD-20 0468482	20-	49 YR	Female	USA
Preferred Term	Product	Comp.	OTO	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransferase Abnormal; Blood Alkaline	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Phosphatase Increased; Hypotension	Atorvastatin			С		Unk			Not Reported
71	Ceftriaxone			С		Unk			Not Reported
	Desvenlafaxine			С		Unk			Not Reported
	Epoetin Alfa			С		Unk			Not Reported
	Famotidine			С		Unk			Not Reported
	Heparin			С		Unk			Not Reported
	Hydrocortisone Sodium Succinate			С		Unk			Not Reported
	Hydrocortisone Sodium Succinate			С		Unk			Not Reported
	Insulin Glargine			С		Unk			Not Reported
	Insulin Lispro			С		Unk			Not Reported
	Methadone			С		Unk			Not Reported
	Methadone			С		Unk			Not Reported



		Metopro	lol			С		Unk			Not Reported
		Potassiu	m Chloride			С		Unk			Not Reported
		Pregaba	lin			С		Unk			Not Reported
		Azithrom	nycin			С		Unk			Not Reported
		Hydroxy	chloroquine			С		Unk			Not Reported
		Acetamii	nophen			С	Oral	650 Mg, Q4hr			Not Reported
		Nystatin				С		Unk			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	178864	171	EXPEDITED (15-DAY)			HO, LT, OT	US-GILEAD-20 0471777	20-	35 YR	Male	USA
Preferred Term		Product	:	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Pleuritic Pa		Remdes	ivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Remdes	ivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
		Choleca	lciferol			С		2000 lu, Qd			Not Reported
		Melatoni	n			С		Unk			Not Reported
		Atorvast	atin			С		Unk			Not Reported
		Methylpr	ednisolone			С		Unk			Not Reported
		Enoxapa	arin			С		Unk			Not Reported
		Humalog	3			С		Unk			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179103	399	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0472995	20-	17 YR	Female	e USA
Preferred Term		Product	:	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Lactic Acid		Remdes	ivir			S	Unknown	Unk			Gilead
Increased		Epineph	rine			С					Not Reported



FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof	Outcome	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179146	699	EXPEDITED (15-DAY)			DE, HO, C	OT US-GILEAD-2 0473311	020-		85 YR	Male	USA
Preferred Term		Produc	<u>et</u>	Comp.	OTO	C Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Abdominal Distension; Output Increased; Dea		Remde	sivir			S	Intravenous (not otherwise specified	200 Mg	, Once			Gilead
		Remde	sivir			S	Intravenous (not otherwise specified	100 Mg I)	, Qd			Gilead
		Acetam	inophen			С		Unk				Not Reported
		Albuter	ol [Salbutamol]			С		Unk				Not Reported
		Amioda	rone			С		Unk				Not Reported
		Amlodip	pine			С		Unk				Not Reported
		Ampicill	lin And Sulbactam			С		Unk				Not Reported
		Apixaba	an			С		Unk				Not Reported
		Atenolo	l			С		Unk				Not Reported
		Atorvas	tatin			С		Unk				Not Reported
		Calcium	n Gluconate			С		Unk				Not Reported
		Chlorhe	exidine Gluconate			С		Unk				Not Reported
		Choleca	alciferol			С		Unk				Not Reported
		Dexme	detomidine			С		Unk				Not Reported
		Dextros	se			С		Unk				Not Reported
		Digoxin				С		Unk				Not Reported
		Etomida	ate			С		Unk				Not Reported
		Famotio	dine			С		Unk				Not Reported
		Fentany	/l			С		Unk				Not Reported
		Glucago	on			С		Unk				Not Reported
		Bromide				С		Unk				Not Reported
		Heparin				С		Unk				Not Reported
		Insulin I	Lispro			С		Unk				Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	17914716	EXPEDITED (15-DAY)			LT, OT	US-GILEAD-20 0472817	20-		41 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Districtions Syndrome; Pneumonia		desivir			S	Intravenous (not otherwise specified)	200 Mg				Gilead
Respiratory Failure	Rem	desivir			S	Intravenous (not otherwise specified)	100 Unk	ζ.			Gilead
		pinephrine Bitartrate ⁄alescent Plasma			C C	Intravenous (not otherwise specified)	2 Units				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	17962822	DIRECT	Υ		DE				81 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>		<u>Mfr</u>
Haemodynamic Instabi Heart Rate Decreased		desivir			S	Intravenous (not otherwise specified)					Gilead
Oxygen Saturation Decreased	Albu	aminophen Iv min 25%			C C	,					Not Reported Not Reported
		terol 0.5% Hhn Prn idopa-Levodopa 25/100			C C						Not Reported Not Reported
	Dopa	amine Infusion			С						Not Reported
		aparin 95 Mg peridol 2.5 Mg Prn			C C						Not Reported Not Reported
	Insul	in Aspart Prn			С						Not Reported
		roprium/Albuterol Hhn			С						Not Reported
		zepam 2 Mg X 1			С						Not Reported
		hine 2 Mg Prn pinephrine Infusion			C C						Not Reported Not Reported
		pinephrine infusion oprazole 40 Mg Iv			C						Not Reported Not Reported
		ivanserin 17 Mg			Ċ						Not Reported
		nosides-Docusate 1 Tab			Č						Not Reported



							. 15			
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179628	74 DIRECT	Υ	I	Ю			84 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Transamina Increased	ases	Remdesivir Acetaminophen 1000 Mg Aspirin 81 Mg Atorvastatin 40 Mg Clopidogrel 75 Mg Dextromethorphan-Guaifenes 30-600 Mg Dexmedetomidine Infusion Dopamine Infusion Enoxaprin 40 Mg Tocilizumab 400 Mg X 1 Furosemide 20-40 Mg Haloperidol 1-2.5 Mg Prn Levothyroxine 50 Mcg Linezolid 600 Mg Iv Melatonin 3-9 Mg Methylprednisolone/Predniso			s 00000 0000000000	Intravenous (not otherwise specified)				Not Reported
		Norepinephrine Infusion Olanzapine 2.5 Mg Pantoprazole 40 Mg Piperacillin-Tazobactam 4.5 Quetiapine 12.5 Mg Rivastigmine 9.5 Mg Td	3		00000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179628	79 DIRECT	Y	(ТС			45 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Glomerular Filtration R Decreased; Jaundice	Rate	Remdesivir			S	Intravenous (not otherwise specified)	1			Gilead
		Azithromycin 500 Mg Ceftriaxone 2 G			C C	. ,				Not Reported Not Reported

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	•	enytoin racetam			C C					Not Reported Not Reported
Rash	Remde	esivir	Υ		S	Intravenous drip				Gilead
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
30-Jun-2020	17962891	DIRECT	Υ	ОТ				51 YR	Male	USA
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	Ceftria Azithro				C C					Not Reported Not Reported
Rash	Remde	esivir			S		Other Frequency:Once;			Gilead
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
30-Jun-2020	17962885	DIRECT	Υ				-	84 YR	Female	e USA
FDA Received Date		Case Type	Health	Prof Ou	tcomes	Mfr Control #	# 503B Facility	Age	Sex	Country
	Senno: Pantor	sides orazole/Famotidine			C C					Not Reported Not Reported
		liazepoxide 100 Mg nethasone			С					Not Reported Not Reported
	Nicard	ipine Infusion			C					Not Reported
		nyl Ivp Prn acurium Infusion			C C					Not Reported Not Reported
	Propof	ol Infusion			С					Not Reported
		plex W/ Zinc kychloroquine			C C					Not Reported Not Reported
		amil 360 Mg			С					Not Reported
		edetomidine Infusion			C					Not Reported
		ninophen Prn Ilol Iv Prn			C C					Not Reported Not Reported
	Guaife	nesin-Codeine Prn			С					Not Reported
		nalidone 25 Mg tasone-Formoterol Inh			C					Not Reported Not Reported
		prednisolone 40 Mg			C C					Not Reported
		n Infusion			С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	17962898	DIRECT	Υ		ОТ			81 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Ns 25 Albute Ascor Chole Daily Enoxa Famo Flona Insulin Lorati Melat Oxym Qid Zinc S	erol Hfa 180 Mcg Q6 Hrs bate 500 Mg Po Q6 Hrs calciferol 2000 lu Oral aparin 60 Mg Sq Daily tidine 20 Mg Po Bid se 50 Mcg Inhaled Daily	ıl		8 000 0000000 00	Intravenous drip				Gilead Not Reported
FDA Received Date		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	Age	Sex	Country
30-Jun-2020	17963068	DIRECT	Υ		ОТ			85 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Ceftri	omycin axone methasone tidine rin	Y		s c c c c c	Intravenous drip				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	17963540	DIRECT	Υ		ОТ			31 YR	Male	USA

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Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mf</u>	<u>r</u>
Alanine Aminotransfera Increased	ase F	Remdesivir			S	Intravenous (not otherwise specified)			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	1796354	6 DIRECT	Υ	(TC				Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	r
Blood Creatinine Increased; Glomerular	F	Remdesivir			S	Intravenous drip	Other Frequency:X1, 100 Mg Q24h;		G	ilead
Filtration Rate Decreas	sed F	Remdesivir			С		g Q2,		N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	1796362	2 DIRECT	Υ	(TC			27 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Hepatic Steatosis; Transaminases Increas		Remdesivir			S	Intravenous (not otherwise specified)			G	ilead
		Ascorbic Acid 500 Mg Po Bid			С	,			N	ot Reported
	E	Vith Food Benonate 200 Mg 2 Caps Po Q8h Prn For Cough			С				N	ot Reported
	(Cholecalciferol 2,000 lu Po Dail Vith Food	У		С				N	ot Reported
	E N	Enoxaparin 80 Mg Sq Q12h Methylprednisolone 20 Mg Iv Q6h			C C					ot Reported ot Reported
	F	Pantoprazole 40 Mg Po Daily Zinc Sulfate 200 Mg Po Daily			C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	1796362	8 DIRECT	Υ					33 YR	Female	USA
Preferred Term		Product	Comp.	ОТС	Role	Route	Dosage Text	Duration	Mf	r



Acute Kidney Injury; Bl	lood	Remdesivir Lyophilize	d Powder			S	Intravenous bol	ıs			(Gilead
Creatine Phosphokinas Increased	se	Dexamethasone Tocilizumab				C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type		Health	Prof (<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179636	DIRECT		Υ						72 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Infusion Site Extravasa	ation	Remdesivir	١	Y		S	Intravenous bol	ıs			(Gilead
FDA Received Date	Case #	Case Type		<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179646	80 EXPEDITED	(15-DAY)				US-GILEA 0477205	D-2020-			Male	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	Duration	<u>M</u>	<u>lfr</u>
Accidental Overdose		Remdesivir				S	Unknown	Unk			C	Gilead
		Remdesivir				S	Unknown	200	Mg, Qd		(Gilead
FDA Received Date	Case #	Case Type		Health	Prof (<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179672	02 DIRECT		Υ	(OT				70 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransfera Increased	ase	Remdesivir Convalescent Plasma		ſ		S C	Intravenous bol	ıs				Gilead Not Reported
FDA Received Date	Case #	Case Type		Health	Prof (<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2020	179672	03 DIRECT		Υ	(ТС				75 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; Pulmonary Hypertensio	on;	Remdesivir				S	Intravenous (no otherwise speci				(Gilead
Right Ventricular Enlargement; Therapy		Ascorbic Acid 500 Mg Times Daily	Po Four			С	2eee epool	,			N	Not Reported

U.S. FOOD & DRUG ADMINISTRATION

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

30-Jun-2020 17967229 DIRECT Y 51 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Liver Function Test Increased Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftriaxone 1 Gm Iv Q24h Cenoxaparin 50 Mg Sq Q12h Famotidine 20 Mg Po Q12h Gualfenesin 200 Mg Po Q8h CC Gualfenesin 200 Mg Po Q8h CC Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily CC Mot Reported Not Reported	Cessation		olcecalciferol 4,000 lu Po			С					Not Reported
Enoxaparin 4 Mg Sq Q12h		Digo	oxin 0.25 Mg Iv Q8h X3			С					Not Reported
Ferrous Sulfate 325 Mg Po Daily C Sabapentin 600 Mg Po Olos C Not Reported Not Repor						С					Not Reported
Separation Color											
Hydrochlorothiazide 12.5 Mg Po Daily Fursemid= 20 Mg N Bid C C C C C C C C C											
Daily Furosemide 20 Mg Iv Bid C C C C C C C C C											
Levothyroxine 75 Mog Po Daily Lisinopril 20 Mg Po Daily Methylprednisolone 20 Mg Iv Q6h Multivitamin 1 Tab Po Daily Ometa-3 Fatty Acids 1 Gram Po Daily Pantoprazole 40 Mg		Dail	у								·
Lisinopril 20 Mg Po Daily Methylprednisolone 20 Mg Iv CO Q6h Multivitamin 1 Tab Po Daily Demandary Farty Acids 1 Gram Po Daily Pantoprazole 40 Mg Po Daily Ramelteon 8 Mg Po Ohs FDA Received Date Preferred Term Product Comp. OTC Role Route Dosage Text Remdesivir Increased Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriavone 1 Gm Iv Q24h Enoxaparin 50 Mg Ng Q12h Enoxaparin 50 Mg Ng Q12h Enoxaparin 50 Mg Ng Q12h Guidenesin 20 Mg Po Q12h Guidenesin 20 M											Not Reported
MethylprednisoTone 20 Mg Iv Q6h Multivitamin 1 Tab Po Daily Ometa-3 Fatty Acids 1 Gram Po Daily Ometa-3 Fatty Acids 1 Gram Po Daily Pantoprazole 40 Mg Po Daily Pantoprazole 40 Mg Po Daily Pantoprazole 40 Mg Po Qhs C Not Reported Not Reported Not Reported Ramelteon 8 Mg Po Qhs C Not Reported											
Comparison of the control of the		Lisir	nopril 20 Mg Po Daily			С					Not Reported
Multivitamin 1 Tab Po Daily Ometa-3 Fatty Acids 1 Gram Po Daily Pantoprazole 40 Mg Po Daily Ramelteons 8 Mg Po Ohs C Not Reported No						С					Not Reported
Ometa-3 Fatty Acids 1 Gram Po Daily Pantoprazole 40 Mg Po Daily Ramelteon 8 Mg Po Qhs FDA Received Date Received Date Product						•					N . B
Daily Pantoprazole 40 Mg Po Daily Ramelteon 8 Mg Po Qhs C FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 30-Jun-2020 17967229 DIRECT Y S 51 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Liver Function Test Increased Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftria											
Pantoprazole 40 Mg Po Daily Ramelteon 8 Mg Po Qhs FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility 30-Jun-2020 17967229 DIRECT Y 51 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Liver Function Test Increased Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Po Bid Azithromycin 500 Mg Po Q24h C Ctravore 1 Gm iv Q24h C Ctravore 1 Gm iv Q24h C C Famouldine 50 Mg Sq Q12h C C Famouldine 50 Mg Sq Q12h C C Famouldine 50 Mg Sq Q12h C C Famouldine 20 Mg Po Q12h C C Gualenesin 200 Mg Po Q8h Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily EDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Mfr Control # 503B Facility Age Sex Country Not Reported Not R						C					Not Reported
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country						0					Not Donortod
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 30-Jun-2020 17967229 DIRECT Y S1 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Liver Function Test Increased Ascorbic Acid 500 Mg Po Bid Ascorbic Acid 500 Mg Po Bid Control # Comp. Comp. Comp. Comp. Comp. OTC Role Route Dosage Text Duration Mfr Ascorbic Acid 500 Mg Po Bid Comp. Ascorbic Acid 500 Mg Po Bid Control # Comp. Comp.						C					
30-Jun-2020 17967229 DIRECT Y 51 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Liver Function Test Increased Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftriaxone 1 Gm Iv Q24h Cenoxaparin 50 Mg Sq Q12h Famotidine 20 Mg Po Q12h Gualfenesin 200 Mg Po Q8h CC Gualfenesin 200 Mg Po Q8h CC Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily CC Mot Reported Not Reported		Raii	neiteon o Mg Po Qns			С					Not Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr S Intravenous (not otherwise specified) Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm Iv Q24h Enoxaparin 50 Mg Sq Q12h Guifenesin 200 Mg Po Q12h Guifenesin 200 Mg Po Q8h Mott Reported Mott Reported Mott Reported Mott Reported Mott Reported Not R	FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
Liver Function Test Increased Remdesivir Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h C Ceftriaxone 1 Gm Iv Q24h Enoxaparin 50 Mg Sq Q12h Famotidine 20 Mg Po Q8h Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily C Sulfate 220 Mg Po Daily S Intravenous (not otherwise specified) Not Reported	30-Jun-2020	17967229	DIRECT	Υ					51 YR	Male	USA
Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftriaxone 1 Gm Iv Q24h Country Enoxaparin 50 Mg Sq Q12h Famotidine 20 Mg Po Q12h Country Country Country Country Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Not Reported	Preferred Term	<u>Pro</u>	duct	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Ascorbic Acid 500 Mg Po Bid Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm Iv Q24h Ceftriaxone 1 Gm Iv Q24h Country Enoxaparin 50 Mg Sq Q12h Famotidine 20 Mg Po Q12h Country Country Country Country Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Not Reported	Liver Function Test	Pon	ndosivir			c					Gilood
Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm I	Increased	Ken	iluesivii			3)			Glieau
Azithromycin 500 Mg Iv Q24h Ceftriaxone 1 Gm I		Asc	orbic Acid 500 Ma Po Bid			С					Not Reported
Ceftriaxone 1 Gm Iv Q24h Enoxaparin 50 Mg Sq Q12h C Famotidine 20 Mg Po Q12h Guaifenesin 200 Mg Po Q8h Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily C FDA Received Date C Ceftriaxone 1 Gm Iv Q24h C Not Reported C Not Reported						С					
Enoxaparin 50 Mg Sq Q12h C Not Reported Famotidine 20 Mg Po Q12h C Not Reported Guaifenesin 200 Mg Po Q8h C Not Reported Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs C Not Reported Zinc Sulfate 220 Mg Po Daily C Not Reported Not											
Famotidine 20 Mg Po Q12h Guaifenesin 200 Mg Po Q8h Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily C C Mot Reported Not Reported											
Guaifenesin 200 Mg Po Q8h Methylprednisolone 40 Mg Iv Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily C Health Prof C Mot Reported Not Reported											
Methylprednisolone 40 Mg Iv C Not Reported Q12h Ramelteon 8 Mg Po Qhs C Not Reported Zinc Sulfate 220 Mg Po Daily C Not Reported Not Re											
Q12h Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily C C FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country											
Ramelteon 8 Mg Po Qhs Zinc Sulfate 220 Mg Po Daily C FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country											
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						С					Not Reported
30-Jun-2020 17967232 DIRECT Y 87 YR Male USA	FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	Sex	Country
	30-Jun-2020	17967232	DIRECT	Υ					87 YR	Male	USA

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

With Food Calcium/Vir Po Bid Cholecalcif Docusate 2 Enoxaparir Famotidine Guaifenesi Methylpred Q12h Zinc Sulfate TPDA Received Date Case # COMPART CASE CASE CASE CASE CASE CASE CASE CASE	ic Acid 1,000 Mg Po Dail bod n/Vitamin D 500mg/200 I alciferol 2,000 lu Po Dail	•		s C	Intravenous (not otherwise specified)	Other Frequency:One Time Only;			Gilead
With Food Calcium/Vir Po Bid Cholecalcif Docusate 2 Enoxaparir Famotidine Guaifenesi Methylpred Q12h Zinc Sulfate Q12h Z	ood n/Vitamin D 500mg/200 I alciferol 2,000 lu Po Dail	•		С	, ,	• •			
Calcium/Vir Po Bid Cholecalcif Docusate 2 Enoxaparir Famotidine Guaifenesii Methylpred Q12h Zinc Sulfate Transaminases Increased FDA Received Date Transaminases Increased Remdesiving FOR Received Term Remdesiving Remdesiving Remdesiving Remdesiving Remdesiving	n/Vitamin D 500mg/200 I alciferol 2,000 Iu Po Dail	u							Not Reported
Cholecalcif Docusate 2 Enoxaparir Famotidine Guaifenesii Methylpred Q12h Zinc Sulfate 30-Jun-2020 17967235 D Preferred Term Product Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesivin	alciferol 2,000 lu Po Daily			С					Not Reported
Docusate 2 Enoxaparir Famotidine Guaifenesii Methylpred Q12h Zinc Sulfate 30-Jun-2020 17967235 D Preferred Term Product Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Remdesivin Blood Creatinine Remdesivin		V		С					Not Reported
Famotidine Guaifenesii Methylpred Q12h Zinc Sulfate FDA Received Date 30-Jun-2020 Preferred Term FDA Received Date FDA Received Date Formular FDA Received Date FDA Receiv	ale Zuu ivig Pu diu	•		С					Not Reported
Famotidine Guaifenesii Methylpred Q12h Zinc Sulfate FDA Received Date 30-Jun-2020 Preferred Term FDA Received Date Transaminases Increased FDA Received Date Transaminases Tran	parin 30 Mg Sq Q12h			С					Not Reported
Methylpred Q12h Zinc Sulfate FDA Received Date Case # C 30-Jun-2020 17967235 D Preferred Term Product Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesivin	dine 20 Mg Iv Q24h			С					Not Reported
Methylpred Q12h Zinc Sulfate FDA Received Date Case # C 30-Jun-2020 17967235 D Preferred Term Product Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesivin	nesin 600 Mg Er Po Bid			С					Not Reported
FDA Received Date 30-Jun-2020 17967235 Preferred Term FDA Received Date 30-Jun-2020 17967239 Preferred Term Product FDA Received Date 30-Jun-2020 17967239 Preferred Term Product Remdesiving Remdesiving Remdesiving	prednisolone 40 Mg Iv			С					Not Reported
30-Jun-2020 17967235 D Preferred Term Product Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesivin	ulfate 220 Mg Po Daily			С					Not Reported
Preferred Term Product Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesivin	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
Transaminases Increased Remdesivin FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesivin	DIRECT	Υ		ОТ			32 YR	Male	USA
FDA Received Date Case # C 30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesiving	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
30-Jun-2020 17967239 D Preferred Term Product Blood Creatinine Remdesiving	esivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing Event Descr;			Gilead
Preferred Term Product Blood Creatinine Remdesivin	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	<u>Sex</u>	Country
Blood Creatinine Remdesivii	DIRECT	Υ					80 YR	Female	USA
Ingragad: Clamprular	rt	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Increased; Glomerular Propofol	<u>u.</u>	Υ		S	Intravenous bolus				Gilead
Filtration Rate increased; Renal Impairment; Sinus				С					Not Reported
Bradycardia FDA Received Date Case # C	esivir								
30-Jun-2020 17967243 D	esivir	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country

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							- 1				
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	<u>Mf</u>	
Heart Rate Decreased	I Remd	esivir	Υ		S	Intravenous drip				Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (Outcomes	Mfr Control	<u># 50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17862152	EXPEDITED (15-DAY)				US-GILEAD-2 0468845	020-		334 DAY	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	<u>Mf</u>	[
Off Label Use; Produc Administered To Patie Of Inappropriate Age		esivir			S	Intravenous (not otherwise specified	37.5 Mg, (Once		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof 9	<u>Outcomes</u>	Mfr Control	<u>#</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17902698	EXPEDITED (15-DAY)		I	DE, OT	US-GILEAD-2 0472649	020-		77 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	<u>Mf</u>	<u>:</u>
Cardiac Arrest	Remd	esivir			S	Intravenous (not otherwise specified	200 Mg, O	nce		Gi	lead
	Remd	esivir			S	Intravenous (not otherwise specified	100 Mg, Q)	d		Gi	lead
	Allopu				С						t Reported
	Apixal				С						ot Reported
	Atorva				С						ot Reported
	Coreg				С						t Reported
	Enoxa Duloxe				C C						ot Reported of Reported
	Ertape				C						ot Reported ot Reported
	Fentai				C						ot Reported
	Folic A				Č						t Reported
	Furose	emide			C C						ot Reported
	Hydro	xychloroquine			С					No	t Reported
	Insulin				С						t Reported
		Iprednisolone			C C						ot Reported
		prazole			С						ot Reported
		rlephrine			С						ot Reported
	Prega	paiin			С					NO	ot Reported



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17908558	EXPEDITED (15-DAY)			НО	US-GILEAD-20 0472776)20-		46 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage 1	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg,	Once			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead
	Insulii Norm Azithr Ceftri Fenta Midaz Aceta Ascor Enoxa Insulii Methy Thian	ntidine n Regular [Insulin Bovine] al Saline romycin axone nyl colam aminophen rbic Acid aparin n Detemir //prednisolone nine Sulfate			0000000000000000						Not Reported
FDA Received Date		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17909732	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0472780	20-		55 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage 1	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Death	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg,	Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead



	Colch	nicine			S	Oral	0.6 Mg			Not Reported
	Asco	rbic Acid			С					Not Reported
	Cisat	racurium			С					Not Reported
	Fenta	anyl			С					Not Reported
	Hepa				C C					Not Reported
		zolam			С					Not Reported
	Nore	pinephrine			Ċ					Not Reported
		acillin/Tazobactam			Č					Not Reported
		ssium Chloride			Ċ					Not Reported
	Prop				C C					Not Reported
		zumab			Č					Not Reported
		erol [Salbutamol]			C					Not Reported
		astatin			C					Not Reported
		hexidine			C C C					Not Reported
		ecalciferol								Not Reported
		otidine			C C C					Not Reported
		n Aspart			C					Not Reported
	Leve	•			C					Not Reported
		ylprednisolone			C C					Not Reported
					C					Not Reported
	Sitag				C					
	Zinc	Sulfate			<u> </u>					Not Reported
DA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
1-Jul-2020	17967464	DIRECT	Υ	ТО	-			42 YR	Female	USA
referred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
anine Aminotransfer		<mark>uct</mark> desivir	Comp.	<u>OTC</u>	Role S	Route Intravenous (not	Dosage Text	<u>Duration</u>		Mfr Not Reported
lanine Aminotransfer creased; Aspartate			Comp.	<u>OTC</u>		Intravenous (not		<u>Duration</u>		_
lanine Aminotransfer creased; Aspartate minotransferase	rase Rem		Comp.	OTC				<u>Duration</u>		_
referred Term Ilanine Aminotransfer Increased; Aspartate Iminotransferase Increased FDA Received Date	rase Rem	desivir		OTC Prof Ou	s C	Intravenous (not)	<u>Duration</u>	<u>Sex</u>	Not Reported
lanine Aminotransfer ncreased; Aspartate minotransferase ncreased	rase Rem	desivir exor Study Drug			S C	Intravenous (not otherwise specified))			Not Reported Not Reported
lanine Aminotransfer creased; Aspartate minotransferase creased DA Received Date 1-Jul-2020	rase Remo	desivir exor Study Drug Case Type DIRECT	Health	Prof Ou	S C	Intravenous (not otherwise specified))	Age	<u>Sex</u> Male	Not Reported Not Reported Country
lanine Aminotransfer ncreased; Aspartate minotransferase ncreased FDA Received Date 01-Jul-2020 referred Term	rase Remo Selin Case # 17968112 Prod	desivir exor Study Drug Case Type DIRECT	Health Y	Prof Ou	S C atcomes	Intravenous (not otherwise specified) Mfr Control	# 503B Facility	Age 46 YR	<u>Sex</u> Male	Not Reported Not Reported Country USA
lanine Aminotransfer ncreased; Aspartate minotransferase ncreased FDA Received Date	rase Remo	desivir exor Study Drug Case Type DIRECT	Health Y	Prof Ou	S C etcomes	Intravenous (not otherwise specified) Mfr Control :	# 503B Facility	Age 46 YR	<u>Sex</u> Male	Not Reported Not Reported Country USA Mfr

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	Insu Fan Proj Nor Lora	K Plus Ilin Lispro notidine pofol epinephrine nzepam romorphone			000000				1 1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968116	DIRECT	Υ	0	Т			64 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Bradycardia		ndesivir mal Saline			S C	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17968121	DIRECT	Υ	0	Т			83 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Atrial Fibrillation	Ren	ndesivir			S	Intravenous drip		5 DAY	١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968349	DIRECT	Υ	0	Т			31 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Pruritus	Ren	ndesivir			S	Intravenous bolus	Other Frequency:Once;		(Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17968402	DIRECT	Υ	0	Т			61 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Aspartate	Ren	ndesivir			S	Intravenous drip			(Gilead
Aminotransferase	Pra	astatin 40 Mg-Home			С	•			1	Not Reported

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ncreased	Med	lication									
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17968586	DIRECT	Υ						52 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Therapy Interrupted	Rem	ndesivir			S	Intravenous bolus				ı	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17968698	DIRECT	Υ						66 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Alanine Aminotransfera Increased; Aspartate	ase Rem	ndesivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Glomerular Filtration Rate Decreas Liver Function Test Increased	sed; Azith Roca Dexa Love Lant	odipine 5mg(Home Med) nromycin 500mg Iv Daily ephin 1g Iv Daily amethasone 6mg Iv Daily enox 100mg Every 12 Hours tus 5-10 Units onix 40mg Iv Daily			C C C C C C C						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17969275	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0476702	020-		64 YR	Female	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Liver Function Test	Rem	ndesivir			S	Unknown	Unk			ı	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17969652	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-2 0477741	020-		87 YR	Male	USA
Preferred Term	Pro	duct	Comp.	отс	Role	Route	Dosage	e Text	Duration	N	Лfr

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Death	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	-	Tocilizumab			С	. ,	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	1796983	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0477758	20-	85 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
]	Dexamethasone			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	1797001	6 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0475372	20-	67 YR	Male	USA
Preferred Term	ļ	<u>Product</u>	Comp.	OTO	Role Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Acute Respiratory Fail Liver Function Test		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Increased; Multiple Or Dysfunction Syndrome Renal Impairment; Sep	e;	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Shock		Alprazolam			С		Unk, Prn			Not Reported
	(Guaifenesin			С		Unk, Prn			Not Reported
	,	Acetaminophen;Hydrocodone			С		Prn			Not Reported
	\	Vecuronium			С		Unk, Prn			Not Reported
	A	Ascorbic Acid			С		Unk			Not Reported
	,	Azithromycin			С	Intravenous (not otherwise specified)	Unk			Not Reported
	A	Azithromycin			С	Oral	Unk			Not Reported
	(Calcium Gluconate			С		Unk			Not Reported
	(Ceftriaxone			С		Unk			Not Reported
	(Cefepime			С	Intravenous (not otherwise specified)	Unk			Not Reported

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	Dopar	mine			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Etomi	date			С	otherwise specifica)	Unk				Not Reported
	Fenta	nyl			С		Unk				Not Reported
	Finast	eride			С		Unk				Not Reported
	Enoxa	aparin			С		Unk				Not Reported
	Fonda	aparinux			С		Unk				Not Reported
	Norma	al Saline			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Furos	emide			С		Unk				Not Reported
		cortisone Sodium			С		Unk				Not Reported
	Succii Norep	nate inephrine			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Pheny	/lephrine			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Phent	olamine			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17970047	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-202 0477761	20-		80 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration		Mfr
Death	Remd	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17970432	EXPEDITED (15-DAY)				US-GILEAD-202 0477650	20-		36 YR	Female	e USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Medication Error	Remd	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead



FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	179708	335	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0477744	20-		83 YR	Male	USA
Preferred Term		Product	:	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Death; Liver Function Increased	Test	Remdes	ivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
		Tocilizur	nab			С	,	Unk				Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	179711	55	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0477738	20-		44 YR	Male	USA
Preferred Term		Product	:	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased	rase	Remdes	ivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
		Ascorbio	Acid			С		Unk				Not Reported
		Dexame	thasone			С		Unk				Not Reported
		Tramado	ol			С		Unk				Not Reported
		Zinc Sulf	fate			С		Unk				Not Reported
		Acetamii	nophen			С		Unk				Not Reported
		Enoxapa	arin			С		Unk				Not Reported
		Guaifene	esin			С		Unk				Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	179711	72	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0477689	20-		44 YR	Male	USA
Preferred Term		Product	:	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased	rase	Remdes	ivir			S	Unknown	Unk				Gilead



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	Age	Sex	Country
01-Jul-2020	17971828	EXPEDITED (15-DAY)	neann	1101	Outcomes	US-GILEAD-2 0477767		32 YR	Female	
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Overdose	Remd	esivir			S	Intravenous (not otherwise specified	200 Mg, Qd)			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified	100 Unk			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17971883	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0477750	020-		Male	USA
<u>Preferred Term</u>	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Respiratory Failure	Remd	esivir			S	Intravenous (not otherwise specified	200 Mg, Qd)			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified	100 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17972596	DIRECT	Υ						Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Bilirubin Increas	sed Remd	esivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17972654	DIRECT	Υ		НО			63 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Body Temperature Increased; Hyperhidro Infusion Related Reac Tachycardia; Tachypn	tion;	esivir	Υ		S	Intravenous drip	Other Frequency:Once;	60 MIN		Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17972661	DIRECT	Y							Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Bilirubin Increas International Normalis Ratio Increased; Prothrombin Time Prolonged		emdesivir			S						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2020	17972667	DIRECT	Υ							Female	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Re	emdesivir			S						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17878097	EXPEDITED (15-DAY)		DI	E, OT	US-GILEAD-20 0470902)20-		70 YR	Male	USA
<u>Preferred Term</u>	<u>Pr</u>	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	Duration		<u>Mfr</u>
Cardiac Arrest; Covid-	·19 Re	emdesivir			S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead
	Pa	ntoprazole			С	. ,	Unk				Not Reported
	Pip	oeracillin / Tazobactam			С		Unk				Not Reported
	Va	ncomycin			С		Unk				Not Reported
	Mi	dazolam			С		Unk				Not Reported
		giotensin li			С		Unk				Not Reported
	Dil	tiazem			С		Unk				Not Reported
	Ke	tamine			С		Unk				Not Reported
		oumadin vophed			C C						Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17882667	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470043)20-		63 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role Role	Route	Dosage '	<u>Text</u>	Duration	<u> </u>	<u> Mfr</u>
Liver Function Test Increased	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Unl	<			Gilead
	Oxybu	ıtin			С		Unk				Not Reported
	Losart	an			С						Not Reported
	Enoxa	•			С						Not Reported
	Potas				00000						Not Reported
	Gabar				С						Not Reported
	Dulox				С						Not Reported
	Loraze				С						Not Reported
	Rocur				Ç						Not Reported
	Melato				C						Not Reported
		nyroxine			С						Not Reported
		ı Lispro			C C						Not Reported
	Buspii				Ç						Not Reported
	Amloc				C						Not Reported
	Predn				С						Not Reported
	Propo				С						Not Reported
	Pencil				С						Not Reported
	Norep	inephrine			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17887632	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470690)20-		50 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	ļ	<u>VIfr</u>
Drug-Induced Liver Inj Ischaemic Hepatitis; Li	ver	esivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
Function Test Increase Shock; Supraventricula Tachycardia				S	Intravenous (not otherwise specified)	100 Unl	<			Gilead	
		larone			S	Unknown					Not Reported



							•			
	P	ripiprazole			С		Unk			Not Reported
		ripiprazole amotidine			C C		Unk			Not Reported Not Reported
	H	lydromorphone			С		Unk			Not Reported
	1	nsulin Lispro			С		Unk			Not Reported
	1	nsulin Regular Hm			С		Unk			Not Reported
	(Ceftriaxone			С		Unk			Not Reported
	E	noxaparin			С		Unk			Not Reported
	١	lorepinephrine			С		Unk			Not Reported
	F	otassium			С		Unk			Not Reported
	F	Propofol			С		Unk			Not Reported
	N	Melatonin			С		Unk			Not Reported
	Е	Bupropion			С		Unk			Not Reported
		Bupropion Cetrizine			C C		Unk			Not Reported Not Reported
	(Sabapentin			С		Unk			Not Reported
	F	Prednisone			С		Unk			Not Reported
	5	Sertraline			С		Unk			Not Reported
		Sertraline Trazodone			C C		Unk			Not Reported Not Reported
	(Ocrelizumab			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	1789259	7 EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470641	20-	75 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Li Function Test Increase	iver F ed	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk			Gilead
	F	Propofol			С		Unk			Not Reported



	Norep	pinephrine			С		Unk				Not Reported
	Melat	onin			С		Unk				Not Reported
	Insuli	n Regular Hm			С		Unk				Not Reported
	Insuli	n Lispro			С		Unk				Not Reported
	Hydro	omorphone			С		Unk				Not Reported
	Famo	tidine			С		Unk				Not Reported
	Levot	hyroxine			С		Unk				Not Reported
	Atorva	astatin			С		Unk				Not Reported
	Linez	olid			С		Unk				Not Reported
	Insuli	n Glargine			С		Unk				Not Reported
	Cefep	pime			С		Unk				Not Reported
	Metol	azone			С		Unk				Not Reported
	Insuli	n Isophane			С		Unk				Not Reported
	Bume	etanide			С		Unk				Not Reported
	Losar	tan			С		Unk				Not Reported
	Metfo	rmin			С		Unk				Not Reported
	Plasm	na			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17918275	EXPEDITED (15-DAY)				US-GILEAD-2 0472228	2020-		73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Medication Error	Remo	lesivir			S	Intravenous (not otherwise specified		lg, Once			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified	100 M	lg, Qd			Gilead
		astatin			С						Not Reported
		omycin axone			C C C C						Not Reported Not Reported
		emide			Č						Not Reported
	Hepa				Č						Not Reported
		bacillus Rhamnosus			С						Not Reported



	Methy Succir	lprednisolone Sodium nate			С				١	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17940380	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-2 0474255	020-	41 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Dyspnoea; Throat Tightness	Remd	esivir			S	Intravenous (not otherwise specified	100 Mg, Qd)		C	Gilead
	Plasm	a			S	Unknown	Unk		N	lot Reported
	Doxyc	ycline			С		Unk		N	lot Reported
	Enoxa	parin			С		Unk		N	lot Reported
	Dextro	amphetamine Sulfate			С		Unk		N	lot Reported
	Citalo	oram			С		Unk		N	lot Reported
	Clona	zepam			С		Unk		N	lot Reported
	Monte	lukast			С		Unk		N	lot Reported
	Amitri	otyline			С		Unk		N	lot Reported
	Tociliz	umab			С		Unk		١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17973626	DIRECT	Υ		HO, RI			63 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Dialysis; Renal Impairment; Respirato Distress; Therapy Interrupted	Remd ry	esivir			S				C	Bilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17973938	DIRECT	Υ		ОТ			64 YR	Female	USA
Preferred Term	Produ	ı <u>ct</u>	Comp.	отс	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u>	fr



Abdominal Tenderness; Oedematous Pancreatitis		desivir			S	Intravenous (not otherwise specified)	1			Gilead
	Dexa	methasone			С	, , , , ,				Not Reported
		fibrate			Č					Not Reported
	Aceta	aminophen			C C					Not Reported
	Atorv	astatin			С					Not Reported
	Ceftri	axone			С					Not Reported
	Cyclo	benzaprine			С					Not Reported
	Diltia				С					Not Reported
	Doxy	cycline			С					Not Reported
	Enox	aparin			C C C					Not Reported
	Ketor	olac			С					Not Reported
	Hydro	omorphone			C C					Not Reported
		thyroxine			С					Not Reported
	Meto				С					Not Reported
		insetron			С					Not Reported
		odone Immediate Release			С					Not Reported
		odone 12 Hour			С					Not Reported
		oprazole			C					Not Reported
		thicone								Not Reported
		nlorperazine			С					Not Reported
	Ropir				С					Not Reported
	Rame	elteon			С					Not Reported
FDA Received Date C	ase #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020 1	7973951	DIRECT	Υ	DI	E			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	desivir			S	Intravenous drip				Gilead
	Dexa	methasone			С					Not Reported
	Hepa				С					Not Reported
	Insuli									Not Reported
	Levet	tiracetam			C C C					Not Reported
		oprazole			С					Not Reported
	Piper	acelli/Tazobactam			C C					Not Reported
	Propo	ofol			С					Not Reported
	Valpr	oic Acid			С					Not Reported



FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
02-Jul-2020	17973957	DIRECT	Υ					37 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased	Rem	ndesivir	Y		S	Intravenous drip				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17973971	DIRECT		(OT			64 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed Rem	ndesivir			S	Intravenous (not otherwise specified)				Not Reported
		aminophen 500mg Po Q6h			С	otherwise specifica)				Not Reported
	Prn Dexa	amethasone 6mg lvp Daily			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17973976	DIRECT		(TO			64 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Renal	Rem	ndesivir			S	Intravenous (not otherwise specified)				Not Reported
Impairment	Dexa	rin 81mg Daily amethasone 6mg Ivp Daily epinephrine Iv Drip			C C C	outer mee opeemee)				Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17973979	DIRECT		H	Ю			65 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate	Rem	ndesivir			S					Not Reported

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Aminotransferase Increased										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974146	DIRECT	Υ					80 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Therapy Cessation	Remo	desivir			S	Intravenous (not otherwise specified)			G	ilead
	Dexa	methasone			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974168	DIRECT	Υ	H	HO, OT			47 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfer Increased; Aspartate	rase Remo	desivir			S	Intravenous (not otherwise specified)			G	ilead
Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration F Decreased		ofol Synephrine			C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974184	DIRECT	Υ					77 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Liver Function Test ncreased	Remo	desivir			S	Intravenous (not otherwise specified)			No	ot Reported
	Lipito				С	. ,				ot Reported
	Roce Zithro				C C					ot Reported ot Reported
	Aspiri				C					ot Reported
	Allopi				Č					ot Reported
	Tylen				С					ot Reported
	Lover	nox			С				No	ot Reported

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	Solur Mucii Prilos Veraj Lantu Huma	sec pamil us			C C C C C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974353	DIRECT	Υ	C	DΤ			63 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remo	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Conv Enox Aceta	methasone 6 Mg Daily alescent Plasma aparin 40 Mg Daily aminophen 650 Mg Every 4 s As Needed			C C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974358	DIRECT	Υ	L	T, OT			58 YR	Male	USA
Preferred Term	Prod	l <u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	rase Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Therapy Interrupted	Albut Cisat Dexa Fenta Hepa Hydra Huma Regla Verse	racurium methasone anyl urin alazine ulin R an ed pinephrine unix			000000000000					Not Reported

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						Dotanoa n	opo. c				
	Senna Robitus Vancom Ceftazio	nycin			C C C					No No	t Reported t Reported t Reported t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974408	EXPEDITED (15-DAY)				US-GILEAD-2 0478162	020-		43 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Product Preparation E	rror Remdes	sivir			S	Intravenous drip	200 M	lg, Once		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974504	DIRECT	Υ	0	Т				77 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Acute Kidney Injury; Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Cardiac Arrest; Glome Filtration Rate Decreas International Normalise Ratio Increased; Liver Function Test Increase Transaminases Increase	rular sed; ed	sivir			S	Intravenous (not otherwise specified	l)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17974863	EXPEDITED (15-DAY)				US-GILEAD-2 0478240	020-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Medication Error					S						



							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17976027	EXPEDITED (15-DAY)				US-GILE 0478186	\D-2020-			Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	Duration	<u>M</u>	<u>fr</u>
Product Storage Error	Remde	esivir			S	Intravenous (no otherwise spec				C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17976305	EXPEDITED (15-DAY)			ОТ	US-GILE 0478153	ND-2020-			Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Liver Function Test Increased	Remde	esivir			S	Unknown	Unk			C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17982134	DIRECT	Υ						52 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Product Dispensing En Therapy Interrupted	ror; Remde	esivir			S	Intravenous (no otherwise spec				C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17982135	DIRECT	Υ		НО				43 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Chronic Kidney Diseas	se Remde	esivir	Υ		S	Intravenous bo	lus			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17982136	DIRECT	Υ		DE				85 YR	Male	USA
Preferred Term	Produ	ct	Comp.	отс	Role	Route	Dosag	o Toyt	Duration	M	<u>fr</u>

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Renal Failure	Docus Epine Hydro Methy Midaz Norep Senno Sucra Vanco Vasop	oime edotomidine sate phrine imorphone rolam oinephrine oside lfate omycin oressin	Y		8000000000000					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17982137	DIRECT		Н)			66 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Ceftria Dexai Docus Metop	zolam nra omycin axone methasone sate	Y		s					Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17982138	DIRECT	Υ					81 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Anxiety; Feeling Hot; Flushing	Lantu Azithr Ceftri	nine Inj s omycin			8 C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported



						Dotanoa No	Port			
		Dexamethasone Enoxaparin Atorvastatin			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	179821	46 DIRECT	Υ					48 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer ncreased	ase	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	179821	50 DIRECT	Υ	0	Г			50 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer ncreased; Aspartate Aminotransferase ncreased; Cardiac Ari Hypoxia; Liver Functio Fest Increased	rest;	Remdesivir	Y		S	Intravenous bolus				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	179821	55 DIRECT	Υ	DI	≣			32 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Fail Cardiac Arrest;	lure;	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Hypercapnia; Hypoxia Metabolic Acidosis; Multiple Organ Dysfunction Syndrome	_	Convalescent Plasma Enoxaparin 60 Mg Sq Q12hrs Methylprednislone 60 Mg Ivp Q6hr			C C	эн эн эн				Not Reported Not Reported Not Reported
		Remdesivir 200 Mg Iv X 1 Remdesivir 100 Mg Iv Once Daily			C					Not Reported Not Reported

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	Ascor	bic Acid 1,000 Mg			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control :	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2020	17982267	DIRECT	Υ		DS, LT, OT				66 YR	Male	USA
Preferred Term	Produ	uct	Comp.	ОТО	Role Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Cardiac Arrest; Hepati Pulseless Electrical Activity	Remd	esivir			S						Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17877919	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470907	20-		91 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role Role	Route	Dosage	Text	<u>Duration</u>		Mfr
Respiratory Failure	Remd	esivir			S	Intravenous (not otherwise specified)		g, Once			Gilead
	Aceta	minophen			С		Unk				Not Reported
	Ceftria	n (E.C.) axone emide prolol			000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17878098	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470903	20-		74 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	<u>Dosage</u>	Text	Duration		Mfr
Acute Respiratory Dist Syndrome; Covid-19;	ress Remd	lesivir			S	Intravenous (not otherwise specified)	100 Mç	g, Qd			Gilead
Multiple Organ Dysfunction Syndrome	vanice	omycin erol Hfa			C C C	•					Not Reported Not Reported Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17887631	EXPEDITED (15-DAY)			OT	US-GILE 0470900	AD-2020-		41 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTO	Role	Route	Dosa	ge Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Rem	desivir			S	Unknown	200	Mg, Once			Gilead
Increased; Aspartate Aminotransferase	Rem	desivir			S	Unknown	100	Mg, Qd			Gilead
Increased	Rem	desivir			S	Unknown	100	Mg, Qd			Gilead
	Plas	ma			С		Unk				Not Reported
	Toci	lizumab			С		Unk				Not Reported
	Arfor Bude Doci Enox Fam Insu Pota Roci Ropi Lora Fent Keta Mida	ssium Chloride uronium nirole zepam anyl mine uzolam medetomidine			00000000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17898305	EXPEDITED (15-DAY)			DE, OT	US-GILE 0471872	AD-2020-		91 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTO	Role	Route	Dosa	ge Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; De	eath Rem	desivir			S	Unknown	200	Mg, Once			Gilead
	Rem	desivir			S	Unknown		Mg, Qd			Gilead
	Amio	odarone			С		Unk	~ ,			Not Reported



								-				
		Apixaban			С			Unk				Not Reported
		Plasma			С			Unk				Not Reported
		Bumex			С			Unk				Not Reported
		Plavix			С			Unk				Not Reported
		Dexamethasone			С			Unk				Not Reported
		Heparin			С			Unk				Not Reported
		Insulin			С			Unk				Not Reported
		Protonix [Omeprazole]			С			Unk				Not Reported
		Metoprolol			С			Unk				Not Reported
		Nitroglycerin			С			Unk				Not Reported
		Hydralazine			С			Unk				Not Reported
		Isosorbide Mononitrate			С			Unk				Not Reported
		Tamsulosin			С			Unk				Not Reported
		Lorazepam			С			Unk				Not Reported
		Hydromorphone			С			Unk				Not Reported
		Bicarbonate			С			Unk				Not Reported
FDA Received Date	Case	<u>Case Type</u>	Health	Prof (<u> Outcomes</u>		Mfr Control #	<u>‡</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17898	779 EXPEDITED (15-DAY)		[DE, DS, LT,	ОТ	US-GILEAD-20 0472460)20-		61 YR	Male	USA
Preferred Term		Product	Comp.	<u>otc</u>	Role	Rou	<u>ite</u>	Dosage	Text	<u>Duration</u>		<u>Mfr</u>
Atrial Flutter; Cerebrovascular Accid	dent;	Remdesivir			S		venous (not wise specified)	200 M	g, Qd			Gilead
Death; Pulmonary Function Test Decreas	sed	Remdesivir			S		venous (not wise specified)	100 M	g, Qd			Gilead
		Plasma			С			Unk				Not Reported
		Norepinephrine			С			Unk				Not Reported
		Amiodarone			С			Unk				Not Reported
		Vancomycin			С			Unk				Not Reported
		Zosyn			С			Unk				Not Reported



	Azithromycin			С					Not Reported
	•					Unk			•
	Lovenox [Enoxaparin Sodium]			С		40 Mg Sq Bid			Not Reported
I	Lovenox [Enoxaparin Sodium]			С		80 Mg Sq Bid			Not Reported
I	Lovenox [Enoxaparin Sodium]			С		40 Mg Sq Bid			Not Reported
	Acetaminophen			С					Not Reported
	Albuterol [Salbutamol]			С					Not Reported
	Aspirin [Acetylsalicylic Acid]			С					Not Reported
	Enoxaparin			С					Not Reported
	Normal Saline			С					Not Reported
	Piperacillin/Tazobactam			C C					Not Reported
	Potassium Chloride			С					Not Reported
	Albuterol;Ipratropium			С					Not Reported
	Famotidine			С					Not Reported
	Fentanyl			C					Not Reported
1	Furosemide			С					Not Reported
	Propofol			С					Not Reported
	Succinylcholine			С					Not Reported
	[Suxamethonium Chloride]								
	Folic Acid			С					Not Reported
1	Lactated Ringers			С					Not Reported
-	Thiamine			C C C					Not Reported
,	Vecuronium			С					Not Reported
	Formoterol								Not Reported
	lohexol			С					Not Reported
	Potassium Phosphate			С					Not Reported
ſ	[Potassium Phosphate Dibasic]								•
	Sodium Bicarbonate			С					Not Reported
I	Lorazepam			С					Not Reported
I	Morphine			С					Not Reported
	Scopolamine [Hyoscine]			С					Not Reported
FDA Received Date Case #	Case Type	<u>Health</u>	Prof Out	comes	Mfr Control #	503B Fac	ility Age	<u>Sex</u>	Country
03-Jul-2020 1791823	32 EXPEDITED (15-DAY)		DE	ОТ	US-GILEAD-202 0473912	20-	88 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Distress Syndrome; Covid-19	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Amlodipine			С	. ,				Not Reported



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	C D E L	holecalciferol yanocobalamin examethasone noxaparin evothyroxine ydromorphone			00000				N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982159	DIRECT	Υ					16 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfe Increased; Aspartate	rase R	emdesivir			S	Intravenous (not otherwise specified	d)		G	ilead
Aminotransferase Increased; Liver Func Test Increased	tion A	cetaminophen Ibuterol examethasone			C C C				N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982172	2 DIRECT	Υ					24 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Liver Function Test Increased	R	emdesivir			S	Intravenous (not otherwise specified	d)		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982173	B DIRECT	Υ	0	Т				Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury; Alanine Aminotransfe Increased; Aspartate Aminotransferase Increased; Cardiac Ar	rase N A	emdesivir orepinephrine torvastatin			S C C				N	ot Reported ot Reported ot Reported



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982174	DIRECT	Υ					35 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>otc</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Rem	ndesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982175	DIRECT	Υ	DI	E			63 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Dialysis	Rem	ndesivir			S	Intravenous (not otherwise specified)				Gilead
	Con	valescent Plasma			С	otherwise specifica,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982177	DIRECT	Υ	Н	0			69 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Creatinine Increased; Hepatic	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Enzyme Increased	Asco Cho Zinc Azitl Ceft Fent Mida Dex	odarone Drip orbic Acid Tablet lecalciferol Sulfate Capsule nromycin Iv riaxone Iv tanyl Drip azolam Drip amethasone Iv xaparin Inj			000000000	, , , , , , , , , , , , , , , , , , , ,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982178	DIRECT	Υ	0	Т			72 YR	Male	USA

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Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasa	ation Rem	desivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	<u>Case Type</u>	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982179	DIRECT	Υ					34 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Incorrect Dose Administered; Product Dose Omission; Transcription Medicati Error		desivir	Y		S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982180	DIRECT	Υ	D	E			37 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Condit Aggravated; Hepatic	ion Rem	desivir			S	Intravenous (not otherwise specified)			Not Reported
Failure; Respiratory Disorder		izumab valescent Plasma			C C		,			Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982188	DIRECT	Υ	D	S, OT			76 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Li Function Test Increase		desivir			S	Intravenous (not otherwise specified)			Gilead
	Dexa Enox Meto	vastatin amethasone caparin oprolol oprazole			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
		grelor			č					Not Reported

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	Fenta Hepa	rin ylephrine			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982194	DIRECT	Υ	DE	Ē			46 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir	Υ		S	Intravenous bolus				Gilead
	Insulii Levof Loraz Aceta Dopai	aparin 90mg n Lispro loxacin 750mg epam 0.5mg iminophen 650mg mine Drip binephrine Drip			0000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	17982200	DIRECT	Υ	LT				55 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir	Υ		S	Intravenous bolus				Gilead
	Cefep Chlori Dexai Enoxa Furos Insulii Linezi Merop Multiv Cisatr Fenta Norep	erol 4mg bime 1g hexidine Mouthwash methasone 6mg aparin 90mg semide 20mg n Lispro olid 600mg benem 1g vitamin racurium Drip anyl Drip binephrine Drip			00000000000000					Not Reported

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		Midazola	m Drip			С					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	179822	01	DIRECT	Υ		LT			65 YR	Male	USA
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Dialysis; General Physical Heal Deterioration; Klebsiel Infection; Liver Function Test Increased; Pneumonia Bacterial; Sepsis	lth la on	Amiodaro Docusate Famotidii Insulin Piperacill Vancomy Senna Fentanyl Midazola Norepine Phenylep Propofol Rocuroni Vasopres	one e Senna ne in/Tazobactam /cin m phrine ohrine	Y		s	Intravenous (not otherwise specified)	2 DAY		Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2020	179822	07	DIRECT	Υ		LT			51 YR	Male	USA
Preferred Term		Product		Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B	lood	Remdesi	vir	Υ		S	Intravenous bolus	Other Frequency:Once;			Gilead
Urea Increased		Remdesi	vir	Υ		S	Intravenous bolus				Gilead
		Dexamet Enoxapa Furosem	ne 10mg			00000000					Not Reported

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						Dotalloa Itt	5 6 6 1			
	M S V P P F N P V	antoprazole 40mg liralax 17g ertraline 100mg ancomycin 1500mg otassium Chloride 20meq recedex Drip entanyl Drip orepinephrine Drip ropofol Drip ersed Drip zithromycin 500mg			0000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17982210	DIRECT	Υ					16 YR	Female	e USA
Preferred Term	P	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer	ase R	emdesivir			S	Intravenous bolus				Gilead
Increased; Aspartate Aminotransferase Increased	Ā	examethasone zithromycin amotidine			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jul-2020	17982208	3 DIRECT	Υ	0	Γ			54 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Transamina Increased		emdesivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jul-2020	17982259	DIRECT	Υ	0	Г			66 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury;	R	emdesivir			S					Not Reported

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Therapy Cessation											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jul-2020	17982241	DIRECT	Y	D	E				59 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Concomitant Disease Aggravated; Covid-19	Calciu Dexa Fenta Hepa				\$ C C C C						Gilead Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jul-2020	17982246	DIRECT	Υ	D	S, HO, OT				56 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Haemodialy		desivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17892593	EXPEDITED (15-DAY)		L	Г, ОТ	US-GILEAD-2 0470929	020-		57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Hypotension	Remo	desivir			S	Intravenous (not otherwise specified		g, Once			Gilead
	Zinc				С						Not Reported
	Panto	prazole			С						Not Reported
		penem			C						Not Reported
		hyroxine			С						Not Reported
		iracetam			С						Not Reported
	Hydro Famo	ocortisone			C						Not Reported Not Reported
		aparin			C						Not Reported
		[Ciprofloxacin]			C						Not Reported
		omycin			C						Not Reported

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		Ascorbic Dopamir Norepine Vasopre: Plasma Nacl Alprazola Calcium	ephrine ssin			0000000					Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	179830	88	DIRECT	Υ	Н)			71 YR	Male	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase		Remdesi	ivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Increased; Blood Creatinine Increased		Ceftriaxo Azithrom				C C					Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	179831	112	DIRECT	Υ	0	Γ			66 YR	Male	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Coagulopathy; Inflammation; Liver Inju	urv	Remdesi 100mg/V	ivir For Injection /ial			S	Intravenous bolus				Gilead
	y	Azithrom Ceftriaxo Dexame	ycin one			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	179831	193	DIRECT		0	Γ				Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Erythema Infusion Site Extravasation; Infusion Site Pain; Infusion Site	1	Remdesi 5mg/MI S	ivir (Emergency Use) Solution	Y		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;			Gilead

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

Swelling; Lip Swelling;

Swollen Tongue										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983340	DIRECT		D	E				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Death		desivir (Emergency Use) MI Solution	Υ		S	Intravenous (not otherwise specified)	Frequency: Q24h		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983444	DIRECT		D	Е				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Death		desivir (Emergency Use) MI Solution	Υ		S		Other Route:Iv		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983447	DIRECT		D	E				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death		desivir (Emergency Use) MI Solution	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;Other Route:Iv		Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983700	DIRECT		D	E				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	, -
Death		desivir (Emergency Use) MI Solution	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Q24h;		Gil	ead



							<u> </u>			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983885	EXPEDITED (15-DAY)				US-GILEAD-2 0478621	020-		Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mfr</u>	
Medication Error	Remd	lesivir			S	Unknown			Gile	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983929	DIRECT	Υ					81 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Diarrhoea	Remd	lesivir	Υ		S	Intravenous bolus		5 DAY	Gile	ead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983955	DIRECT		Н	O, OT			66 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased; Oxygen Saturation Decreased; Renal Impairment	Remd	lesivir			S	Intravenous bolus			Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17983959	DIRECT	Y	0	Г			44 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer	ase Remd	lesivir	Υ		S	Intravenous drip			Gil	ead
Increased; Aspartate Aminotransferase Increased	Famo Docus Morph Furos	sate			C C C	·			No No	t Reported t Reported t Reported t Reported



FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17984057	DIRECT	Υ	(TC			70 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Bradycardia	Remo	desivir			S	Intravenous (not otherwise specified)		(Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17984090	DIRECT	Υ					40 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatinine		desivir			S	Intravenous drip			(Gilead
Increased; Sars-Cov-1 Test Positive	Cabo	sonide 0.5 Mg Nebulizer xymethylcellulose nalmic Drops			C C					Not Reported Not Reported
	Cisati	acurium			C					Not Reported
	Fenta Insuli	nyl n Aspart & Detemir			C C					Not Reported Not Reported
		ropium-Albuterol Nebulizer			С				!	Not Reported
	Ketar				С					Not Reported
	Midaz Norer	zoiam Dinephrine			C C					Not Reported Not Reported
	Propo				Č					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17984415	DIRECT	Υ	(TC			70 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; B Creatinine Increased; Prerenal Failure; Respiratory Failure	lood Remo	lesivir			S	Intravenous (not otherwise specified	Other Frequency:Once;		(Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17984440	DIRECT	Υ	(ТС			57 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	Aceta Cefep Dexai Lisino Monte Tams	minophen ime methasone pril elukast ulosin			S C C C C C C C	Intravenous (not otherwise specified)	Other Frequency:Once;			Not Reported
		omycin m Chloride 0.9%			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17984443	DIRECT	Υ					70 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Asthenia; Cough;	Remo	lesivir			S	Intravenous drip				Gilead
Dyspnoea; Pyrexia	Remo	lesivir			S	Intravenous drip				Gilead
	Ophth Cisatr Dexm Enoxa Fenta	nyl ılazine า			0 000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
06-Jul-2020	17984445	DIRECT	Υ	(ТС		•	76 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>

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Aspartate Aminotransferase	Rem	ndesivir			S	Intravenous drip	Other Frequency:One Time Dose;			Gilead
Increased	Ator Dexa Eno: Ond Ergo	taminophen vastatin amethasone xaparin ansetron ocalciferol Sulfate			0000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17985429	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0479043	20-	81 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Albu	terol Hfa			С	. ,				Not Reported
	Asco	orbate De Sodium			С					Not Reported
	Cho	lecalciferol			С					Not Reported
		xaparin			С					Not Reported
		otidine			С					Not Reported
		ase [Fluticasone Propionate]			С					Not Reported
	Insu				С					Not Reported
		tadine			С					Not Reported
		atonin			С					Not Reported
		metazoline			С					Not Reported
		Sulfate			С					Not Reported
	Pron	nethazine With Codeine			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17987868	DIRECT	Υ					47 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Swelling; Thrombotic Thrombocytopenic Purpura	Rem	ndesivir			S	Intravenous (not otherwise specified)				Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17987887	DIRECT	Υ	0	T			14 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer ncreased; Aspartate	ase Remo	desivir			S	Intravenous (not otherwise specified)		1 DAY		Gilead
Aminotransferase ncreased; Therapy Cessation	Remo	desivir			S	Intravenous (not otherwise specified)		2 DAY		Gilead
	Anak				C					Not Reported
		amycin			С					Not Reported
	Cefe				С					Not Reported
	Conv	alescent Plasma			C C					Not Reported Not Reported
	Adva				C					Not Reported
		" elukast			C					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
06-Jul-2020	17987893	DIRECT	Υ	D	E			63 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>luct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Respiratory Fail Brain Death; Brain	ure; Remo	desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Herniation; Cerebral	Remo	desivir	Υ		S	ound opcomed)				Gilead
nfarction;	Δtovs	astatin	•		Č					Not Reported
Cerebrovascular Accid	dent;				Č					Not Reported
Pupil Fixed; Renal Fai		ecalciferol			Č					Not Reported
	Clopi	dogrel			C					Not Reported
	Aspri				С					Not Reported
		rbic Acid			С					Not Reported
		dipine			С					Not Reported
		methasone			С					Not Reported
	Docu				C					Not Reported
	Hepa				С					Not Reported
	Huma				С					Not Reported
	Lantu				С					Not Reported
	vanc	omycin			С					Not Reported

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		Norepin				00000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	179879	000	DIRECT	Υ	ОТ				88 YR	Male	USA
Preferred Term		Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Hepatic Enzyme		Remdes	sivir			S	Intravenous drip				Gilead
Increased		Atorvas Ceftriax Ampicill Dexame Furoser Sertralir Heparin	one in ethasone mide ne			000000					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	179879	005	DIRECT	Υ	DE				31 YR	Female	e USA
Preferred Term		Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Haemodynamic Instab Haemoglobin Decreas		Remdes	sivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Klebsiella Infection; Multiple Organ Dysfunction Syndrome	ā.	Remdes	sivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Pneumonia Pseudomo		Albutero				C C					Not Reported
Respiratory Failure;		Ascobio				С					Not Reported
Thrombocytopenia		Choleca				C					Not Reported
		Fentany Humalo				C					Not Reported Not Reported
		Merope	•			C					Not Reported
			erdnisolone Tapper			Ċ					Not Reported
		Micafun	gin			С					Not Reported

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FDA Received Date	Protor Selen Zinc Vancc Tpn Hepar Levop Verse Rocur Vasop Fonda Hepar		Woolth	Prof. C	C C C C C C C C C C	Mfr Control #	£ 503B Facility	Ago	Sov	Not Reported
FUA Received Date	<u>Uase #</u>	<u>case rype</u>	nealth			WIII CONTROL #	DUDD FACILITY	<u>Age</u>	<u>Sex</u>	
06-Jul-2020	17987929	DIRECT	Υ	D	E			60 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remd	lesivir			S	Intravenous bolus				Gilead
Increased	Azithr Dexm Dexar D5 Ns Docus Enoxa Hours Fenta Guaife Lactol Levofl Loraz Norep	nyl 0.35-05mcg/Kg enesin 400mg bacillus loxacin 750mg			000000 000000 0					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17987937	DIRECT	Υ	Н	Ю			43 YR	Male	USA



Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remde Azithro Ceftria Dexam	mycin	Y		S C C C	Intravenous drip		5 DAY		Gilead Not Reported Not Reported Not Reported
FDA Received Date Ca	se #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020 179	988013	DIRECT	Υ	F	Ю			49 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Blood Urea Increased; C-Reactive Protein Increased; Chest X-Ray Abnormal; Covid-19; Dyspnoea; Interleukin Level Increased; Parosmia; Platelet Count Decreased; Respiratory Failure; Sars-Cov-2 Test Positive; Taste Disorder	Remde	esivir			S					Not Reported
FDA Received Date Ca	<u>se #</u>	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020 179	988060	DIRECT	Υ		ÞΕ			60 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress		esivir			S	Intravenous (not otherwise specified)			Not Reported
Syndrome; Blood Calcium Decreased; Blood	Remde	esivir			S	Intravenous (not	Other Frequency:Every 2	4		Not Reported

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Creatinine Increased; Blood Sodium Decreased; Blood Urea Increased; Cardiac Arrest; Covid- Pneumonia; Oxygen Saturation Decreased; Renal Tubular Necrosi Respiratory Failure; Sa Cov-2 Test Positive; Sepsis	19 Aspirin Ceftria Azithro s; Guaife	xone omycin parin			000000	otherwise specified)	Hour;		No No No No	ot Reported of Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
06-Jul-2020	17988148	DIRECT	Υ	C	T			66 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Sars-Cov-2 Test Positi Vaginal Haemorrhage	ve; Remde	esivir			S	Intravenous (not otherwise specified)			Gil	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	17988186	DIRECT	Υ	H	Ю			63 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Ammonia Increased; Aspartate	Remde				_					
Aminotransferase Increased; Blood Biliru Increased; Chills; Cou- Dyspnoea; Hypotensio Myalgia; Nausea; Oxy- Saturation Decreased; Platelet Count Decrease Pneumonia Viral; Pyre Renal Failure; Urine	gh; on; gen sed;	esivir			S				No	ot Reported
Aminotransferase Increased; Blood Biliru Increased; Chills; Coupyspnoea; Hypotension Myalgia; Nausea; Oxystaturation Decreased; Platelet Count Decreased; Pneumonia Viral; Pyre Renal Failure; Urine Output Decreased	gh; on; gen sed;	esivir Case Type	Health	Prof C	S Outcomes	Mfr Control #	503B Facility	<u>Age</u>	No.	t Reported Country

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							<u> </u>			
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Alanine Aminotransfera Increased; Aspartate	se	Remdesivir 100 Mg/20 Ml Iv Solution (Eua Suppl	Y		S	Intravenous (not otherwise specified)			G	Gilead
Aminotransferase Increased; Hepatic Enzyme Increased		Tocilizumab (Actemra) 800mg			S				٨	lot Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2020	179884	109 DIRECT	Υ						Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera Increased	se	Remdesivir			S				٨	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17910 ²	EXPEDITED (15-DAY	()		DE, OT	US-GILEAD-20 0473143)20-	46 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Blood Creatinine Increased; Death;		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	Gilead
Hepatotoxicity; Hypotension; Infection;		Acetylcysteine			С	Oral	Unk		N	lot Reported
Ischaemic Hepatitis;		Ascorbic Acid			С		Unk		N	lot Reported
Ischaemic Hepatitis; Liv Function Test Increased		Aspirin [Acetylsalicylic Acid]			С		Unk		N	lot Reported
Platelet Count Decrease		Enoxaparin			С		Unk			lot Reported
Pneumonia; Renal Impairment; Septic Sho	ck	Fentanyl			С		Unk			lot Reported
paioni, copilo ono		Insulin Lispro			С		Unk			lot Reported
		Levalbuterol [Levosalbutamol]			С		Unk			lot Reported
		Norepinephrine			С		Unk			lot Reported
		Pantoprazole			С		Unk		N	lot Reported
		Propofol			С		Unk		N	lot Reported
		Normal Saline			С		Unk		N	lot Reported
		Zinc Sulfate			С		Unk		N	lot Reported

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	Zos	yn			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17988860	DIRECT	Υ					73 YR	Female	USA
Preferred Term	<u>Pro</u>	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Alanine Aminotransfer ncreased; Aspartate	ase Ren	ndesivir	Υ		S	Intravenous (not otherwise specified)		10 DAY		Gilead
Aminotransferase	Asp	irin			С					Not Reported
ncreased		hromycin			С					Not Reported
		triaxone			С					Not Reported
		atracurium			C					Not Reported
		adron			С					Not Reported
	Digo				С					Not Reported
		tanyl			С					Not Reported
	Las				С					Not Reported
		oarin			C C					Not Reported
		epinephrine rivan			C					Not Reported Not Reported
	Ырі									Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17988990	DIRECT	Υ		ОТ			29 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Calculus Bladder; Flar Pain; Haematuria	nk Ren	ndesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17988996	DIRECT	Υ					84 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Dyspnoea; Respiratory Symptom	y Ren	ndesivir			S	Intravenous (not otherwise specified)				Gilead
		xaparin 40 Mg vastatin 40 Mg			C	. ,				Not Reported Not Reported

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	Asp	pirin Ec 81 Mg			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989008	DIRECT	Υ		ОТ			60 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; White Blood Cell Cour		ndesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Decreased		monium Lactate Topical 1 o Bid			С	. ,				Not Reported
		nazepam 0.5 Mg Po Bid			С					Not Reported
		kamethasone 6 Mg Po Daily			С					Not Reported
	Tab	alproex Sodium 125 Mg Ec blet Po Tid			С					Not Reported
		etiracetam 1000 Mg Po Hs			С					Not Reported
	Mirt Hs	tazapine 15 Mg Dis Tablet Po)		С					Not Reported
		tulose 40 G Po Bid Prn			С					Not Reported
	Mel	atonin 15 Mg Po Hs			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989012	DIRECT	Υ					53 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Nausea; Vomiting	Rer	ndesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Hyd 1.5r	drocodone-Homatropine 5-			С					Not Reported
		ctrim Ds			С					Not Reported
	Cep	ohalexin 500mg			С					Not Reported
		ulin Lispro 4 Units			С					Not Reported
		ulin Glargine 6 Units			С					Not Reported
		nzonatate 200mg			C C					Not Reported
		etaminophen 650mg			С					Not Reported
		oxaparin 40mg			C					Not Reported
		kamethasone 6mg lv			Ç					Not Reported
	Albı	uterol 2.5mg Inh			С					Not Reported



Electrical Activity;

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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989536	DIRECT	Υ		ОТ			73 YR	Female	USA
Preferred Term	<u>Pi</u>	roduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Abdominal Tenderness Anorectal Discomfort;	•	emdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Hypophagia; Nausea; Candidiasis; Oral Discomfort; Oral	Oral Re	emdesivir			S	Intravenous (not otherwise specified)				Gilead
Discomfort; Therapy Cessation; Tongue Discomfort	Di Fa Fl Hy M Ny Oi Po Pr	corvastatin 10mg Iltiazem 240mg Cd amotidine 20mg ecainide 150mg ydrochlorothiazide 12.5 Mg etoprolol 25mg ystatin 5ml Oral Suspension meprazole 40mg otassium ednisone 40mg varoxaban 20mg			00000000000					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989541	DIRECT	Υ		DE			78 YR	Female	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Myocardial Infarction; Acute Respiratory Failure; Bradycardia; Cardiac Arrest; Chest Pain; Confusional State; Electrocardiogram Abnormal; Hypoxia; Metabolic Encephalopathy; Pneumonia Viral; Pulse Absent; Pulseless		emdesivir			S	Intravenous bolus				Gilead



Troponin Increased										
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	179895	79 DIRECT			ОТ			68 YR	Male	USA
Preferred Term		Product	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed	Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
		Amiodarone 200mg Po Daily Aspirin 162mg Po Daily Dexamethasone 8mg Ivp Daily Dexmedetomidine Iv Drip Dexamethasone 6mg Ivp Daily			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	179895	82 EXPEDITED (15-DAY	")		ОТ	US-GILEAD-20 0479372	020-	48 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Rosuvastatin Insulin Glargine Tocilizumab Enoxaparin Furosemide Metoprolol			00000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	179895	84 DIRECT			ОТ			68 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Impairment		Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
		Enoxaparin 40mg Sq Daily Aspirin 162mg Po Daily			C C	. ,				Not Reported Not Reported

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						Detailed Ne	Port				
	Dexme Furose Dexan	nethasone 8mg Ivp Daily edetomidine Iv Drip emide 40mg Ivp Bid nethasone 6mg Ivp Daily nephrine Iv Drip			C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989596	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0479362	20-		46 YR	Male	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Enoxa Bio K I Insulin Famot Propol Norepi Loraze	Plus Lispro idine fol nephrine			00000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989615	EXPEDITED (15-DAY)		Н)	US-GILEAD-20 0479459	20-		66 YR	Male	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Docus Metop	olam nra omycin xone nethasone ate			8 0000000	Unknown	Unk				Gilead Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17989632	EXPEDITED (15-DAY)			НО	US-GILEAD-2 0479491	020-		69 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Hepatic Enzyme Increased	Ascor Chole Zinc S Azithr Ceftric Fenta Midaz	darone bic Acid calciferol Sulfate omycin axone nyl			8 00000000	Intravenous (not otherwise specified	100 Mg)	g, Qd			Gilead Not Reported
_	Enoxa	aparin			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17990947	EXPEDITED (15-DAY)				US-GILEAD-2 0479511	020-		34 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Intentional Dose	Remd	lesivir			S	Unknown	200 Mg	1			Gilead
Omission; Product Dispensing Error	Remd	lesivir			S	Unknown	200 Mg)			Gilead
Disperising Error	Remd	lesivir			S	Unknown	100 Un	ık			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17993587	DIRECT	Υ		DE				45 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Inflammatory Marker	Remd	lesivir			S	Intravenous bolus	Other F	requency:Once;			Gilead
Increased; Pulseless Electrical Activity; Suspected Covid-19	Reme Nimbe Fenta Midaz	nyl			C C C			,			Not Reported Not Reported Not Reported Not Reported

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Cefeprime Azithromycin C C C Not Foot Not Foot Not Foot Not Foot Ceftriaxone C C C Not Foot N							Detailed IN	eport			
Preferred Term		Ce Az	efepime ithromycin			C C					Not Reported Not Reported Not Reported Not Reported
Preferred Term	FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
Multiple Organ Dysfunction Syndrome Remdesivir S Intravenous bolus Gilea	07-Jul-2020	17993623	DIRECT	Υ		DE			84 YR	Male	USA
Cettriaxone 1 Gm Iv	Preferred Term	Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
O7-Jul-2020 17993627 DIRECT Y HO Role Route Dosage Text Duration Mfr Renal Impairment Remdesivir Sulfasalazine Y S C Not Found in Enoxaparin Not Found in Enoxaparin C Not Found in Enoxaparin Not Found in Enoxaparin C Not Found in Enoxaparin Not Found in Enoxaparin C Not Found in Enoxaparin		Ce Alt Ap Az De Fa Me Fe No	oftriaxone 1 Gm Iv buterol-Ipratropium 3 MI bixaban 2.5 Mg ithromycin 500 Mg Tab examethasone 6 Mg Tab motidine 20 Mg Iv etoprolol 50 Mg Tab ntanyl Iv prepinephrine Iv opofol Iv			0000000000	Intravenous bolus				Gilead Not Reported Not Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Renal Impairment Remdesivir Y S Gilea Sulfasalazine C Not F Famotidine C Not F Furosemide C Not F Enoxaparin C Not F Doxazosin Benazepril C C Not F Not F Not F C Not F Not F Doxazosin Benazepril C C Not F Not F C Not F Not F C Not F C Not F C Not F Not F C	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
Renal Impairment Remdesivir Y S Gilea Sulfasalazine C Not Famotidine C Not Ferrosemide C Not Ferrosemi	07-Jul-2020	17993627	DIRECT	Υ		НО			57 YR	Male	USA
Sulfasalazine C	Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
	Renal Impairment	Su Fa Fu En De	Ifasalazine motidine rosemide oxaparin examethasone oxazosin	Y		000000					Gilead Not Reported
07-Jul-2020 17993645 DIRECT Y HO, LT, OT 59 YR Male	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
	07-Jul-2020	17993645	DIRECT	Υ		HO, LT, OT			59 YR	Male	USA

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Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Dialysis; Hyperkalaem		desivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17993651	DIRECT	Υ					74 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Rem	desivir			S	Intravenous bolus	Other Frequency:Once;			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17993658	DIRECT	Υ					70 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Rem	desivir (Eua)			S	Intravenous (not otherwise specified	Other Frequency:Once;			Gilead
		odipine (Norvasc) Tablet 2.5			С	от от от от от от	,			Not Reported
		orbic Acid (Vitamin C)			С					Not Reported
	Aspi	min C) Tablet 500 Mg rin Tablet 325 Mg			С					Not Reported
	Ator Mg	/astatin (Lipitor) Tablet 80			С					Not Reported
	Ceftr	riaxone (Rocephin) 2 Gm In rose 5 % 100 MI Ivpb			С					Not Reported
	Azith	romycin (Zithromax) 500			С					Not Reported
	(D5v	n Dextrose 5 % In Water v) 250 MI								
		amethasone (Decadron) et 6 Mg			С					Not Reported
	Eno	kaparin (Lovenox) 40 Mg/0.4			С					Not Reported
	Fam	jection 40 Mg otidine (Pepcid) 20 Mg In			С					Not Reported
		um Chloride (Pf) 0.9 % lv fenesin (Mucinex) 12 Hr			С					Not Reported
		et 600 Mg			-					

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		zapine (Remeron) Tablet			С						Not Reported
		lg nipexole (Mirapex) Tablet 5 Mg			С						Not Reported
	Tam	sulosin (Flomax) 24 Hr			С						Not Reported
	Thia	sule 0.8 Mg mine Mononitrate (Vit B1)			С						Not Reported
		et 100 Mg Sulfate (Zincate) Capsule Mg			С						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17993663	DIRECT	Υ						51 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Biling Increased		desivir			S	Intravenous drip					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17993705	DIRECT	Υ	F	RI, OT				66 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Cefta Albu Mdi 4	desivir azidime 2 G (Fortaz/Tazicef) terol 90 Meg/Actuation Hfa 4 Puff air/Proventilnentolin)			S C C						Gilead Not Reported Not Reported
	Peci	d 20mg			С						Not Reported
	Fent Soln	anyl (Pf) In Ns 10 Mcg/Ml Iv			С						Not Reported
		peridol Lactate In] 2 Mg			С						Not Reported
	Lora	zepam In] 2 Mg (Ativan) zolam (Pf) In] 2 Mg			C C						Not Reported Not Reported



							.				
		epinephrine In Ns 8 Mg/250 32 Mcg/Ml) Lv Premix			С					١	lot Reported
	Phe Sod	nylephrine 200 Mg In ium Chloride 0.9% 250 MI Iv			С					١	lot Reported
		n etiapine Tab 25 Mg roquel) :			С					١	lot Reported
	Van	comycin Per Protocol			C C						lot Reported
		lafaxine Tab 75 Mg (Effexor) hromycin 500mg (Zithromax)			C						lot Reported lot Reported
	Ceft	riaxone Add Vial 2 G			Č						lot Reported
	•	cephin) x 40mg			С					١	lot Reported
		uronium Inj 7.5 Mg rcuron)			С					١	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17993808	DIRECT	Y	0	Т				46 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera Increased	Eno Hyd Ceft Insu Dex Hep Ace Insu Albu Mor Ond	ndesivir xaparin 150 Mg ralazine rriaxone 1 Gm rlin Glargine amethasone 10 Mg arin 5000 taminophen 650 rlin Lispro uterol netasone lansetron matic Inhaler			%000000000000					P P P P P P P	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2020	17993885	DIRECT	Υ						75 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage	Tevt	<u>Duration</u>	M	<u>fr</u>



Nausea; Vomiting		Remdesivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
		Doxycycline Convalescent Plasma			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	178779	52 EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470593	20-	74 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Pneumothorax; Pseudomonal	I	Blinded Placebo			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Bacteraemia		Blinded Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	I	Blinded Tocilizumab			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Ceftriaxone			С		Unk			Not Reported
		Doxycycline			С		Unk			Not Reported
		Furosemide			С		Unk			Not Reported
		Heparin			С		Unk			Not Reported
		Midazolam			С		Unk			Not Reported
		Ketamine			С		Unk			Not Reported
		Ativan Morphine Convalescent Plasma			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	1788230	04 EXPEDITED (15-DAY)			DE, LT, OT	US-GILEAD-20 0470944	20-	75 YR	Female	e USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Aminotransferase Increased; Blood Lacti Acid Increased;	ic	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Bronchiectasis; Death	;	Convalescent Plasma			С		Unk			Not Reported

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Emphysema; Fibrin D	Doxyo	cycline			С		Unk				Not Reported	
Dimer Increased; Inflammatory Marker	Ceftri	axone			С		Unk				Not Reported	
Increased; Oxygen		sate Sodium			С		Unk				Not Reported	
Consumption Increase Pulmonary Embolism;		oezil			С		Unk				Not Reported	
Shock Symptom	Enoxa	aparin			С		Unk				Not Reported	
	Fluox	etine			С		Unk				Not Reported	
	Melate	onin			С		Unk				Not Reported	
	Omep	orazole			С		Unk				Not Reported	
	Potas	sium Chloride			С		Unk				Not Reported	
	Propo	ofol			С		Unk				Not Reported	
	Rispe	ridone			С		Unk				Not Reported	
	Senna	a [Senna Alexandrina]			С		Unk				Not Reported	
	Quetia	apine			С		Unk				Not Reported	
	Polye	thylene Glycol [Macrogol]			С		Unk				Not Reported	
	Fenta	nyl			С		Unk				Not Reported	
	Hepai	rin			С						Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>503B</u>	Facility	<u>Age</u>	<u>Sex</u>	Country	
08-Jul-2020	17917676	EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-20 0473055	20-		68 YR	Male	USA	
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text		<u>Duration</u>		<u>Mfr</u>	
Aspartate Aminotransferase	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Onc	е			Gilead	
Increased	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd				Gilead	
	Enoxa Mirala Protoi	nx nix [Omeprazole] Medrol			C C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	



FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17993892	DIRECT	Υ	0	Γ			37 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17994296	DIRECT	Υ	LT				32 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased;		desivir			S	Intravenous (not otherwise specified)			Not Reported
Glomerular Filtration F Decreased	Methy	methasone /lprednisilone pril/Hctz 20/25mg			C C C	·	,			Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17994533	DIRECT	Υ	Н	O, OT			71 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Creatinine Increased; Condition Aggravated; Sepsis; Therapy Interrupted	Methy Furos Dexm	desivir ylprednisolone semide nedatomidine oinephrine			S C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17994568	DIRECT		DE	Ē			82 YR	Femal	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Allopu	desivir urinol otrxate	Υ		S C C					Gilead Not Reported Not Reported

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Val	sartan			C C C				No	ot Reported ot Reported ot Reported
Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17994788	DIRECT	Υ	LT	-			69 YR	Female	USA
Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Re bea; loea	mdesivir			S	Intravenous bolus			Gi	lead
Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17994791	DIRECT	Υ	DE	≣			76 YR	Male	USA
Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Re ; oea	mdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gi	lead
Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17994796	DIRECT	Y	DE	≣			61 YR	Female	USA
Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
lure; Re	mdesivir			S	Intravenous drip			Gi	lead
Hu Ce Ro Ro De	man Albumin fepime cephine xamethasone			C C C C C				No No No	ot Reported
	Val Nei Case # 17994788 Pro Rei Dea; Dea; Dea T7994791 Pro Rei T7994796 Pro Uure; Rei Hui Cei Hui Cei d; Dei Lov	Product Remdesivir Dea; Dea; Dea	Valsartan Nebumetone Case # Case Type Health 17994788 DIRECT Y Product Comp. Remdesivir Dea; Dea; Dea Type Health 17994791 DIRECT Y Product Comp. Remdesivir Remdesivir Type Health	Valsartan Nebumetone Case # Case Type Health Prof On 17994788 DIRECT Y LT Product Comp. OTC Remdesivir Dea; Dea; Dea Case # Case Type Health Prof On 17994791 DIRECT Y DE Product Comp. OTC Remdesivir Remdesivir Comp. OTC Product Comp. OTC Remdesivir Comp. OTC Remdesivir Comp. OTC Comp. OTC Comp. OTC Comp. OTC Product Comp. OTC Ure; Remdesivir Diamox Human Albumin Cefepime Rocephine Comp. OTC Comp. OTC	Valsartan Nebumetone C C C Case # Case Type Health Prof Outcomes 17994788 DIRECT Y LT LT Product Comp. OTC Role Remdesivir S S 17994791 DIRECT Y DE DE Product Comp. OTC Role Remdesivir S S Oea Health Prof Outcomes 17994796 DIRECT Y DE Product Comp. OTC Role ure; Remdesivir S Diamox C C Human Albumin C C Cefepime C C d; Dexamethasone C Levency C C	Valsartan Nebumetone Case # Case Type Health Prof Outcomes Mfr Control is 17994788 DIRECT Product Comp. OTC Role Route Remdesivir S Intravenous bolus 17994791 DIRECT Product Comp. OTC Role Route Case # Case Type Health Prof Outcomes Mfr Control is 17994791 DIRECT Product Comp. OTC Role Route Remdesivir S Intravenous (not otherwise specified) Ocea Case # Case Type Health Prof Outcomes Mfr Control is 17994796 DIRECT Product Comp. OTC Role Route Case # Case Type Health Prof Outcomes Mfr Control is 17994796 DIRECT Product Comp. OTC Role Route Ure; Remdesivir S Intravenous drip Cefepime C C Cefepime C C Rocephine C C C C C C C C C C C C C C C C C C C	Valsartan Nebumetone Case # Case Type Health Prof Outcomes Product Comp. OTC Role Route Dosage Text Remdesivir Product Comp. OTC Role Route Dosage Text Remdesivir Product Comp. OTC Role Route Dosage Text Remdesivir Remdesivir	Valsartan Nebumetone C C Nebumetone C C C Nebumetone C C C C C C C C C C C C C C C C C C C	Valsartan Nebumetone C

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FDA Received Date	Case #	Case Type	Haalth	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
						MIII COIILIOI #	303B Facility	_		-
08-Jul-2020	17994799	DIRECT	Y		HO, OT			84 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Impairment	Remo	desivir	Υ		S	Intravenous bolus				Not Reported
	Dutas Enoxa Ezetir Panto Fenta Dexm	methasone steride aparin mibe oprazole anyl nedetomidine binephrine			000000000					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17994804	DIRECT	Υ		HO, OT			64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir	Y		S	Intravenous (not otherwise specified)				Gilead
	Cefep Dexal Insulii Midoo Panto Fenta	methasone n Aspart/ Ssi drine oprazole unyl ylephrine			000000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test Increased	Rer	ndesivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17995169	DIRECT	Υ		ОТ			53 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Rer	ndesivir			S	Intravenous bolus				Gilead
	Dex Hep	irin rvastatin camethasone parin ulin Nph			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17995173	DIRECT	Υ		DE			52 YR	Female	e USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rer	ndesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY		Gilead
	Rer	ndesivir			S	Intravenous drip		1 DAY		Gilead
	Rer	ndesivir			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17995201	DIRECT	Υ		ОТ			32 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Rer	ndesivir			S	Intravenous bolus				Gilead
Increased	Zyrt Dex Enc Fan	azonatate 100mg Q8h dex 10mg Q24h dexamethasone 6mg Qday dexaparin 40mg Q12h dexidine 20mg Q12h dexidine 600mg Q12h			000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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						Dotalioa	toport				
	Lev	ulin /othyroxine alax			C C C						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17995224	DIRECT	Υ	C)T				40 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	ļ	<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase Sars-Cov-2 Test Positi	Ace Tre Thi id; Zin ive Nic The No Rol Fol De: Azi	etaminophen ental emine c Sulfate coderm Cq eradex-M volog bitussin ic Acid xamethasone thromycin eminophen etamin C			80000000000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contro	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17996062	EXPEDITED (15-DAY)		[DE, OT	US-GILEAD 0480084	-2020-		63 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	!	<u>Mfr</u>
Death	Re	mdesivir			S	Unknown	200 Mg,	Once			Gilead
	Re	mdesivir			S	Unknown	100 Mg,				Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17996089	EXPEDITED (15-DAY)		C	DΤ	US-GILEAD 0479988	-2020-			Female	USA
B (Dre	oduct	Comp.	OTC	Role	Route	Dosage T	ext	<u>Duration</u>	j	Mfr
Preferred Term	PIC	Jauot									

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						otherwise specified)				
	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	E	Enoxaparin			С	Subcutaneous	30 Mg, Bid			Not Reported
	(Ceftriaxone			С	Intravenous (not otherwise specified)	1 G, Qd			Not Reported
	A	Azithromycin			С	Oral	500 Mg, Qd			Not Reported
	[Dexamethasone			С	Intravenous (not otherwise specified)	6 Mg, Bid			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	1799618	EXPEDITED (15-DAY)	1	ŀ	НО	US-GILEAD-20 0479551	20-	43 YR	Male	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	F	Remdesivir			S	Unknown	Unk			Gilead
Increased	[Blood Plasma Dexamethasone Oxygen			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	1799676	66 EXPEDITED (15-DAY)	1	[DE, OT	US-GILEAD-20 0480078	20-	32 YR	Male	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Hypercapnia; Hypoxia;		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
Metabolic Acidosis; Multiple Organ Dysfunction Syndrome		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Qd			Gilead
Respiratory Failure	, (Convalescent Plasma			С		Unk			Not Reported
	E	Enoxaparin			С		Unk			Not Reported
	1	Methylprednisolone			С		Unk			Not Reported
	Ž	Zinc			С		Unk			Not Reported
		Ascorbic Acid			С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17997341	EXPEDITED (15-DAY)		С	·Τ	US-GILEAD-20 0480039	020-		66 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Blood Bilirubin Increase Coagulopathy; Fibrin D		lesivir			S	Intravenous (not otherwise specified)	Unk Ur)	nk, Qd			Gilead
Dimer Increased; Inflammation; Liver Inju	urv: Azithr	omycin			С		Unk				Not Reported
Prothrombin Time	Ceftri	axone			С		Unk				Not Reported
Prolonged; Serum Ferr Increased; Transamina Increased		methasone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17997547	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0480700	020-		31 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Death; Thrombocytope	enia Remo	lesivir			S	Intravenous (not otherwise specified)		g, Once			Gilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg)	g, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17997766	EXPEDITED (15-DAY)		С	т	US-GILEAD-20 0479946	020-		88 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme	Remo	lesivir			S	Intravenous drip	100 Mg	g, Qd			Gilead
Increased	Ceftria Ampio Dexar	sillin nethasone emide			000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	Contro				Č						Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17998717	DIRECT	Υ	0	Γ			39 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Flushing; Lacrimation Increased	Rem	desivir	Y		S	Intravenous (not otherwise specified)		5 DAY	G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17998751	DIRECT	Υ					16 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate	ase Rem	desivir			S	Intravenous (not otherwise specified)			G	ilead
Aminotransferase Increased; Liver Funct Test Increased	tion Fam Azith Onda	amethasone otadine romycin ansetron aminophen			00000	outer mee opeemee,			N N N	ot Reported ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17998765	DIRECT	Υ	DE	<u> </u>			52 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Condition Aggravated; Hypoxia; Pulseless Electrical Activity	; Rem	desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17998772	DIRECT	Υ					32 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfer Increased; Therapy	rase Rem	desivir			S	Intravenous drip			G	ilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17998777	DIRECT	Υ				•	76 YR	Female	PRI
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Phlebitis	Remo	lesivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2020	17998781	DIRECT	Υ	DI	≣			51 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Lactic Acidosis; Pulsel Electrical Activity	ess Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
		axone			С	. ,				Not Reported
		omycin methasone			C C					Not Reported Not Reported
	Potas	sium Chloride			С					Not Reported
		m Bicarbonate rin Sodium			C C					Not Reported Not Reported
		oxime Axetil			C					Not Reported
		omycin			С					Not Reported
		emide			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>		utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2020	17998787	DIRECT	Υ	DI	≣			87 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Death	Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;			Gilead
		aparin 40 Mg Daily			С					Not Reported
		aparin 40 Mg Bid emide 20 Or 40 Mg			C C					Not Reported Not Reported

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	Ceft Azitl Levo Esci	vediol 25mg Bid riaxone 2 Gm Daily nromycin 500mg Daily othyroxine 88mcg Daily talopram 20 Mg Daily rin 325 Mg Daily			00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	17877683	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469518	20-		70 YR	Female	e USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTO	Role	Route	Dosage	Text	Duration		Mfr
Transaminases Increa	sed Rem	ndesivir			S	Intravenous (not otherwise specified)	200 Mg	g, Once			Gilead
	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Toci	lizumab			С		Unk				Not Reported
	Eno	xaparin			С		Unk				Not Reported
	Fen	anyl			С		Unk				Not Reported
	Furd	semide			С		Unk				Not Reported
	Insu	lin 2			С		Unk				Not Reported
	Line	zolid			С		Unk				Not Reported
	Mer	openem			С		Unk				Not Reported
		zepam nylephrine			C C		Unk				Not Reported Not Reported
	Prop	oofol			С		Unk				Not Reported
	Ace	aminophen			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	17910384	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0472974	20-		60 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>



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Acidosis; Acute Kidney Injury; Blood Creatinine		esivir		S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead
Increased; Blood Press Decreased; Death; Encephalopathy;	ure Remd	esivir		S	Intravenous (not otherwise specified)	100 Ur	nk			Gilead
Pneumonia Bacterial;	Acetai	minophen		С		Unk				Not Reported
Renal Failure; Renal Tubular Necrosis;	Albute	rol [Salbutamol]		С		Unk				Not Reported
Respiratory Failure;	Ascorl	oic Acid		С		Unk				Not Reported
Sepsis; Shock	Azithro	omycin		С		Unk				Not Reported
	Ceftria	ixone		С		Unk				Not Reported
	Enoxa	parin		С		Unk				Not Reported
	Dextro	enesin And omethorphan		С		Unk				Not Reported
	•	codone/Acetaminophen		С		Unk				Not Reported
	-	nadrine		С		Unk				Not Reported
	Zinc S	ulfate		С		Unk				Not Reported
	Cisatra	acurium		С		Unk				Not Reported
	Fentai	ıyl		С		Unk				Not Reported
	Lubric	ant Eye Ointment		С		Unk				Not Reported
	Loraze	epam		С		Unk				Not Reported
	Norep	inephrine		С		Unk				Not Reported
	Propo	fol		С		Unk				Not Reported
		nylcholine methonium]		С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Outcomes	Mfr Control #	!	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	17960463	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLAE 2020M1059896				Male	NLD
Preferred Term	Produ	<u>ict</u>	Comp.	OTC Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Acute Kidney Injury	Furos	emide		S		Unk				Not Reported
	Remd	esivir		S	Intravenous (not otherwise specified)	Unk				Mylan



	F	aracetamo	ıl			С	Oral	Unk			Mylan
	٨	loradrenali	ne /00127502/			С	Intravenous (not otherwise specified)	Unk			Mylan
	F	Remifentani	I			С	Intravenous (not otherwise specified)	Unk			Mylan
	C	Ceftriaxon				С	Intravenous (not otherwise specified)	Unk			Mylan
	N	lovicolon				С	Oral	Unk			Mylan
	N	ladroparin				С	Subcutaneous	Unk			Mylan
	C	Cisatracuriu	m			С	Intravenous (not otherwise specified)	Unk			Mylan
	F	ropofol				С	Intravenous (not otherwise specified)	Unk			Mylan
	S	Supradyn /0	7499601/			С	Oral	Unk			Mylan
FDA Received Date	Case #	Ca	ise Type	Health	Prof	Outcomes	Mfr Control #	503B Fac	ility Age	<u>Sex</u>	Country
09-Jul-2020	1799942	9 DI	RECT	Υ		ОТ			38 YR	Female	USA
Preferred Term	<u> </u>	Product		Comp.	ото	Role	Route	Dosage Text	Duration	<u>n</u>	Mfr
Choking Sensation; Dyspnoea; Lip Swellin		Remdesivir				S	Intravenous (not otherwise specified)	Other Frequency:	Once;		Gilead
	F C	Rocephin 1	n 500mg Daily g Twice Daily sone 6mg Iv Daily			8 C C C C C					Not Reported Not Reported Not Reported Not Reported



							•			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	17999519	DIRECT	Υ					57 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
ntercepted Product Dispensing Error; Prod Preparation Error; Pro Preparation Issue	duct	desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	17999532	DIRECT	Υ	0	Γ			35 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfer ncreased; Aspartate Aminotransferase ncreased	ase Remo	desivir			S			2 DAY	G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18000460	DIRECT	Υ					66 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
cute Kidney Injury; Cardiac Arrest; Septic		desivir			S	Intravenous (not otherwise specified))		G	ilead
hock	Dexa	methasone			С				No	ot Reported
		aparin			С					ot Reported
		semide			С					ot Reported
	Hepa				C C					ot Reported
	Linez	n Glargine olid			C					ot Reported ot Reported
	Losar				C					ot Reported
		penem			Č					ot Reported
		orolol Succinate			С					ot Reported
	Nitrog	glycerin Topical			С				No	ot Reported
	Nore	oinephrine Infusion			С				No	ot Reported

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						P			
	Ondansetron Pantoprazole Piperacillin-Tazobactam Propofol Infusion Sodium Bicarbonate Vancomycin Acetaminophen Hydrocodone/Acetaminophen Amlodipine Aspirin			000000000					Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020 18000	DIRECT	Υ		DE			63 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Failure; Cardiac Arrest; Cardio-	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Respiratory Arrest;	Albuterol Neb			С					Not Reported
laemodynamic Instability	Levaquin 750mg/150ml lv Q24h			С					Not Reported
	Losartan 100mg 1qd			С					Not Reported
	Solu-Medrol 80 Iv Push			С					Not Reported
	Decadron 6mg Qd			С					Not Reported
	Furosemide 40mg Once			С					Not Reported
	Etomidate 10 Mg Once			С					Not Reported
	Hydrochlorothiazide 25mg 1qd			C C C					Not Reported
	Heparin 5,000 Units								Not Reported
	Lorazepam 1mg			C C C					Not Reported
	Pantoprazole 40mg Daily			C					Not Reported
	Fentanyl 50mcg Q1hprn			C					Not Reported
	Humalog 6 Units Once			С					Not Reported
	Midazolam			C C					Not Reported
	Epinephrine 1mg lv			C					Not Reported
	Norepinephrine 16mg lv			С					Not Reported
	Phenelyephrine 10mg lv			С					Not Reported
	Vasopressin 20 Units Iv			С					Not Reported
FDA Received Date Case	Vasopressin 20 Units Iv	Health	Prof	C Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country



Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Aspartate Aminotransferase Increased	Warfaı Norepi Insulin Famot	x ed Ringer rin inephrine 8 Mg Glargine idine nethasone			800000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u> #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18000773	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0479976	2020-		47 YR	Male	USA
Preferred Term	Produ	ı <u>ct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u> Text</u>	Duration		<u>Mfr</u>
Infusion Site Extravasation; Swelling Thrombotic Thrombocytopenic Purpura	Remde g;	esivir			S	Intravenous (not otherwise specified	200 Mg d)	g, Qd			Gilead
FDA Received Date			Hoalth	Duet			1#	503B Facility	A	0	Country
	Case #	Case Type	Health	Prot	<u>Outcomes</u>	Mfr Control	<u> </u>	JUSE Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	Case # 18000951	Case Type EXPEDITED (15-DAY)	<u>Health</u>		DE, OT	Wir Control US-GILEAD-2 0480889		JUSE FACILITY	<u>Age</u> 82 YR	<u>Sex</u> Female	
		EXPEDITED (15-DAY)	Comp.		DE, OT	US-GILEAD-2				Female	
09-Jul-2020	18000951 Produ Remde	EXPEDITED (15-DAY) ICT esivir rinol trexate statin tan			DE, OT	US-GILEAD-2 0480889	2020-		82 YR	Female	USA
09-Jul-2020 Preferred Term	18000951 Produ Remde Allopu Metho Pravas Valsar	EXPEDITED (15-DAY) ICT esivir rinol trexate statin tan	Comp.	OTO	DE, OT Role S C C C C	US-GILEAD-2 0480889 Route	Dosage Unk		82 YR	Female	Mfr Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
09-Jul-2020 Preferred Term Death	18000951 Produ Remdo Allopu Metho Pravas Valsar Nabun	EXPEDITED (15-DAY) ICT esivir rinol trexate statin tan netone	Comp.	OTO Prof	DE, OT Role S C C C C C	US-GILEAD-2 0480889 Route Unknown	Dosage Unk	e Text	82 YR Duration	Female	Mfr Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Hepatic Enzyme Increased	Rem	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Azith	romycin			С	. ,	Unk				Not Reported
	Ceftr	riaxone			С		Unk				Not Reported
	Dexa	amethasone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18001041	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0480947)20-		72 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Rem	desivir			S	Intravenous (not otherwise specified)	200 Mg	, Once			Gilead
	Rem	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Vano	comycin			S	Intravenous (not otherwise specified)	2 G, On	ce			Not Reported
	Vano	comycin			S	Intravenous (not otherwise specified)	1 G, Bio	i			Not Reported
	Vano	comycin			S	Intravenous (not otherwise specified)	1250 M	g, Tid			Not Reported
	Vano	comycin			S	Intravenous (not otherwise specified)	1 G, Bio	İ			Not Reported
		oprazole			С						Not Reported
		/astatin			C C C						Not Reported
		terol [Salbutamol]			C						Not Reported
	Albur				С						Not Reported
	Thiar				C C C						Not Reported
	Furo: Lanti	semide			C						Not Reported Not Reported
		vitamin With Minerals			C						Not Reported
		imibe			C						Not Reported
		ochlorothiazide;Irbesartan			C C C						Not Reported
		orbide Mononitrate			č						Not Reported
		sulosin			Č						Not Reported
		iaxone			C C						Not Reported
	Enox	aparin			С						Not Reported

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						Dotano	a itopoit					
	Azithr	omycin			С						Not Reported	
	Cefep				C						Not Reported	
	Fenta				С						Not Reported	
	Propo	ofol			000000000						Not Reported	
	Midaz	colam			С						Not Reported	
	Levop	hed			С						Not Reported	
		oressin			С						Not Reported	
	Lactul				С						Not Reported	
		ex [Nimesulide]			С						Not Reported	
	Linezo				С						Not Reported	
	Merop				С						Not Reported	
		cortisone			С						Not Reported	
		darone			С						Not Reported	
	Hepar				000000						Not Reported	
	Rifaxii				С						Not Reported	
		/lephrine			С						Not Reported	
	Micafu				С						Not Reported	
		m Bicarbonate			C						Not Reported	
	Oxyge	en			С						Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
09-Jul-2020	18001053	EXPEDITED (15-DAY)		DI	≣, HO, OT	US-GILE 0480857	EAD-2020- 7		63 YR	Male	USA	
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration		Mfr	
Renal Failure	Remd	lesivir			S	Unknown	200 M	g, Once			Gilead	
	Remd	lesivir			S	Unknown	100 M	g, Qd			Gilead	
	Cepha	alexin [Cefalexin]			С						Not Reported	
	Gabar				С						Not Reported	
	Melox				С						Not Reported	
	Metop				С						Not Reported	
	Ceftria				С						Not Reported	
		dron [Dexamethasone]			00000000000						Not Reported	
	Enoxa				C						Not Reported	
	Folic A				С						Not Reported	
	Thiam				C						Not Reported	
	Doxyo				С						Not Reported	
	Midaz				C						Not Reported	
	Propo				C						Not Reported	
	Lactul	lose			С						Not Reported	



	Ace Alb Fer Rifa	rophed etylcysteine umin ntanyl aximin parin			C C C C C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004849	DIRECT	Υ	0	Γ			71 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	rase Rei	mdesivir			S	Intravenous drip				Not Reported
Increased; Aspartate Aminotransferase Increased	Alb Aro Ber Cef Tus Dez Far Gua Hep Me Noi Odi Pot	etaminophen uterol matic Inhaler nzanotate triaxone ssionex kamethasone notidine anfenesin dralazine toprolol triptyline nansetron assium Bicarbonate mazepam azosin			00000000000000000	minavonodo di ip				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004869	DIRECT	Υ	0	Γ			50 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Therapy Cessation	rase Rei	mdesivir	Υ		S	Intravenous drip				Gilead



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

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004873	DIRECT	Υ		ОТ				47 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OT(</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Renal Impairment; Urir	nary R	emdesivir			S	Intravenous bolus				١	lot Reported
Tract Infection	B D D E F D G H L L L L L M S M	aclofen 5mg Peg Tid enztropine 1mg Peg Bid examethasone 6mg Po Daily ocusate 100mg Peg Bid noxaparin 40mg Subcut Daily errous Sulfate 325mg Peg aily abapentin 300mg Peg Bid eparin 5,000 Unit Subcut Q8h acosamide 150mg Peg Bid evetiracetam 1000mg Peg Bid evofloxacin 750mg Iv Q24h nezolid 600mg Iv Q12h agnewsium Hydroxide 8% usp 30ml Oral Bid irtazapine 30mg Peg Qbedtim lanzapine 20mg Peg Bid									lot Reported
	S	razosin 1mg Peg Qbedtime enna 8.6mg Peg Daily			C C						lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004892	2 DIRECT	Y		ОТ				56 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OT(</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blindness; Eye Irritation Infusion Related React	,	emdesivir	Υ		S	Intravenous (not otherwise specified)		requency:Once;		G	Gilead
Nausea	Е	noxaparin 40mg Subq Q24h			С					N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004899	DIRECT	Υ						82 YR	Female	USA

Note: If the field is blank, there is no data.



<u>Preferred Term</u>		Product	Comp.	OTO	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; At Fibrillation; Creatinine	rial	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY		Gilead
Renal Clearance		Azithromycin 500 Mg Po Daily			С	, ,				Not Reported
Decreased		Ceftriaxone 1 Gram Iv Q24h			Ċ					Not Reported
		Famotidine 20 Mg Iv Q12h			С					Not Reported
		Methylprednisolone 20 Mg Iv Q6h			С					Not Reported
		Fentanyl 50 Mcg/Hr			С					Not Reported
		Heparin 1200 Unit/Hr			С					Not Reported
		Norepinephrine 4 Mg/250 MI			С					Not Reported
		Titrated								•
		Propofol 20 Mcg/Kg/Min			С					Not Reported
		Amiodarone 450 Mg/250 MI Titrated			С					Not Reported
FDA Received Date	Case #		Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jul-2020	180049	007 DIRECT	Υ		OT			56 YR	Male	USA
09-Jul-2020	100048	DIRECT	ī		Oi			30 TK	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Dyspnoea; Nausea		Remdesivir			S	Intravenous bolus				Not Reported
		Budesonide 0.5mg Neb Q12h			С					Not Reported
		Dexamethasone 6mg Iv Daily			С					Not Reported
		Docusate 100mg Po Bid			С					Not Reported
		Insulin Glargine 10 Unit Subcut			С					Not Reported
		Qbedtime								•
		Insulin Lispro Sliding Scale			С					Not Reported
		Senna 8.6mg Po Daily			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	180049	DIRECT	Υ		ОТ			65 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Cirrhosis; Hepa	atic	Remdesivir			S	Intravenous bolus	Other Frequency:Once;			Not Reported
Steatosis; Hyperlipidae						initiavenous bolus	outer i requericy. Office,			•
, ,,		Ascorbic Acid 500mg Po Daily Dexamethasone 6mg lv Daily			C C					Not Reported Not Reported

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						Detailed IN	eport			
	Rifax	ulose 20g Po Q6h kimin 550mg Po Bid Sulfate 220mg Po Daily			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004976	DIRECT	Υ	0	Т			72 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Respiratory Failure	Rem	desivir			S	Intravenous bolus				Not Reported
	Azith Ceftr Clon Dexa Enox Hydr Daily Levo Daily Meth Valsa	thyroxine 137mcg Oral	ı		0000000 0 000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18004983	DIRECT	Υ	0	Т			71 YR	Female	e USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Azith	desivir romycin 500 Mg Iv Q24h			s C	Intravenous drip				Gilead Not Reported
	Dexa Fam	pime 2 Gm Iv Q12h amethasone 6 Mg Iv Q24h otidine 20 Mg Iv Q12h arin Sodium 5,000 Units Sq			C C C					Not Reported Not Reported Not Reported Not Reported
	Magi Vand Hydr	nesium Sulfate 4 Gm Iv comycin omorphone Iv pinephrine			C C C					Not Reported Not Reported Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	1800499	0 DIRECT	Υ	(ОТ			77 YR	Femal	e USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Cardio	- F	Remdesivir			S	Intravenous bolus				Not Reported
Respiratory Arrest	E	Azithromycin 500mg Iv Daily Budesonide 0.5mg Nebulized Bid			C C					Not Reported Not Reported
	((((((Cefepime 2mg Iv Q12h Ceftriaxone 2g Iv Daily Dexamethasone 6mg Iv Daily Docusate 100mg Oral Bid Pantoprazole 40mg Oral Daily Senna 8.6mg Daily			C C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	1800499	6 DIRECT	Υ	(TC			53 YR	Male	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased	5 F	Remdesivir Senna Famotidine Dexamethasone Enoxaparin	Y		S C C C					Gilead Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2020	1800500	4 DIRECT	Υ					46 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Condition		Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Aggravated; Nonalcoh Fatty Liver Disease; Therapy Interrupted	, (Ascorbic Acid 500 Mg Po Daily Ceftriaxone 1 Gram Iv Q24h Dexamethasone 4 Mg Iv Daily Doxycycline 100 Mg Po Bid			C C C					Not Reported Not Reported Not Reported Not Reported

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		enesin Er 600 Mg Po Bid sulfate 220 Mg Po Daily			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18005627	DIRECT	Υ					74 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration R Decreased; Therapy Cessation	Fental Propo Tylenc Azithro Ceftria Famol Atrvas Enoxa Pipera Hepar Zofrar Calquo Lasix Potass	nyl tol bl pmycin axone tidine tin aparin acillin-Tazobactam			8000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jul-2020	18005852	DIRECT	Υ					44 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Infusion Related Reaction	d Remd	esivir			S					Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	17867998	EXPEDITED (15-DAY)		(OT	US-GILEAD-20 0469207	020-	69 YR	Male	USA
<u>Preferred Term</u>	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		Mfr
Aspartate Aminotransferase	Remd	esivir			S	Intravenous (not	100 Mg, Qd			Gilead

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Increased						otherwise	e specified)					
	Albut	terol;Ipratropium			С			Unk				Not Reported
	Famo	otidine			С			Unk				Not Reported
	Senr	nosides			С			Unk				Not Reported
	Docu	usate			С			Unk				Not Reported
	Insul	in Lispro			С			Unk				Not Reported
		prostenol pinephrine			C C			Unk				Not Reported Not Reported
	Нера	arin			С			Unk				Not Reported
	Meth	ylprednisolone			С			Unk				Not Reported
	Mido	drine			С			Unk				Not Reported
	Ampi	icillin			С			Unk				Not Reported
	Meto	lazone			С			Unk				Not Reported
	Keta	mine			С			Unk				Not Reported
	Hydr	omorphone			С			Unk				Not Reported
	Cisat	tracurium			С			Unk				Not Reported
	Aceta Ampi Aspir Calci Enox Insul Bovir Loraz Oxyo Potas	aminophen azolamide icillin And Sulbactam rin [Acetylsalicylic Acid] ium Gluconate aparin in Nph [Insulin Isophane			00000000 0000							Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	<u>M</u> 1	fr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	17877788	EXPEDITED (15-DAY)			DE, OT		S-GILEAD-202 70621	:0-		63 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route]	Dosage	e Text	<u>Duration</u>		Mfr



Acute Respiratory Failur Cardiac Arrest; Covid-19		esivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	ilead
Septic Shock	Azithr	omycin			С	. ,	Unk		N	lot Reported
	Ceftria	axone			С		Unk		N	lot Reported
	Enoxa	aparin			С		Unk		N	lot Reported
	Famo	tidine			С		Unk		N	lot Reported
	Kaye	calate			С		Unk		N	lot Reported
	Fenta	nyl			С		Unk		N	lot Reported
	Rocui	ronium			С		Unk		N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020 1	17877916	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470625	20-	66 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>M</u> :	<u>fr</u>
Covid-19; Hypoxia; Respiratory Arrest	Remo	esivir			S	Intravenous (not otherwise specified)	200 Mg		G	Bilead
	Remo	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Conva	alescent Plasma			С		Unk		N	lot Reported
	Tocilia	zumab			С		Unk		N	lot Reported
		zumab minophen			C C		Unk			lot Reported lot Reported
	Panto	prazole			С		Unk		N	lot Reported
	Tmp-	Smx			С		Unk		N	lot Reported
FDA Received Date (Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	17886205	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0471139	20-	90 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransferas Increased; Aspartate Aminotransferase	se Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	Bilead

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						201000	- p				
ncreased; Blood	Asco	rbic Acid			С		Unk				Not Reported
Creatinine Increased	Aspir	in [Acetylsalicylic Acid]			С		Unk				Not Reported
	Atorv	astatin			С		Unk				Not Reported
	Chole	ecalciferol			С		Unk				Not Reported
	Code	ine And Guaifenesin			С		Unk				Not Reported
	Docu	sate			С		Unk				Not Reported
	Enox	aparin			С		Unk				Not Reported
	Fenta	anyl			С		Unk				Not Reported
	Furos	semide			С		Unk				Not Reported
	Hydra	alazine			С		Unk				Not Reported
	Insuli	n			С		Unk				Not Reported
	Leve	tiracetam			С		Unk				Not Reported
	Levo	thyroxine			С		Unk				Not Reported
		vitamin [Vitamins Nos]			С		Unk				Not Reported
		oprazole			С		Unk				Not Reported
DA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Control	# !	503B Facility	<u>Age</u>	<u>Sex</u>	Country
0-Jul-2020	17887728	EXPEDITED (15-DAY)		ОТ	-	US-GILEAD-2 0469658	020-		63 YR	Male	USA
eferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage 1	<u>ext</u>	<u>Duration</u>		Mfr
cute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified	100 Mg,	Qd			Gilead
	Symb	picort			С	•					Not Reported
	Asa				С						Not Reported
		r [Atorvastatin]			С						Not Reported
	Zetia	nox [Enoxaparin Sodium]			C C						Not Reported Not Reported
	Zelia Insuli				C						Not Reported
		erol Sulfate			C						Not Reported
	Bume				Č						Not Reported
		us Sulfate			Č						Not Reported
		pentin			Č						Not Reported
	Glipiz				C						Not Reported



		etoprolol			С					Not Reported
		kycodone			0000000					Not Reported
		intyl			C					Not Reported
		ujeo Solostar			C					Not Reported
		sartan			C					Not Reported
		lenol			C					Not Reported
		oventil Hfa [Salbutamol			C					Not Reported
		ılfate] entolin Hfa			С					Not Reported
	As	pirin (E.C.)			C C C					Not Reported
		sacodyl ´			С					Not Reported
	De	extrose			С					Not Reported
	Dy	clonine			00000000					Not Reported
	Ez	etimibe			С					Not Reported
		eparin			С					Not Reported
		oney			С					Not Reported
		sulin Lispro			С					Not Reported
		agnesium Hydroxide			С					Not Reported
		rtazapine			С					Not Reported
		orphine			С					Not Reported
		fran Melt			С					Not Reported
	So	odium Chloride			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	17892605	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0471871	20-	57 YR	Male	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage Text</u>	Duration		<u>Mfr</u>
Cardiac Arrest; Hypox Tachycardia; Ventricul		emdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Tachycardia	Re	emdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Ac	etaminophen			С		Unk			Not Reported
	As	corbic Acid			С		Unk			Not Reported
	Dip	phenhydramine			С		Unk			Not Reported
	En	noxaparin			С		Unk			Not Reported
	Fu	ırosemide			С		Unk			Not Reported
	Zir	nc Gluconate			С		Unk			Not Reported



	F	Prednisone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	1790220	8 EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0470939	020-		79 YR	Male	USA
Preferred Term	ļ	Product	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Aspartate Aminotransferase		Remdesivir			S	Intravenous (not otherwise specified	100 Mg	g, Qd			Gilead
Increased; Blood Biliru Abnormal	, , , , , , , , , , , , , , , , , , ,	Atorvastatin Cisatracurium Sennosides Docusate Enoxaparin Epoprostenol Famotidine Fentanyl Furosemide Insulin Ketamine Methylprednisolone Norepinephrine Zosyn Propofol Aspirin [Acetylsalicylic Acid] Piperacillin & Tazobactam Prednisone Vancomycin			000000000000000000000000000000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	1796445	9 EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0477229	020-		85 YR	Femal	e USA
Preferred Term	!	<u>Product</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Chest Pain	F	Remdesivir			S	Intravenous (not otherwise specified	200 Mg	g, Qd			Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18006250	DIRECT	Υ		ОТ			79 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	ото	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)			Not Reported
	Fenta Aspir	in n Lispro nox			000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18006415	DIRECT			OT			48 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Bradycardia	Remo	desivir			S	Intravenous (not otherwise specified)			Not Reported
	Alpra Tocili Asco Zinc S	dine 0.1mg Po Q6h Prn zolam 0.25mg Po Qhs Prn zumab Iv 800mg Once rbic Acid 500mg Po Bid Sulfate 220mg Po Daily methasone 6mg Ivp Daily			$\circ\circ\circ\circ\circ\circ$					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18006881	DIRECT	Υ		ОТ			32 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Bradycardia	Remo	desivir			S	Intravenous bolus	Other Frequency:X 1;			Gilead
	Fenta Ceftri	ylprednisilone anyl axone cycline			C C C		• • •			Not Reported Not Reported Not Reported Not Reported

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	Eno	xaparin			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18006887	DIRECT	Υ					54 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Liver Funct Test Increased; Respiratory Disorder; Transaminases Increa	Dex Azit ion Cef	ndesivir amethasone hromycin triaxone			S C C C	Intravenous drip				Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18006892	DIRECT	Υ	0	Т			74 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Alanine Aminotransfer Increased	ase Ren	ndesivir	Υ		S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18006963	DIRECT	Υ					75 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Seizure	Ren	ndesivir			S	Intravenous (not otherwise specified)				Gilead
		taminophen 1000 Mg Po			С	,				Not Reported
	Q8h Asp Dail	irin Chewable 81 Mg Po			С					Not Reported
	Aztr	eonam 2,000 Mg Iv Q8h			С					Not Reported
		damycin 600 Mg Iv Q8h amethasone 6 Mg Iv Daily			C					Not Reported Not Reported
	End	xaparin 40 Mg Subq Nightly			С					Not Reported
	Dro	o Ellipta 200/25 Mcg 1 Puff			С					Not Reported

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		nh Daily								Not Deported
		actobacillus Capsule Po Twice Daily			С					Not Reported
	ı	idocaine 5% Transdermal			С					Not Reported
	 	Patch Daily Pantoprazole 40 Mg Iv Daily Polyethylene Glycol 17 G Po			C C					Not Reported Not Reported
	I	Daily Potassium Chloride 40 Meq Iv Dnce			С					Not Reported
	;	Senna-Docusate 8.6/50 Mg Po Daily			С					Not Reported
	;	Spiriva Inhalation Capsule 18 Mcg Daily			С					Not Reported
		Remdesivir Injection			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	1800696	7 DIRECT	Υ	(T			73 YR	Male	USA
Preferred Term	1	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration R Decreased	tate I	Remdesivir			S	Intravenous (not otherwise specified)		3 DAY		Gilead
	 	Dexamethasone Iv Amiodarone Iv Phenylephrine Iv Norepinephrine /ecuronium Midazolam Iv /asopressin Propofol Enoxaparin Pantoprazole Ceftriaxone			00000000000	·				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	1800697	1 DIRECT	Υ					68 YR	Male	USA
Preferred Term	1	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



Abdominal Abscess;		Tocilizumab			S	Intravenous bolus	Other Frequency:Once;			Not Reported
Leukocytosis; Peritonii Pneumoperitoneum		Remdesivir Dexamethasone 6mg Po Daily			S S					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	180074	DIRECT	Υ		ОТ			76 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Alanine Aminotransfer	ase	Remdesivir			S			5 DAY		Gilead
Increased; Aspartate Aminotransferase Increased		Remdesivir			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	180094	96 EXPEDITED (15-DAY)		DE, OT	US-GILEAD-20 0481284	20-	51 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Hypoxia; Pulseless		Remdesivir			S	Unknown	Unk			Gilead
Electrical Activity		Tocilizumab Dexamethasone Enoxaparin			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	180102	03 EXPEDITED (15-DAY))		ОТ	US-GILEAD-20 0481436	20-	16 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u> </u>	<u>VIfr</u>
Transaminases Increa	sed	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Remdesivir			S	Intravenous (not otherwise specified)	100 Unk			Gilead
		Dexamethasone			С		Unk			Not Reported
		Famotidine			С		Unk			Not Reported
		Azithromycin			С		Unk			Not Reported



		01	-4					•				Not Donostod
		Ondans				С		Unk				Not Reported
-		Acetami	nopnen			С		Unk				Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof O	utcomes	ļ	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	180107	87	EXPEDITED (15-DAY)		H	O, OT		US-GILEAD-2020- 0481389		57 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>		<u>Mfr</u>
Anuria; Renal Impairm	nent	Remdes	ivir			S	Unkno	wn Unk				Gilead
		Sulfasal	azine			С		Unk				Not Reported
		Famotid	ine			С		Unk				Not Reported
		Furosen	nide			С		Unk				Not Reported
		Enoxapa	arin			С		Unk				Not Reported
		Dexame	thasone			С		Unk				Not Reported
		Doxazos	sin			С		Unk				Not Reported
		Benazer	oril			С		Unk				Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof O	utcomes]	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	180107	99	EXPEDITED (15-DAY)		H	0		US-GILEAD-2020- 0481317		66 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasa	ation	Remdes	ivir			S	Unkno	wn				Gilead
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof O	utcomes]	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	180125	58	DIRECT	Υ	DI	E				83 YR	Female	USA
<u>Preferred Term</u>		Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Fail Covid-19 Pneumonia; Dyspnoea; Tachypnoe		Remdes	ivir			S	Intrave	nous bolus				Gilead



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

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012559	DIRECT	Υ					46 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Extravasation	Remde	esivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012560	DIRECT	Υ	0	Т			56 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>fr</u>
Device Malfunction; Product Dose Omissic	Remde on	esivir			S				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012572	DIRECT	Υ	DI	E			85 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>fr</u>
Anuria; Asthenia; Bloc Bilirubin Increased; Bl Creatinine Increased; Cardiac Arrest; Confusional State; Diarrhoea; Fall; Hypotension; Hypothermia; Nausea Pulmonary Oedema; Respiration Abnormal Respiratory Arrest; Respiratory Failure; Unresponsive To Stim	lood I;	esivir			S	Intravenous (not otherwise specified)			G	ilead
	C#	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	Case #	<u> </u>								

Note: If the field is blank, there is no data.



Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransfera	ase Rer	ndesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
Increased; Aspartate Aminotransferase Increased	Am Azit Dex Enc Fur Lido Met Par	uterol Mdi lodipine hromycin camethasone exaparin exemide exiderm Patch exprolol etoprazole exphin			000000000	·				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012582	DIRECT	Υ	0	Т			77 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dyspnoea; Glomerular Filtration Rate Decreas		ndesivir			S					Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012588	DIRECT	Υ	0	Т			31 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased		ndesivir camethasone			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012595	DIRECT	Υ	0	Т			67 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Sars-Cov-2		ndesivir			S	Intravenous bolus				Gilead

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Test Positive; Therapy

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012601	DIRECT	Υ	D	E			86 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Drug Ineffective; Pallia	tive Remo	lesivir			S	Intravenous drip				Gilead
Care	Insulii Midaz Norep				C C C C C	·			 	Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012606	DIRECT	Υ	D	E			41 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Death	Remo	lesivir			S	Intravenous drip				Gilead
	Cisatı Fenta Insuliı Ketan Midaz	n nine			C C C C				 	Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012608	DIRECT	Υ	D	E			82 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Death	Remo	lesivir			S	Intravenous drip				Gilead
	Remo	lesivir			S	Intravenous drip			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012610	DIRECT	Υ	С	T			41 YR	Male	USA

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Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Liver Function Test Increased	Ren	ndesivir			S	Intravenous (not otherwise specified))			Gilead
		kinra amethasone			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control:	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012616	DIRECT	Y	ŀ	Ю			42 YR	Female	e USA
Preferred Term	Pro	duct	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia; Pancreatitis	Ren	ndesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Ren	ndesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
		amethasone			С					Not Reported
		xaparin			С					Not Reported
		italopram rol X L			C C					Not Reported Not Reported
		tonix			C					Not Reported
		nalog Sliding Scale			Č					Not Reported
		papentin			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jul-2020	18012811	DIRECT	Υ					31 YR	Male	USA
Preferred Term	<u>Pro</u>	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Ren	ndesivir			S	Intravenous bolus				Not Reported
Increased; Aspartate	Dex	amethasone			С					Not Reported
Aminotransferase Increased; Blood Alka Phosphatase Increase Transaminases Increa	ed;									·
		Case Type	Health	Prof (Outcomes	Mfr Control	# 503B Facility	Age	Sex	Country
FDA Received Date	Case #	<u>case rype</u>	Health					<u> </u>	<u> </u>	<u> </u>

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Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	Duration	1	<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Therapy Interrupted		desivir imethasone			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2020	18012653	DIRECT	Υ					59 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Alkali Phosphatase Increased Blood Bilirubin Increase Therapy Cessation	ne d;	desivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2020	18012654	DIRECT	Υ	DI	E			51 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Cardiac Arrest; Pulsele Electrical Activity	ess Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2020	18012659	DIRECT	Υ	0.	Т			61 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	1	<u>Mfr</u>
Hypotension; Infusion Related Reaction	Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;	5 DAY		Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2020	18012667	7 DIRECT	Υ					32 YR	Male	USA
Preferred Term	<u>P</u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Chills; Transaminases Increa		emdesivir	Υ		S	Intravenous bolus	Other Frequency:One Time- Loading;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2020	1801267	5 DIRECT			LT, OT			65 YR	Male	USA
Preferred Term	<u>P</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Therapy Interrupted	R	emdesivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2020	18012622	2 DIRECT	Υ		ОТ			54 YR	Male	USA
Preferred Term	<u>P</u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
International Normalise	ed R	emdesivir			S	Intravenous bolus				Gilead
Ratio Increased; Thrombocytopenia		ecadron 6mg Iv Daily ctemra 400mg Iv X One			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2020	18012626	6 DIRECT			ОТ			34 YR	Male	USA
Preferred Term	<u>P</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer ncreased; Liver Funct		emdesivir	Υ		S	Intravenous (not otherwise specified	1	5 DAY		Gilead
Test Increased	R	emdesivir 200 Mg Iv X1 emdesivir 100 Mg Daily			C C	outorwise specified	J			Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health I</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	17812574	EXPEDITED (15-DAY)			DE, HO, OT	GB-PFIZER INC 2020198894	D-	61 YR	Male	GBR
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Multiple Organ	·	nolactone			S	Oral	50 Mg, 2x/Day (100mg Pe	er		Pfizer
Dysfunction Syndrome	Spiror	nolactone			S		Unk			Pfizer
	Furose	emide			S	Intravenous (not otherwise specified)	40 Mg			Not Reported
	Furos	emide			S	Intravenous (not otherwise specified)	40 Mg, 2x/Day (80 Mg Pe Day)	r		Not Reported
	Furos	emide			S	Intravenous (not otherwise specified)	20 Mg			Not Reported
	Furos	emide			S	Intravenous (not otherwise specified)	40 Mg			Not Reported
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, 1x/Day			Not Reported
	Atorva	astatin			С		Unk			Not Reported
	Ipratro	ppium			С		Unk			Not Reported
	Azithro	omycin			С	Intravenous (not otherwise specified)	Unk			Not Reported
		noxiclav kicillin;Clavulanate siuml			С		Unk			Not Reported
		prazole			С		Unk			Not Reported
	Parac	etamol			С		Unk			Not Reported
	Parac Midaz	etamol olam			C	Intravenous (not otherwise specified)	Unk			Not Reported Not Reported
	Metoc	lopramide			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Metoc Morph	lopramide iine			C C	Intravenous (not	Unk			Not Reported Not Reported



		otherwise specified)		
Morphine Salbutamol	C C	Respiratory (inhalation)	Unk	Not Reported Not Reported
Noradrenaline [Norepinephrine]	С		Unk	Not Reported
Rocuronium	С	Intravenous (not otherwise specified)	Unk	Not Reported
Rocuronium Piperacilin/Tazobactam	C C		Unk	Not Reported Not Reported
Erythromycin	С	Intravenous (not otherwise specified)	Unk	Not Reported
Heparin	С	Subcutaneous	Unk	Not Reported
Vasopressin	С		Unk	Not Reported
Fentanyl	С	Intravenous (not otherwise specified)	Unk	Not Reported
Mupirocin	С		Unk	Not Reported
Carbocisteine	С		Unk	Not Reported
Propofol	С	Intravenous (not otherwise specified)	Unk	Not Reported
Senna [Sennoside A+B]	С		Unk	Not Reported
Sodium Chloride	С		Unk	Not Reported
Vancomycin	С		Unk	Not Reported
Sildenafil	С		Unk	Not Reported
Pabrinex [Ascorbic Acid;Benzyl Alcohol;Nicotinamide;Pyridoxine Hydroch	С	Intravenous (not otherwise specified)	Unk	Not Reported
Budesonide	С	Respiratory (inhalation)	Unk	Not Reported
Enoxaparin	С	Subcutaneous	Unk	Not Reported
Acetylcysteine	С	Respiratory (inhalation)	Unk	Not Reported
Movicol Plain	С		Unk	Not Reported
Prosource Tf	С		Unk	Not Reported



	Mil	rinone			С		Unk				Not Reported
	Pa	ntoprazole			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Pai	ntoprazole			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Me	thylprednisolone			С		Unk				Not Reported
	Atr	acurium			С	Intravenous (not otherwise specified)	Unk)				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	17892304	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0469828)20-		32 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role Role	<u>Route</u>	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration R Decreased; Renal Impairment	Azi Ce De En Fel Ro He Ins Top Mic No On	mdesivir thromycin ftriaxone xmedetomidine oxaparin ntanyl bitussin [Guaifenesin] parin ulin Aspart orol XI dazolam repinephrine dansetron opofol rmal Saline			8 000000000000	Unknown	Unk				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	17927793	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0474348)20-		80 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Re	mdesivir			S	Intravenous (not otherwise specified)		g, Once			Gilead



						Detailed Ne	port				
		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qc	d			Gilead
		Ascorbic Acid			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> 503</u>	BB Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	180121	114 EXPEDITED (15-D	AY)		DE, DS, HC OT	9, LT, BE-CELLTRION 2020BE024090				Unkno	wn BEL
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Tex	<u>t</u>	Duration		<u>Mfr</u>
Hepatitis Toxic;		Rituximab (Unknown)			S	Unknown	Unk				Not Reported
Respiratory Failure		Remdesivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
		Remdesivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
		Imuran [Azathioprine]			S	Unknown					Not Reported
		Cetirizine			С		Unk				Not Reported
		Thyroxine			С	Oral	Unk				Not Reported
		Calciumcarbonaat			С	Oral	Unk				Not Reported
		Livial			С	Oral	Unk				Not Reported
		Medrol [Methylprednisolone]			С	Oral	Unk				Not Reported
		Omeprazole]			С		Unk				Not Reported
		Domperidone Flamingo			С	Oral	Unk				Not Reported
		Aldactone [Spironolactone]			С	Oral	Unk				Not Reported
		Xanax			С	Oral	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503	BB Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	180141	20 DIRECT	Υ						62 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>t</u>	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Liver Funct		Remdesivir (Eua) (Remdesiv (Eua))	rir		S	Intravenous (not otherwise specified)					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014165	DIRECT	Υ		HO, OT			74 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mf</u>	ŗ
Abdominal Pain; Diarrhoea; Hyperhidros nfusion Related Reacti Nausea; Vomiting	sis; (Eua)	lesivir (Eua) (Remdesivir)			S	Intravenous (not otherwise specified)			No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014188	DIRECT	Υ		DE			68 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfera ncreased; Blood Creatinine Increased; Cardio-Respiratory Arre Pulseless Electrical Activity	Ceftri. Fenta Norep Propo Vasop Albute Ascor Vitam Doxyo Enoxa Famo Novol Scale Lever	axone nyl Drip 20 Mcg/Ml binephrine Drip 8mg/250ml binephrine Drip 8mg/250ml birol Drip 1000mg/100ml bressin Drip 20 Units/100ml brol Hfa bic Acid 500mg Tab in D3 5000units Cap bycline 100mg Cap bycline 100mg Inj tidine 20mg Inj og 100units/Ml Sliding	Y		% 000000000000 000	Intravenous bolus	Other Frequency:Once;		No No No No No No No No No No No No No N	lead of Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014193	DIRECT	Υ		ОТ			66 YR	Female	USA
Preferred Term	Prod	uet	Comp.	ОТС	Role	Route	Dosage Text	Duration	<u>M</u> fı	•

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

Blood Calcium Increas	sed Remde	esivir	Υ		S	Intravenous bolus	Other Frequency:Once;	1 DAY	No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014196	DIRECT	Υ		ОТ			83 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Blood Creatinine Increased; Glomerular Filtration Rate Increas Liver Function Test Increased		esivir	Υ		S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014202	DIRECT	Υ					87 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase Remde	esivir			S				Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014233	DIRECT	Υ					48 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Chills; Diarrhoea; Dizziness; Fatigue; Presyncope; Sinus Tachycardia; Unresponsive To Stim Vomiting	(Eua))	esivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)	Frequency: Am		No	t Reported
	Coco #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	<u>Case #</u>									

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury	Dexa Hepa	desivir methasone ırin prolol			S C C C					Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014251	DIRECT	Υ	(TO			58 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir	Υ		S	Intravenous (not otherwise specified)			Gilead
	Aceta	aminophen			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014254	DIRECT	Υ	[DE			54 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Haemorrhage Intracra	nial Remo	desivir			S	Intravenous bolus				Gilead
		aparin methasone			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014258	DIRECT	Υ	[DE			45 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Renal Failure; Renal		desivir			S	Intravenous bolus				Gilead
Replacement Therapy	Dexa	methasone alescent Plasma			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
I DA Neceived Date										

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Professor d Tarres	Donald.		0	0.70	Data	Bassia	Parama Tand	Donathan		NAC
<u>Preferred Term</u>	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	lesivir			S	Intravenous bolus				Gilead
	Cova	methasone escent Plasma xychloroquine			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014268	DIRECT	Υ	I	LT, OT			25 YR	Female	e USA
Preferred Term	<u>Prod</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Disease Progression	Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:One Time;			Gilead
	Ceftri Dexa Hepa Regu Proto Lasix Nysta	lar Insulin nix			000000000	,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2020	18014273	DIRECT	Υ					59 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Extra Dose Administer Liver Function Test Increased; Product Dispensing Error	Aspiri Dexa	lesivir n 81 Mg Daily methasone 6mg Daily erol Inhaler			S C C C					Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014279	DIRECT	Υ	I	DE			78 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Death	Re	emdesivir			S	Intravenous bolus				Gilead
	Co	ovid Antibody Plasma			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014283	DIRECT	Υ					63 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate		ocilizumab (Tocilizumab lmg/Ml Inj, Soln, 4ml)			S	Intravenous (not otherwise specified)	Frequency: Once			Not Reported
Aminotransferase Increased		emdesivir (Eua) (Remdesivir ua))			S	,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014292	DIRECT	Υ	DI	Ξ			49 YR	Male	USA
Preferred Term	Pr	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19; Disease Complication; Haemorrhagic Stroke	As Ca Ce Pe De Ep Fa Mi Inf Es Tit Ins Tit Ins Unf Hy	emdesivir spirin 81 Mg Daily alcium Chloride 19 Iv X1 efepime 19 Iv Q8h eridex Mouth Wash 15 MI Bid examethasone 6 Mg Lv Daily binephrine 0.1mg/Kg Le1 amotidine 20 Mg Lv Daily irosemide 40 Mg Iv Q12h etoclopramide 5 Mg Lv Q8h dazolam Lv Continuous fusion Titrated entanyl Lv Continuous Infusion erated entanyl Lv Continuous Infusion erated sulin Lv Continuous Infusion erated entanyl Lv Continuous Infusion erated existing Lv Continuous fusion			%000000000 0 0 0 0 0					Not Reported

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		ontinuous Infusion 20ml/Hr nin 5% 250 MI X 2			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014295	DIRECT	Y					62 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Remd (Eua))	lesivir (Eua) (Remdesivir)			S	Intravenous (not otherwise specified)			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014315	DIRECT	Υ	Н	O, LT			73 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remd (Eua))	lesivir (Eua) (Remdesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014631	DIRECT	Υ					59 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Device Infusion Issue; Product Dose Omissio Wrong Technique In Device Usage Process	n; Azithr Ceftria	omycin axone nethasone aparin			800000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014674	DIRECT	Y	0	T				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Gastrointes	Remd stinal	esivir			S					Not Reported

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Haemorrhage; Glomerular Filtration Rate Decreased; Therapy Cessation

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014675	DIRECT	Υ	DE				61 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardio-Respiratory Ar General Physical Heal Deterioration; Hypotension; Renal Failure; Renal Replacement Therapy	lth	lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014678	DIRECT	Υ	ОТ					Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Therapy Cessation	ase Remd	esivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014683	DIRECT	Υ	НС)			34 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Remd	esivir Eua			S	Intravenous drip	Other Frequency:One Loading Dose;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	18014688	DIRECT	Υ	ОТ				55 YR	Male	USA

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransfera Increased; Liver Funct Test Increased		sivir			S					٨	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014693	DIRECT	Y	(ТС				90 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Bradycardia	Remde Levoph Preced Propofo Fentan	ed ex ol			S C C C					N N	Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014698	DIRECT	Υ	(TC				21 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransfera Increased; Maternal Exposure During Pregnancy		sivir ninophen			S C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18014923	EXPEDITED (15-DAY)				US-GILE 0481995	AD-2020-		59 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Product Storage Error	Remde	sivir			S	Unknown				<u> </u>	Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18017847	EXPEDITED (15-DAY)		(TC	US-GILE 0481381	AD-2020-		75 YR	Female	USA

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							-				
Acute Kidney Injury; Vomiting		desivir vcycline ma			S C C	Intravenous bolus	200 M Unk Unk	lg, Once			Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18018077	DIRECT	Υ						43 YR	Male	USA
Preferred Term	Proc	luct	Comp.	отс	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	rase Rem	desivir	Υ		S	Intravenous drip			3 DAY		Gilead
Increased; Aspartate Aminotransferase	Rem	desivir	Υ		S	Intravenous drip			2 DAY		Gilead
Increased	Azith Core Cefti Love Cello Nifed Proto Pred Tacr	iaxone nox cept dipine			00000000000						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18018090	DIRECT	Υ		ОТ				43 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alka Phosphatase Increase	line ed;	desivir			S	Intravenous (not otherwise specified)		30 MIN		Gilead
Serum Ferritin Increase FDA Received Date		Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfera Increased	ase Remo	lesivir	Y		S	Intravenous (not otherwise specified)			(Gilead
	Remo	lesivir	Υ		S	Intravenous (not otherwise specified)			(Gilead
	Azithr	omycin 500 Mg Daily			С	. ,			1	Not Reported
		erol Hfa Inhaler			С					Not Reported
	Chole	calciferol 2000 Units Daily			С				1	Not Reported
		ocobalamin 1000 Mcg Daily			С					Not Reported
		methasone 6 Mg Daily			С					Not Reported
	Daily	lomine 20 Mg Four Times			С					Not Reported
		aparin 40 Mg Daily			С					Not Reported
		alopram 5 Mg Daily			С					Not Reported
	Famo Daily	tidine 20 Mg Two Times			С				ı	Not Reported
		adine 10 Mg Daily			С				1	Not Reported
		ital Plus Vitamin Daily			С					Not Reported
		doephedrine 30 Mg Four			С				1	Not Reported
		s Daily pamil 240 Mg Daily			С				ı	Not Reported
		Sulfate 220 Mg Daily			С					Not Reported
		minophen 650 Mg Every 4 s As Needed			С				ľ	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18018101	DIRECT	Υ	07	Г			92 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Renal Failure	Remo Remo				S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020	18018164	DIRECT	Υ	07	Г			26 YR	Male	USA

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Alanine Aminotransferase	Remo	desivir			S	Intravenous drip				Not Reported
Increased; Aspartate Aminotransferase		ıminophen			С					Not Reported
Increased; Hepatic	Albute				С					Not Reported
Enzyme Increased		atic Inhaler			С					Not Reported
,		methasone			C C					Not Reported Not Reported
		cycline aperin			C					Not Reported
		opium Bromide			C					Not Reported
		etasone			Č					Not Reported
		nsetron			С					Not Reported
	Tociliz	zumab			С					Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020 180	18360	DIRECT	Υ	D	ÞΕ			63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	desivir			S	Intravenous bolus				Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date Cas	se #	Case Type	Health	Prof C	outcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
13-Jul-2020 180	19094	DIRECT	Υ	D	ÞΕ			68 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	desivir			S	Intravenous bolus				Gilead
	Acten	nra			S	Intravenous drip				Genentech
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2020 180	19213	DIRECT	Υ	C	T			52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Condition	Remo	desivir			S	Intravenous bolus				Gilead
Aggravated; Hypoxia; Sinus Node Dysfunction	Azithr Cefep	omycin Dime			C C					Not Reported Not Reported

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FDA Received Date	Enox: Insuli Dexa Potas Butall Apap Onda	oprazole aparin n Aspart methasone ssium Chloride bital/Apap/Caffeine insetron Case Type	Health	Prof	C C C C C C C	Mfr Control #	503B Facility	Age	Sex	Not Reported
14-Jul-2020	17861932	EXPEDITED (15-DAY)		I	HO, OT	US-GILEAD-20 0469014	20-	43 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Dyspnoea;		desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Hyperphosphataemia; Renal Failure	Nore	pinephrine			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Ns				С	Intravenous (not otherwise specified)	100 MI/Hr			Not Reported
	Ceftri	axone			С	Intravenous (not otherwise specified)	2 G			Not Reported
	D5lrs				С	Intravenous (not otherwise specified)	125 MI/Hr			Not Reported
	Doxy	cycline			С	Intravenous (not otherwise specified)	100 Mg			Not Reported
	Fenta	anyl			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Hepa	rin			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Insuli	n Regular Hm			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Insuli	n Regular Hm			С		7 Units			Not Reported
	Zosyr	า			С	Intravenous (not otherwise specified)	2.25 G			Not Reported
	Propo	ofol			С	Intravenous (not	Unk			Not Reported



							otherwise specified)				
		Albutero	Hfa			С	Respiratory (inhalation)	2 Puff			Not Reported
		Amlodipi	ne			С	Oral	5 Mg			Not Reported
		Ascorbic	Acid			С	Oral	500 Mg			Not Reported
		Atorvasta	atin			С	Oral	20 Mg			Not Reported
		Bupropio	n			С	Oral	300 Mg			Not Reported
		Buspiron	е			С	Other	10 Mg			Not Reported
		Cholecal	ciferol			С	Other	1000 Units			Not Reported
		Famotidi	ne			С	Intravenous (not otherwise specified)	20 Mg			Not Reported
		Novolog				С	Subcutaneous	Unk			Not Reported
		Insulin D	etemir			С	Subcutaneous	9 Units			Not Reported
		Ketamin	9			С	Intravenous (not otherwise specified)	100 Mg			Not Reported
		Lorazepa	am			С	Intravenous (not otherwise specified)	1 Mg			Not Reported
		Midazola	ım			С	Intravenous (not otherwise specified)	5 Mg			Not Reported
		Morphine	9			С	Intravenous (not otherwise specified)	2 Mg			Not Reported
		Rocuron	ium			С	Intravenous (not otherwise specified)	100 Mg			Not Reported
		Thiamine)			С	Oral	100 Mg			Not Reported
		Zinc Sulf	ate			С	Oral	220 Mg			Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	178763	54	EXPEDITED (15-DAY)		C	T	US-GILEAD-202 0469633	20-	82 YR	Female	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
International Normalise Ratio Increased	ed	Remdes	vir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead



	Remd	esivir				Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Eliquis	3			_	Oral	5 Mg, E	id			Not Reported
	Eliquis	3			С		2.5 Mg				Not Reported
	Albute	erol Hfa			С	Respiratory (inhalation)	- 3				Not Reported
	Amiod	larone			С	,	200 Mg				Not Reported
	Amlod	lipine			С		5 Mg				Not Reported
	Atorva	astatin			С		40 Mg				Not Reported
	Azithro	omycin			С		500 Mg				Not Reported
	Methy	Iprednisolone			С		50 Mg				Not Reported
	Metop	rolol Succinate			С		25 Mg				Not Reported
	Tociliz	rumab			С		400 Mg				Not Reported
	Tociliz	rumab			С		200 Mg				Not Reported
	Panto	prazole			С		40 Mg				Not Reported
	Sodiu	m Polystyrene Sulfonate			С		15 G				Not Reported
	Zinc S	Sulfate			С		220 Mg				Not Reported
	Nacl					Intravenous (not otherwise specified)					Not Reported
	Acetai	minophen			С		650 Mg				Not Reported
	Benzo	onatate			С		100 Mg				Not Reported
	Melato	onin			С		3 Mg				Not Reported
	Ceftria	axone			С		1000 M	g			Not Reported
	Diphe	nhydramine			С		25 Mg				Not Reported
	Furose	emide			С		40 Mg				Not Reported
	Levoth	nyroxine			С		112 Mc	g			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #		503B Facility	<u>Age</u>	Sex	Country
14-Jul-2020	17892588	EXPEDITED (15-DAY)		0	Г	US-GILEAD-202 0470679	20-		69 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>

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Blood Pressure Decreased; Chills; Hea	art	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Rate Decreased; Hyperhidrosis; Infusion		Acetaminophen			С	. ,				Not Reported
Related Reaction	1	Albuterol [Salbutamol]			С					Not Reported
Related Reaction		Azithromycin			С	Intravenous (not otherwise specified)	500 Mg			Not Reported
		Ceftriaxone			С	Intravenous (not otherwise specified)	1000 Mg			Not Reported
		Heparin			С	Subcutaneous	7500 Units			Not Reported
		Ipratropium Bromide And Albuterol Sulfate			С	Respiratory (inhalation)	1 Puff			Not Reported
		Methylprednisolone			С	Intravenous (not otherwise specified)	40 Mg			Not Reported
		Morphine			С					Not Reported
		Ns			С					Not Reported
		Ondansetron			С					Not Reported
		Pravastatin			С					Not Reported
		Thiamine			С					Not Reported
		Iohexol			С					Not Reported
		Quetiapine [Quetiapine Fumarate]			С	Oral	200 Mg			Not Reported
FDA Received Date	Case #	<u>Case Type</u>	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	179488	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0475659	20-	52 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Liver Function Increased	Test	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Cefepime			С					Not Reported
		Hydrocortisone			С					Not Reported
		Protonix [Omeprazole]			С					Not Reported
		Vancomycin			С					Not Reported
		Fentanyl			С					Not Reported
		Propofol			С					Not Reported
		1 1000101			Č					Not Reported

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							Detailed Ne	port			
		Heparin Norepind Humalog Zinc Versed Meroper Micafung Sodium Insulin	ephrine g nem			00000000					Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	179493	327	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0475661	20-	84 YR	Female	USA
<u>Preferred Term</u>		Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Cardiac Arrest; Multiple Organ Dysfunction	e	Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Syndrome		Remdes	sivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Heparin				С	Intravenous (not otherwise specified)	Unk			Not Reported
		Fentany	I			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Midazola	am			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Rocuron	nium			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Levophe	ed			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Vasopre	essin			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Neosyne	ephrine			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Plasma				С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	17949328	EXPEDITED (15-DAY)		I	DE, OT	US-GILEAD-20 0475657	20-	68 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Cardiac Arrest	Rem	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Rem	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Hepa	arin			С					Not Reported
	Insuli				С					Not Reported
	Apixa				С					Not Reported
		orbic Acid			C C					Not Reported
	Zinc				C					Not Reported
	Chole	ecalciferol			С					Not Reported
	Docu				C C C C					Not Reported
	Seler				С					Not Reported
	Famo	otidine			С					Not Reported
	Sero	quel			С					Not Reported
		medrol			С					Not Reported
	Vano	comycin			С					Not Reported
	Mero	penem			C C					Not Reported
	Fenta				С					Not Reported
	Nore	pinephrine			C					Not Reported
		zolam			C					Not Reported
	Prop	ofol			С					Not Reported
		ıronium			С					Not Reported
	Plasr	ma			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	17963319	EXPEDITED (15-DAY)		1	HO, OT	US-GILEAD-20 0476755	20-	47 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase Rem	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Aminotransferase	Aceta	aminophen			С	Oral	650 Mg			Not Reported
Increased	Asco	rbic Acid			С	Oral	1000 Mg, Bid			Not Reported

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	Aspirin	81			С	Oral	81 Mg, (Qd			Not Reported
	Dexam	ethasone			С	Oral	6 Mg, Q	d			Not Reported
	Enoxap	parin			С	Subcutaneous	40 Mg				Not Reported
	Azithro	mycin			С	Oral	500 Mg,	Qd			Not Reported
	Ceftriax	kone			С	Intravenous (not otherwise specified)	Unk, Qd	I			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	17986012	EXPEDITED (15-DAY)		H	HO, OT	US-GILEAD-20 0479047)20-		79 YR	Female	e USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Fext</u>	Duration		<u>Mfr</u>
Bradycardia	Remde	sivir			S	Intravenous (not otherwise specified)	200 Mg,	Qd			Gilead
	Remde	sivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead
	Propofo	ol			S	Unknown					Not Reported
	Enoxap Methylp	oarin orednisolone			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019363	DIRECT	Υ						71 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage 1	Гехt	<u>Duration</u>		<u>Mfr</u>
Infusion Site Discomfo Infusion Site Extravasation; Infusion Site Swelling		sivir			S	Intravenous (not otherwise specified)	1				Gilead
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019365	EXPEDITED (15-DAY)		[DE, OT	GB-STRIDES ARCOLAB LIM 2020SP008079			84 YR	Male	GBR

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Livedo Reticularis	Vanco	omycin			S	Intravenous (not otherwise specified)	1 Gram, Bid			Strides
	Pipera	acillin & Tazobactam			S	Intravenous (not otherwise specified)	4.5 Gram, Tid			Not Reported
	Dexar	methasone			S	Oral	6 Milligram, Qd			Not Reported
	Remd	lesivir			S	Intravenous (not otherwise specified)	200, Stat			Not Reported
	Oxyge	en			С	Unknown	Unk			Not Reported
	Allopu	ırinol			С	Unknown	Unk			Not Reported
	Fexof	enadine			С	Unknown	Unk			Not Reported
	Atorva	astatin			С	Unknown	Unk			Not Reported
	Omep	orazole			С	Unknown	Unk			Not Reported
	Dalter	oarin			С	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019366	DIRECT	Υ					41 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remd	lesivir	Υ		S	Intravenous bolus		3 DAY		Gilead
Increased; Therapy Interrupted	Allopu Atorva Dexar	astatin			C C C					Not Reported Not Reported Not Reported



		minophen nsetrol			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019372	DIRECT	Υ					70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Remo	desivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019392	DIRECT	Υ	01	Γ			64 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Therapy Cessation	Tocili: Zinc Senna Rocui Queti Polye Pento Multiv Levot Insulii Hepa Aztree Atorva Aspiri Ascor	ronium apine apine athylene Glycol oxifylline oprazole vitamins chyroxine n ine onam astatin			<i>®</i> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019398	DIRECT	Υ					42 YR	Male	USA

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Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test	Remd	esivir			S	Intravenous (not otherwise specified))			Gilead
	Propo Sublin Levop	naze			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control a	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019402	DIRECT	Υ	(TC			41 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Aspirii Cefep Dexar Dexm Fenta Folic / Hepar Insulir Ketam Keppr Loraz Metro Multiv Norep Panto Pento Propo Thiam	ime methasone edetomidine nyl Acid rin n nine ra epam nidazole itamin inephrine prazole xifylline fol			8000000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019408	DIRECT	Υ	ı	Ю			60 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Troponin Increased	Remd	esivir			S	Intravenous (not				Gilead

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						otherwise specified)				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019547	DIRECT			LT			39 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Blood Creatinine Increased; Brain Death Brain Midline Shift; Bra Oedema; Cardiac Arre Cerebral Haemorrhage Creatinine Renal Clearance Decreased; Pupil Fixed; Unrespon To Stimuli; Vomiting	ain ≀st; ⊋;	lesivir			S				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019555	DIRECT	Υ		ОТ			56 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Abdominal Pain Upper Cardio-Respiratory Arr Chest Discomfort; Dyspnoea; Hypoxia; Pharyngeal Swelling; Swollen Tongue; Wheezing		lesivir			S	Intravenous bolus			Gi	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18019894	DIRECT	Υ		ОТ			72 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Atrial Fibrillation	Remo	lesivir			S	Intravenous (not otherwise specified)			Gi	lead
	Na				С	/			No	t Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18020193	DIRECT	Υ	0	Т			79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Transamina Increased		desivir			S			5 DAY	١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18020200	DIRECT	Υ					30 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Ast/Alt Ratio Abnormal Liver Function Test Increased	l; Remo	desivir	Y		S	Intravenous drip			C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18020210	DIRECT	Υ	H	0			48 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Bradycardia	Acten	desivir nra methasone Inj			S C C				N	Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18020211	DIRECT	Υ	D	E			70 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Pyrexia	Remo	desivir			S	Intravenous drip			C	Gilead
	Remo	desivir			S	Intravenous drip			C	Silead
	Carbo	oxymethylcellulose			С				N	lot Reported

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	Cisa Eno Fen Hyd Insu Nor	athalmic Drops atracurium xaparin tanyl ralazine ulin epinephrine pofol			000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18021105	EXPEDITED (15-DAY)		0	E, OT	US-GILEAD-20 0482478	20-	86 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Nor	ılin azolam epinephrine assium Chloride			C C C C	,				Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18021134	EXPEDITED (15-DAY)		C	T	US-GILEAD-20 0482469	20-	71 YR	Female	e USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		Mfr
Alanine Aminotransfer Increased; Aspartate	ase Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Aminotransferase Increased	Azit	hromycin			С		500 Mg, Qd			Not Reported
moreasea	Cefe	epime			С	Intravenous (not otherwise specified)	2 G, Bid			Not Reported
	Dex	amethasone			С	Intravenous (not otherwise specified)	6 Mg, Qd			Not Reported
	Fam	notidine			С	Intravenous (not otherwise specified)	20 Mg, Bid			Not Reported
	Нер	arin Sodium			С	Subcutaneous	5000 Units			Not Reported
	Мад	gnesium Sulfate			С	Intravenous (not	4 G			Not Reported

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						otherwise specified))				
	\	/ancomycin			С		Unk				Not Reported
	H	Hydromorphone			С	Intravenous (not otherwise specified)	Unk)				Not Reported
	١	Norepinephrine			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	1802206	9 EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0482487	020-		53 YR	Male	USA
Preferred Term	<u>!</u>	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Aspartate	F	Remdesivir			S	Unknown	100 Mg)			Gilead
Aminotransferase Increased	[E	Famotidine Dexamethasone Enoxaparin Gennaplant			C C C						Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	1802208	9 EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0469452	020-		67 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Transaminases Increa	ased F	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
	(C H H L F S M	Ascorbic Acid Deftriaxone Dexamethasone Doxycycline Heparin Hydralazine Loperamide Potassium Chloride Multivitamins [Vitamins Nos] Dndansetron Dextromethorphan Hbr &			000000000000						Not Reported
		Juairenesin Zinc Sulfate			С						Not Reported

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		usate;Senna aminophen			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024034	DIRECT	Y		ОТ			44 YR	Male	USA
Preferred Term	Prod	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Transamina Increased		ndesivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024044	DIRECT	Υ					30 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain Upper	r; Rem	ndesivir			S	Intravenous drip				Gilead
Nausea; Vomiting	Dexa Enox Zinc Code	orbic Acid 2000mg Qday amethasone 6mg Po Qday xaparin 40mg Subq Q12h Sulfate 220mg eine-Guaifenesin 10-100mg Prn Cough			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024053	DIRECT	Υ		ОТ			79 YR	Male	USA
Preferred Term	Prod	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase Rem	ndesivir			S					Gilead



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024056	DIRECT	Υ	Н)				66 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ige Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase Blood Bilirubin Increas	line ed;	esivir			S	Intravenous (not otherwise specif					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024064	DIRECT	Υ	0	Γ				76 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	<u>ige Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remd	esivir			S						Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024070	DIRECT	Υ	0	Γ				96 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ige Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remd	esivir			S						Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024080	DIRECT	Υ	0	Γ				89 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosa</u>	<u>ige Text</u>	<u>Duration</u>		<u>Mfr</u>

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Atrioventricular Block Degree; Atrioventricula Block Second Degree Bradycardia	ar	Remdes Lisinopri Dexame	l				s C C	Intravenous bolus			1	Gilead Not Reported Not Reported
FDA Received Date	Case #	!	Case Type		<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	180241	161	DIRECT		Υ					88 YR	Female	USA
Preferred Term		Product	i	9	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase	Remdes	ivir				S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	!	Case Type		<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	180241	171	DIRECT		Υ		ОТ			75 YR	Male	USA
Preferred Term		Product	i	9	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased	ase	Remdes	ivir	Y			S	Intravenous (not otherwise specified)	Other Frequency:Once- Loading Dose;		(Gilead
		Remdes	ivir	Y			S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	1	Case Type		Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
14-Jul-2020	180241	176	DIRECT		Υ		ОТ			81 YR	Male	USA
Preferred Term		Product	į	9	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase	ase	Remdes	ivir				S				(Gilead
Increased			•	•		Dest	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
FDA Received Date	Case #	<u> </u>	Case Type		<u>Health</u>	Prot	<u>Outcomes</u>	WIII COILLIOI #	303B Facility	<u>Aye</u>	<u>Sex</u>	Country

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Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	Remo	lesivir	Υ		S	Intravenous drip				Not Reported
Increased	Aspiri Vitam Dexar Famo Zosyr Rocur Vanco	erol Inhaler n 81 Mg in D3 2000 Units methasone 6 Mg tidine 20 Mg n 3.375 G ronium omycin Sulfate 220 Mg rin			0000000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024196	DIRECT	Υ	0	Т			28 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase Remo	lesivir	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024205	DIRECT	Υ	Н	O, OT			55 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remo	lesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Remo	lesivir			S	Intravenous drip				Gilead
	Albute Solu-I Enoxe Sodiu Doxyo Ceftrie Tociliz Novol	Medrol aparin m Chloride cycline axone zumab			0000000000					Not Reported

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	Z	ofran			С				No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024217	7 DIRECT	Υ					47 YR	Female	USA
Preferred Term	<u>P</u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Papule; Rash Pruritic; Therapy Cessation	R	emdesivir	Υ		S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024252	2 DIRECT	Υ	(DΤ			78 YR	Female	USA
Preferred Term	<u>P</u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Therapy Cessation	R	temdesivir	Υ		S	Intravenous (not otherwise specified)			Gil	ead
	В	enazepril 40 Mg Po Nightly sudesonide-Formoterol 160-4.5 dcg/Actuation 2 Puffs			C C	,				t Reported t Reported
	C	calcium Carbonate 500 Mg Chewable Tablet			С				No	t Reported
	C	Chlortahlidone 25 Mg Po Daily			С					t Reported
		oiltiazem Er 120 Mg Po 2 Times Paily	5		С				No	t Reported
	Н	lydrocodone-Acetaminophen			С				No	t Reported
	P R V	0-325 Mg Po 2 Times Daily Pro Pantoprazole 40 Mg Po Daily Livaroxaban 15 Mg Po Daily Vitamin D 2000 Units Po 2 Times Daily	1		C C				No	t Reported t Reported t Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	1802426	1 DIRECT	Υ	l	.T			50 YR	Female	USA
Preferred Term	<u> P</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arr Liver Function Test	rest; R	temdesivir			S	Intravenous (not			Gil	ead

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

Increased; Seizure					otherwise specified)				
	Acetaminophen Alprazolam Aripiprazole Ascorbic Acid Dexamethasone Enoxaparin Levofloxacin Levetiracetam Sertraline Zinc Sulfate			000000000					Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020 1802 ²	1263 DIRECT	Υ		ОТ			54 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Cardiac Arrest; Hypotension; Inflammatory Marker Increased; International Normalised Ratio Increased; Oxygen Saturation Decreased	Aspirin Ec 81mg Po Daily Atorvastatin 20mg Po Qhs Azithromycin 500mg Iv Q24h Ceftriaxone 1g Iv Once Dexamethasone 6mg Daily Enoxaparin 30mg Subq Q12h Epinephrine Iv Continuous Infusion Epoprostenol Continuous Neb Famotidine 20mg Iv Q12h And Q24h Fentanyl Infusion Furosemide 20mg Iv Daiily Lantus Qhs Insulin Lispro Sliding Scale 4x/D Midazolam Iv Continuous Infusion Norepinephrine Infusion Phenylephrine Infusion Propofol Infusion			» 000000 00 00000 000	Intravenous (not otherwise specified)	Other Frequency:200mgx1, 100mg/D 4;			Not Reported



						Dotalica No	Port			
		Rocuronium Iv Pushes Prn For Vent Dyssynchrony			С					Not Reported
		Sodium Bicarbonate Infusion			С					Not Reported
		Vasopressin Iv Continuous			Č					Not Reported
		Infusion			•					. tot i top oitod
	,	Vecuronium Iv Continuous Infusion			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	1802427	70 DIRECT	Υ		DE, LT, OT			55 YR	Male	USA
<u>Preferred Term</u>		<u>Product</u>	Comp.	ото	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation; Blood Creatinine Increased; International Normalise		Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg/D, 100mgx4;			Gilead
Ratio Increased		Amiodarone Bolus And Infusior	,		С		3 ,			Not Reported
		Azithromycin 500mg Iv Daily	•		Č					Not Reported
		Benztropine 1mg Ng Q8h			Č					Not Reported
		Cefepime 1g Iv Q6h			Ċ					Not Reported
		Ceftriaxone 1g Iv Once			Č					Not Reported
		Daptomycin 6 Mg/Kg Iv Daily			Č					Not Reported
		Dexamethasone 6mg Iv Daily			Č					Not Reported
		Precedex Infusion			Ċ					Not Reported
		Diazepam 5mg lv Q6-12h			C					Not Reported
		Enoxaparin Prophy Then			C					Not Reported
		Treatment								•
		Fentanyl 25mcg Iv Prn			С					Not Reported
		Insulin Lispro Sliding Scale			С					Not Reported
	4	4x/Day								·
	(Culturelle Capsule Q24h			С					Not Reported
		Meropenem 500mg Iv Q6h			С					Not Reported
		Metoprolol 5mg Iv Q6h			С					Not Reported
		Norepinephrine Infusion			С					Not Reported
		Phenylephrine Infusion			С					Not Reported
	1	Pip/Tazo 3.375g lv Q8h			С					Not Reported
	;	Sodium Bicarbonate Infusion			С					Not Reported
	•	Vitamin C 1000mg Daily			С					Not Reported
	;	Zinc Sulfate 220mg Daily			С					Not Reported



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024360	DIRECT	Y	Н	0			29 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased		minophen enasin	Υ		S C C C					Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2020	18024375	DIRECT	Υ	DI	E			75 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	17882785	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0469801	20-	64 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Seizure	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Aztrec	onam			С	Intravenous (not otherwise specified)	2 G			Not Reported
	Furos	emide			С	Intravenous (not otherwise specified)	20-40mg			Not Reported
	Levofl	oxacin			С	Intravenous (not otherwise specified)	750 Mg			Not Reported
	Tociliz	zumab			С	Intravenous (not otherwise specified)	800 Mg			Not Reported

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	Ace	taminophen			С	Oral	650 Mg			Not Reported
	Albu	iterol [Salbutamol]			С	Respiratory (inhalation)	2.5 Mg			Not Reported
		pine pidogrel			C C	Oral	75 Mg			Not Reported Not Reported
	Doc	usate			С	Oral	100 Mg			Not Reported
	Нер	arin			С	Subcutaneous	5000 Units			Not Reported
	Leve	othyroxine			С	Oral	50 Mcg			Not Reported
	Mida	azolam			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Nore	epinephrine			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Pan	toprazole			С	Intravenous (not otherwise specified)	40 Mg			Not Reported
	Prop	oofol			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Ace	tylcysteine			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	17887629	EXPEDITED (15-DAY)		(OT	US-GILEAD-202 0470645	20-	61 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation; Blood Pressure Decreased;	d Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Heart Rate Irregular	Asc	orbic Acid			С	Oral	500 Mg, Bid			Not Reported
	Ator	vastatin			С	Oral	40 Mg			Not Reported
	Azitl	nromycin			С	Intravenous (not otherwise specified)	500 Mg, Qd			Not Reported
	Ben	zonatate			С	Oral	100 Mg, Q8h			Not Reported
	Ceft	riaxone			С	Intravenous (not otherwise specified)	1 G, Qd			Not Reported
	Cod				С					Not Reported

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		Enoxapari	in			С	Subcutaneous	75 Mg			Not Reported
		Guaifenes	sin			С	Oral	1200 Mg, Bid			Not Reported
		Heparin				С	Subcutaneous	Unk Unk, Bid			Not Reported
		Ibuprofen				С	Oral	600 Mg, Once			Not Reported
		Losartan				С	Oral	50 Mg, Qd			Not Reported
		Metoprolo	l Succinate			С	Oral	25 Mg, Qd			Not Reported
		Metoprolo	l Tartrate			С	Oral	25 Mg, Bid			Not Reported
		Zinc Sulfa	te			С	Oral	220 Mg, Qd			Not Reported
FDA Received Date	Case #	9	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	178922	214 I	EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-20 0469666	20-	49 YR	Male	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Proteinuria; Renal Tubu		Remdesiv	rir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Necrosis; Rhabdomyoly	/SIS	Azithromy	rcin			С	Oral	500 Mg			Not Reported
		Ceftriaxor	ne			С	Intravenous (not otherwise specified)	2 G			Not Reported
		Acetamino	ophen			С	Oral	650 Mg			Not Reported
		Enoxapari	in			С	Subcutaneous	30 Mg			Not Reported
		Guaifenes	sin			С	Oral	200 Mg			Not Reported
		Guaifenes	sin			С	Oral	200 Unk			Not Reported
		Lactated F	Ringers			С	Intravenous (not otherwise specified)	Unk			Not Reported
		Lokelma				С		10 G			Not Reported
		Lokelma				С		10 Unk			Not Reported
		Ns				С		500 MI			Not Reported
		Tocilizuma	ab			С	Intravenous (not otherwise specified)	400 Mg			Not Reported
		Albuterol;	Ipratropium			С		2			Not Reported
		Albuterol;	Ipratropium			С		3			Not Reported

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	Etomid	ate		С	Intravenous (not otherwise specified)	40 Mg		No	ot Reported
	Midazo	olam		С	Intravenous (not otherwise specified)	Unk		No	ot Reported
	Rocurd	onium		С	Intravenous (not otherwise specified)	150 Mg		No	ot Reported
	Atracui	rium		С	Intravenous (not otherwise specified)	Unk		No	ot Reported
	Hydron	norphone		С		Unk		No	ot Reported
	Propofe	ol		С	Intravenous (not otherwise specified)	Unk		No	ot Reported
	Cefepir	me		С	Intravenous (not otherwise specified)	2 G		No	ot Reported
	Vancor	mycin		С	Intravenous (not otherwise specified)	2750 Mg		No	ot Reported
	Vancor	mycin		С	Intravenous (not otherwise specified)	2250 Unk		No	ot Reported
	Famoti	dine		С	Intravenous (not otherwise specified)	20 Mg		No	ot Reported
	Metocle	opramide		С	Intravenous (not otherwise specified)	10 Mg		No	ot Reported
	Oxycoo	done		С	Oral	10 Mg		No	ot Reported
	Furose	emide		С	Intravenous (not otherwise specified)	Unk		No	ot Reported
	Bumeta	anide		С	Intravenous (not otherwise specified)	5 Mg		No	ot Reported
	Chlorot	thiazide		С	Intravenous (not otherwise specified)	1000 Mg		No	ot Reported
	Sodium	n Bicarbonate		С	Intravenous (not otherwise specified)	150 Meq		No.	ot Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	17940034	EXPEDITED (15-DAY)		ОТ	US-GILEAD-202 0473153	20-	78 YR	Female	USA



<u>Preferred Term</u>	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Glomerular Filtration Rat Decreased	e Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		G	ilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	Bilead
	Amlod	ipine			С				N	lot Reported
		oic Acid			С					lot Reported
	Atorva				С					lot Reported
	Ceftria				C					lot Reported
	Diltiaz				C C					lot Reported
	Gabap				C					lot Reported
	Glime				С					lot Reported
		Glargine			С					lot Reported
		Lispro bide Dinitrate			C C					lot Reported lot Reported
		nyroxine			C					lot Reported
		prednisolone			C					lot Reported
		lopramide			C C					lot Reported
		orazole			Č					lot Reported
	Zinc S				Č					lot Reported
FDA Received Date C	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facili	ty Age	Sex	Country
15-Jul-2020 1	8021510	EXPEDITED (15-DAY)			но, от	US-GILEAD-20 0481896	20-	63 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Renal Impairment; Respiratory Distress	Remde	esivir			S	Intravenous (not otherwise specified)	Unk		G	Gilead
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facili	ty Age	<u>Sex</u>	Country
15-Jul-2020 1	8021816	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0482431	20-	56 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blindness; Eye Irritation; Nausea	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		G	Gilead
					С	. ,				lot Reported

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024742	DIRECT	Y	D	E			58 YR	Male	USA
<u>Preferred Term</u>	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Pulmonary Oedema; Agitation; Atr Fibrillation; Lung Infiltration; Obstructive Airways Disorder; Puls	ial Meto Amic	desivir prolol darone semide			S C C C	Intravenous (not otherwise specified)			Not Reported Not Reported
Absent; Rales; Respira Failure; Respiratory Ra Decreased	ttory Etom tte Rocu Mida Enox Dexa Atory	nidate Ironium zolam caparin Imethasone vastatin			$\circ\circ\circ\circ\circ\circ$					Not Reported
		in Determir in Lispro			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024764	DIRECT		Н	0			71 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Respiratory Arrest	Rem	desivir			S	Intravenous bolus				Gilead
	Azith	romycin 500 Mg Ivpb Once romycin 250 Mg Po Daily romycin 500 Mg Ivpb Every			C C					Not Reported Not Reported Not Reported
		iaxone 1 Gram lvpb Every			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024782	DIRECT	Υ	D	E			69 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rem	desivir			S	Intravenous bolus	Other Frequency:X1;			Gilead

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	Acte	mra			S	Intravenous bolus	Other Frequency:X1;		C	Senentech
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024787	DIRECT	Υ		ОТ			51 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
nternational Normalise Ratio Increased	ed Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4;		C	Silead
		aminophen 325mg Q6h Prn 1-3. Fever			С	• •			١	Not Reported
		romycin 500mg Iv Daily			С				N	Not Reported
		iaxone 1g lv Daily			Ċ					lot Reported
		methasone 6mg lv Daily			С				N	Not Reported
		aparin 30mg Subq Q12h			С				N	Not Reported
		us Qhs			С					Not Reported
		in Lispro Sliding Scale 4x/D			С					Not Reported
		pinephrine Iv Infusion			С					Not Reported
	Tocil	izumab 400mg Iv X 1			С				N	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024788	DIRECT	Υ		ОТ			22 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfera	ase Rem	desivir			S	Intravenous drip			C	Silead
ncreased; Aspartate Aminotransferase		methasone			С					Not Reported
ncreased		iaxone			С					Not Reported
Holeaseu		romycin			С					Not Reported
		d Convalescent Plasma			С					Not Reported
	Albut				С					Not Reported
	Flutio	casone			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024789	DIRECT	Υ					21 YR	Female	USA
Preferred Term	Proc		Comp.	отс	Role	Route	Dosage Text	Duration	<u>M</u>	£

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Liver Function Test Increased		Remdesivir Remdesivir			s C	Intravenous bolus				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	180247	90 DIRECT	Υ		ОТ			77 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Manine Aminotransfera	ase	Remdesivir	Υ		S	Intravenous drip				Gilead
ncreased; Aspartate Aminotransferase ncreased		Acetaminophen 650 Po Q6h P Ascorbic Acid 500mg Qd Atenolol 25mg Qd Atorvastatin 20 Qpm Bicalutamide 50mg Qd Dexamethasone 6mg Iv Q 24 Famotidine 20 Mg Qd Heparin 5000 Sc Q8 Tocilizumab 100 MI Iv Once Levothyroxine 100mcg Qs Ondansteron 4mg Q8 Prn Zinc Sulfate 220 Mg Qd	rn		000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
5-Jul-2020	180248	09 DIRECT	Υ					74 YR	Male	USA
referred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Liver Function Test Increase /entricular Tachycardi		Remdesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	180248	de DIRECT	Υ		ОТ			82 YR	Female	USA
referred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
ransaminases Increas	sed	Remdesivir Eua Product Dexamethasone 6 Mg Iv Daily			s C	Intravenous bolus				Gilead Not Reported

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						Detailed IN	Sport				
		umab 400 Mg Iv X2 acurium 37.5 Mg/Hr Iv			C C						Not Reported Not Reported
		yl 50 Mcg/Hr Iv			С					1	Not Reported
		ol 50 Mcg/Kg/Min Iv			С					1	Not Reported
		nephrine 5 Mcg/Min Iv			С					1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# <u>503B</u>	Facility 1	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18024817	DIRECT	Υ					3	32 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	1	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfera	ase Remde	esivir			S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# <u>503B</u>	Facility 1	Age	<u>Sex</u>	Country
15-Jul-2020	18024833	DIRECT	Y	DE	=			Ę	59 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	1	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Death	Remde	esivir			S					(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	<u>#</u> <u>503B</u>	Facility 1	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18026374	EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-2 0482857	020-	2	42 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	1	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Pancreatitis	Remde	esivir			S	Unknown	200 Mg, Qd			(Gilead
	Remde	esivir			S	Unknown	100 Unk			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Control	# <u>503B</u>	Facility 1	Age	<u>Sex</u>	Country
15-Jul-2020	18026584	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-2 0482356	020-	Ę	50 YR	Male	USA
<u>Preferred Term</u>	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	1	<u>Duration</u>	<u>N</u>	<u>lfr</u>

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Alanine Aminotransferase Increased	Remdesivir			S	Intravenous drip	200 Mg, Qd		Gi	lead
FDA Received Date Case #	<u>Case Type</u>	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020 18026	641 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470338	20-	67 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	:
Acute Kidney Injury; Acute Respiratory Distress	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		Gi	lead
Syndrome; Blood Bilirubin Increased; Blood Creatinine Increased;	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		Gi	lead
Jugular Vein Thrombosis;	Acetaminophen			С	Oral	650 Mg		No	t Reported
Pneumonia; Respiratory	Acetaminophen			С	Oral	975 Mg		No	ot Reported
Disorder; Transaminases Increased	Acetaminophen			С	Other	975 Mg		No	ot Reported
	Acetaminophen			С	Other	650 Mg		No	t Reported
	Acetaminophen			С	Other	650 Mg		No	t Reported
	Acetaminophen			С	Other	650 Mg			ot Reported
	Acetaminophen			С	Other	650 Mg		No	t Reported
	Albuterol Hfa Azithromycin Ceftriaxone Chlorhexidine Dexmedetomidine Docusate Duloxetine Enoxaparin Etomidate Famotidine Fentanyl Furosemide Haloperidol Hydroxyzine Heparin Insulin Lorazepam Midazolam			0 0000000000000000000000000000000000000	Other	650 Mg		NG NG NG NG NG NG NG NG NG NG NG NG NG N	of Reported



	Or Ox Po Pro Ro Se Su	orepinephrine odansetron cycodone lyethylene Glycol 3350 egabalin opofol ocuronium onna S ccinylcholine uxamethonium]			000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18027006	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0482904	020-	31 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Transaminases Increa	ised Re	emdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd			Gilead
	De	examethasone			С	•				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18027028	EXPEDITED (15-DAY)		0	Γ	US-GILEAD-20 0477223	020-		Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Pneumonia; Respirato Failure; Suspected Co 19		emdesivir			S	Intravenous (not otherwise specified	Unk)			Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18027438	EXPEDITED (15-DAY)		DE	≣, OT	US-GILEAD-20 0482916	020-	48 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Haemorrhagic Stroke	Re	emdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd)			Gilead
	As	pirin [Acetylsalicylic Acid]			С	•	Unk			Not Reported
	Ca	llcium Chloride			С		Unk			Not Reported

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							•				
		Cefepime			С		Unk				Not Reported
		Peridex [Chlorhexidine Gluconate]			С		Unk				Not Reported
		Dexamethasone			С		Unk				Not Reported
		Epinephrine			С		Unk				Not Reported
		Famotidine			С		Unk				Not Reported
		Furosemide			С		Unk				Not Reported
		Metoclopramide			С		Unk				Not Reported
		Midazolam			С		Unk				Not Reported
		Esmolol			С		Unk				Not Reported
		Fentanyl			С		Unk				Not Reported
		Insulin			С		Unk				Not Reported
		Norepinephrine			С		Unk				Not Reported
		Hypertonic Saline Solution			С		Unk				Not Reported
		Normal Saline			С		Unk				Not Reported
		Albumin			С		Unk				Not Reported
											·
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	180282	282 EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0472223	20-		59 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased	llood	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg,	Qd			Gilead
		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead
		Albuterol Hfa			С						Not Reported
		Aspirin (E.C.)			С						Not Reported
		Calcium Gluconate			C C C						Not Reported
		Vitamin D3 Clonidine			C						Not Reported
		Cioniunte			C						Not Reported
					()						Not Papartad
		Famotidine Furosemide			C C						Not Reported Not Reported



	Potass Potass Sodiur Sodiur Sulfan Trimet Thiam Oxyco Fentar Acyclo	tamins [Vitamins Nos] sium Chloride sium Phosphate Dibasic m Chloride m Phosphate nethoxazole And hoprim ine done nyl pvir [Aciclovir]			000000 0000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029374	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20: 0482872	20-	75 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Seizure	Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg		(Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		(Gilead
	Acetar	minophen			С		Unk		1	Not Reported
	Aspirir	n [Acetylsalicylic Acid]			С		Unk		1	Not Reported
	Aztreo	nam			С	Intravenous (not otherwise specified)	2 G Q8hr		1	Not Reported
	Clinda	mycin			С		Unk		1	Not Reported
	Dexan	nethasone			С	Intravenous (not otherwise specified)	6 Mg, Qd		1	Not Reported
	Lidoca	ine			С		Unk		1	Not Reported
	Enoxa	parin [Enoxaparin Sodium]			С		Unk		1	Not Reported
	Breo E	Ellipta			С		Unk		1	Not Reported
	Lactob	pacillus			С		Unk		1	Not Reported
	Pantor	orazole			С		Unk		1	Not Reported
	Polyet	hylene Glycol 3350			С		Unk		1	Not Reported



						Detailed N	eport				
	Pota	ssium Chloride			С		Unk			Not Reported	
	Docu	usate;Sennoside A+B			С		Unk			Not Reported	
	Spiri	va			С		Unk			Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country	
15-Jul-2020	18029500	DIRECT	Υ	DE				80 YR	Male	USA	
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>	
Cardio-Respiratory Ar Unresponsive To Stim	nuli Apixa Benz Cefe Dexa Doxy Pant Vanc	desivir aban zonatate pime amethasone /cycline oprazole comycin o-Codeine			800000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country	
15-Jul-2020	18029545	DIRECT	Υ	DE	<u> </u>			78 YR	Female	e USA	
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>	
Anaphylactic Shock	Rem	desivir	Υ		S	Intravenous bolus				Gilead	
	Enox Fami Furo Merr Mont Senr Spiro Vano	amethasone kaparin otidine semide em telukast			00000000000					Not Reported Not Reported	



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029550	DIRECT	Υ	Н)			42 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Rei	mdesivir			S	Intravenous bolus				Gilead
Increased; Aspartate Aminotransferase Increased	Ace Asc Azi Cet Cho Dex Eto Fer Ket Lor Me Mic Par Vec	rmev 1000mg/100ml etaminophen Oral corbic Acid 500mg thromycin ftriaxone blecalciferol xamethasone midate htanyl cosemide corolac azepam latonin dazolam htoprazole pofol curonium c Sulfate			00000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029557	DIRECT	Υ	Н)			50 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	Rei	mdesivir			S	Intravenous bolus				Gilead
Increased	Azi Cef Cho Dex End Fer	corbic Acid thromycin ftriaxone blecalciferol xamethasone bxaparin htanyl azepam			00000000					Not Reported

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							<u>• </u>			
		atonin			С					t Reported
		lox+Lidocaine			С					t Reported
	Maa				С					t Reported
		azolam			С					t Reported
	Mon	telukast			С				No	t Reported
		etidine			С					t Reported
	Pant	oprazole			С					t Reported
		nethazine			С					t Reported
	Prop				С					t Reported
		alfate			С					t Reported
		othyroxine			С					t Reported
	Zinc	Sulfate			С				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029588	DIRECT	Υ	0	Т			79 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer Increased	ase Rem	desivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once- Loading;		Gil	ead
	Rem	desivir	Υ		S	Intravenous (not otherwise specified)			Gil	ead
	Toci	lizumab			С	. ,			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029595	DIRECT	Υ	0	Т			61 YR	Female	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Alanine Aminotransfer Increased	ase Rem	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once- Loading;		Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029605	DIRECT	Υ					71 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Confusional State;	Rem	desivir			S	Intravenous drip			Gil	ead

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Pyrexia; Unresponsive Stimuli	Ce Br Pr Mi Ind	examethasone eftriaxone eo Ellipta otonix rapex cruse Ellipta uncomycin			0000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029631	DIRECT	Υ	0	т			62 YR	Male	USA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Re	emdesivir			S	Intravenous bolus				Gilead
	Az Ce De En Gl: Lis	etaminiophen cithromycin eftriaxone examethasone noxaparin argine Insulin spro Insulin 9% Nacl			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029641	DIRECT	Υ	0	Т			25 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase Re	emdesivir			S	Intravenous (not otherwise specified)		4 DAY		Gilead
Aminotransferase Increased; Blood Alkali Phosphatase Increase Liver Function Test Increased	ine Az d; Ce Va	examethasone Iv cithromycin Iv eftriaxone Iv ancomycin Iv aoxaparin			C C C C	. ,				Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029648	DIRECT	Υ	D	E			74 YR	Male	USA

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Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route Dos	age Text	<u>Duration</u>	<u>Mfr</u>
Death	Remdesivir			S	Intravenous (not otherwise specified)			Gilead
	Albumin			С				Not Reported
	Promethazine W/Codeine			С				Not Reported
	D5w			C				Not Reported
	Dig			C				Not Reported
	Norco			C				Not Reported
	Kcl			C				Not Reported
	Lorazepam			Ċ				Not Reported
	Norepinephrine			Č				Not Reported
	Propofol			Ċ				Not Reported
	Sod Bicarb			C C				Not Reported
	Ns			Č				Not Reported
	Ceftriaxone			C C				Not Reported
	Ca Gluconate			Č				Not Reported
	Ceftazidime			Č				Not Reported
	Vanco			Č				Not Reported
	Amio			Č				Not Reported
	Mag Sulfate			Č				Not Reported
	Metronidazole			Č				Not Reported
	Azithromycin			č				Not Reported
	Pip/Tazo			Č				Not Reported
	Tocilizumab			Č				Not Reported
	Vanco							Not Reported
	Meropenem			C C C				Not Reported
	K Phos			C				Not Reported
	Acetaminophen			Č				Not Reported
	Bumex			C				Not Reported
	Dexamethasone			C C				Not Reported
	Enoxaparin			C				Not Reported
	Guaifenesin Dm			C				Not Reported
	Haldol			C				Not Reported
	Reg Insulin			C				Not Reported
	Reglan			C				Not Reported
				C				Not Reported
	Metoprolol Zofran			C				Not Reported
	Zorran Proamatine			C C C				
				0				Not Reported
	Atropine			0				Not Reported
	Epi Katanala			С				Not Reported
	Ketorolac			С				Not Reported



		zolam inylcholine			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18029681	DIRECT	Υ		ОТ			65 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Liver Function Test Increased	Rem	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Rem	desivir			S	Intravenous (not otherwise specified)		2 DAY		Gilead
	Onda	ansetron			С					Not Reported
		oprazole			С					Not Reported
		xetine			C C C					Not Reported
		rastatin			C					Not Reported
		elukast			С					Not Reported
		methasone			С					Not Reported
	Apixa				C C					Not Reported
		in Aspart			C					Not Reported
		penem			C					Not Reported
		apentin			С					Not Reported
	Prop	otol um Bicarbonate			С					Not Reported
					C C					Not Reported
		ated Ringers			C					Not Reported Not Reported
		omycin			C					
	Hepa Nore	nn pinephrine			C					Not Reported Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
15-Jul-2020	18030037	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0482899)20-	60 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Liver Function Test	Rem	desivir			S	Unknown	100 Mg			Gilead
Increased	Dexa Oxyg	methasone jen			C C					Not Reported Not Reported



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

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18030692	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0483267	20-	55 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfera Increased	ase Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	ilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Oxyge	n			С				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2020	18035551	DIRECT	Υ						Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Physical Product Label Issue; Product	I Remde	esivir Injection			S	Intravenous (not otherwise specified)			G	ilead
Administration Error; Product Label Confusion Product Use Complain	on;	esivir Injection			S	Intravenous (not otherwise specified)	Powder For Reconstitution	ı	G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	17896499	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0469667	20-	62 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mf</u>	<u>r</u>
Acute Kidney Injury; Death; Hypoxia	Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	ilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Vanco	mycin			S	Intravenous (not otherwise specified)	1500 Mg		N	ot Reported
	Genvo	ya			С	Oral	1 Dosage Form, Qd			ilead
	Biktarv	'Y			С	Oral	1 Dosage Form, Qd		G	ilead

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						20141104110	P • · · ·				
		oxaparin epime			C C	Subcutaneous Intravenous (not otherwise specified)	30 Mg 2 G				Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	17957797	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0476807	20-		85 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Death	Rer	ndesivir			S	Intravenous (not otherwise specified)	200 Mg	g, Once			Gilead
	Rer	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Dex End Fan Hyd Mei	irin [Acetylsalicylic Acid] camethasone oxaparin notidine Iralazine oprolol amine			000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	17969655	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0477743	20-		91 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation; Death Dyspnoea; Haemoptys	sis;	ndesivir			S	Intravenous (not otherwise specified)		g Iv X1, Then 100 X 4 Days			Gilead
Pulmonary Congestion	Lev	ofloxacin			С	. ,	Unk	•			Not Reported
		rfarin Iromorphone			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18027827	EXPEDITED (15-DAY)				US-GILEAD-20 0482378	20-			Female	USA

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Product Storage Error		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	180313	19 DIRECT	Υ		DE			77 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury		Remdesivir Dexamethasone			S C					Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	180313	53 DIRECT	Υ		ОТ			67 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Therapy Cessation	ase	Remdesivir Acetaminophen(Tylenol) Table 650 Mg Albuterol Inhaler Ceftriaxone 1 G In Ns Azithromycin 500 Mg In Ns Heparin 7,500 Unit Inj Dextromethorphan-Guainfenesi 20mg Levothyroxin Tablet 137 Mcg Ondansetron Disintegrating Tablet 4 Mg			8 0 00000 00	Intravenous bolus	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	180313	61 DIRECT	Υ		ОТ			40 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased		Remdesivir Remdesivir			S S	Intravenous bolus Intravenous bolus	Other Frequency:Once;			Gilead Gilead



							-				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031365	DIRECT	Υ	C	T				88 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	ase Remd	lesivir	Y		S				4 DAY		Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031451	EXPEDITED (15-DAY)				US-GILE 0482855	EAD-2020-			Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Intercepted Product Preparation Error	Remo	lesivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031615	DIRECT	Υ						67 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Rash Papular; Scab	Remo	lesivir For Injection			S	Intravenous d	rip				Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031625	DIRECT	Υ	С	ÞΕ				47 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Coagulopathy; Disseminated Intravascular Coagulat Ischaemic Hepatitis; L Disorder; Liver Functio	tion; iver	lesivir I On Previous Medwatch			S C						Gilead Not Reported

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Test Increased										
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	Age	<u>Sex</u>	Country
16-Jul-2020	18031630	DIRECT	Υ					77 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Hepatic Enzyme Increased	Remo	desivir			S	Intravenous bolus			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031742	DIRECT	Υ					31 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	:
Bradycardia	Remo	desivir			S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031745	DIRECT	Υ	0	Т			39 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	Mfr	
Infusion Site Erythema Infusion Site Extravasa		desivir			S	Intravenous (not otherwise specified)			Gil	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031962	DIRECT	Υ					59 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Chest Discomfort; Cho Sensation; Cough; Dyspnoea; Nausea	•	desivir aparin			S C	Intravenous bolus				ead It Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18031968	DIRECT	Υ	0	Т			72 YR	Male	USA

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Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4;			Gilead
Aminotransferase Increased	Dexamethasone 6mg lv Q6h Then Daily			С	. ,	<i>y</i>			Not Reported
	Enoxaparin 30mg Sq Q12h			С					Not Reported
	Famotidine 20mg Po Q12h			C C					Not Reported
	Culturelle 1 Cap Daily Vitamin C 1 Gram Po Daily			C					Not Reported Not Reported
	Zinc Sulfate 220mg Po Daily			C					Not Reported
FDA Received Date Case	# Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020 1803 ⁻	1980 DIRECT	Υ	DI	E			64 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S		Other Frequency:X 1 Dose;			Gilead
Aminotransferase	Methylprednisolone			С					Not Reported
ncreased; Renal Failure; Respiratory Failure; Septic	Cefepime			С					Not Reported
Shock	Ascorbic Acid			С					Not Reported
	Azithromycin Protonix			C					Not Reported Not Reported
	Zinc Sulfate			Č					Not Reported
FDA Received Date Case	# Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020 18032	2087 DIRECT	Υ	0	Т			37 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase	Remdesivir			S					Not Reported
ncreased	Albuterol			C					Not Reported
	Benzonatate			С					Not Reported
	Dexamethasone Enovaparin			C					Not Reported Not Reported
	Enoxaparin Ceftriaxone			C					Not Reported
	Bio-K Plus			Č					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18032093	DIRECT	Υ		ОТ			60 YR	Male	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Oxygen Saturation Decreased; Platelet Co Increased	ount Asp Azit Ben Car	ndesivir irin Ec 81mg Po Daily hromycin 500mg Iv Daily zonatate 100mg Q8h vedilol 6.25mg Bid			s C C C C	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mgx4d;			Not Reported Not Reported Not Reported Not Reported Not Reported
	Dex Eno Fam Cult Vita	riaxone 1g Iv Daily amethasone 6mg Iv Daily xaparin 30mg Subq Q12h notidine 20mg Po Q12h urelle 1 Cap Po Daily min C 1000mg Daily To Bid s Sulfate 200mg Po Daily			000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18032103	DIRECT	Υ		DE			77 YR	Femal	e USA
Preferred Term	Pro	<u>duct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Hypoxia; Pulse Absent		ndesivir Under Emergency Authorization	Υ		S	Intravenous bolus		1 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18033239	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0483276)20-	55 YR	Male	USA
Preferred Term	<u>Pro</u>	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation; Deatl	h Ren	ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		hromycin ztropine [Benzatropine]			C C	. ,				Not Reported Not Reported

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						Detailed IN	ероп			
		Cefepime Ceftriaxone Daptomycin Dexamethasone Precedex Diazepam Enoxaparin Fentanyl nsulin Lispro Culturelle Meropenem Metoprolol Norepinephrine			00000000000000	Detailed N	ероп			Not Reported
		Phenylephrine Piperacillin / Tazobactam			C					Not Reported Not Reported
	S	Piperacillin / Tazobactam Sodium Bicarbonate Vitamin C [Ascorbic Acid] Zinc Sulfate			00000					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	1803492	28 DIRECT	Y	DE	≣			48 YR	Female	USA
Preferred Term]	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Cardio- Respiratory Arrest	, , , , , , , , , , , , , , , , , , ,	Remdesivir Albuterol Ascorbic Acid Azithromycin Ceftriaxone Dexamethasone Enoxaparin nsulin Nph Novolog Insulin pratropium Thiamine Hydrocodone/Acetaminophen Fentanyl Continuous Infusion Norepinephrine Propofol Potassium Phosphate			% 000000000000000	Intravenous drip				Gilead Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	1803492	9 DIRECT	Υ		ОТ			69 YR	Femal	e USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased	ase	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once- Loading;			Gilead
	I	Remdesivir	Υ		S	Intravenous (not otherwise specified)	-			Gilead
		Azithromycin			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	1803493	2 DIRECT	Υ		ОТ			57 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mg/Dx4d;			Gilead
Aminotransferase Increased; Blood Biliru		Azithromycin 500mg Iv Daily			С					Not Reported
Increased; Blood	,	Carbamazepine 200mg Po Q Ceftriaxone 1g Iv Daily	12h		C C					Not Reported Not Reported
Creatinine Increased;		Dexamethasone 6mg Iv Daily	,		C					Not Reported
Inflammatory Marker		Enoxaparin 40mg Subq Q12h			Č					Not Reported
Increased; Pneumonia		Famotidine 20mg lv Q12h			Č					Not Reported
Staphylococcal; Thera _l Cessation	py	entanyl Infusion			С					Not Reported
Cessation		Meropenem 1g Iv Q6h			С					Not Reported
		Midazolam Infusion			С					Not Reported
		Propofol Infusion			C					Not Reported
		Risperidone 0.5mg Po Qhs			С					Not Reported
		Γocilizumab 400mg X 1			С					Not Reported
		/ancomycin Varying Doses			С					Not Reported
		/itamin C 1000mg Daily			С					Not Reported
	•	Zinc Sulfate 220mg Po Daily			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		Mfr
Liver Function Test Increased		ndesivir ilizumab	Y		S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034934	DIRECT	Υ					62 YR	Female	e USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Fail Renal Impairment	Azit Cef Cef Van	ndesivir hromycin triaxone epime comycin epinephrine	Y		s c c c c	Intravenous drip				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034935	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Liver Funct Test Increased	Acte	ndesivir emra	Y		S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034936	DIRECT	Υ					75 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Product Administration Error; Product Dispens Error; Product Prepara Issue	sing	ndesivir Injection			S	Intravenous drip				Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034938	DIRECT	Υ					55 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Er Product Preparation Is		desivir			S	Intravenous drip			Gil	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034939	DIRECT	Υ					69 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Blood Bilirubin Increas Pneumonia Pseudomo Systemic Candida		desivir	Y		S				No	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034940	DIRECT	Υ					55 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Incorrect Dose Administered; Product Dispensing Error; Prod Label Issue; Product Preparation Issue		desivir			S	Intravenous drip			Gil	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034941	DIRECT	Υ	DI	=			80 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Death	Rem	desivir			S	Intravenous drip	Other Frequency:200 Mg X1, 100 Mg;		Gil	lead
	Deva	methasone			С		,		No	t Reported

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FDA Received Date	Case #	Case T	<u>ype</u>	<u>Health</u>	Prof (Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	180349	42 DIREC	Γ	Υ	[DE			72 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Myocardial Infarction; Cardiac Arre Oxygen Saturation Decreased		Remdesivir Cefepime 2g Iv C Dexamethasone Enoxaparin 1 Mg	6 Mg Iv Qdaily			S C C	Intravenous drip				Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case T	<u>ype</u>	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	180349	43 DIREC	Г	Υ	(OT			51 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer: Increased; Aspartate Aminotransferase Increased		Remdesivir Sodium Chloride Acetaminophen I Albuterol Inhaler Regular Insulin S Dexamethasone Losartan Docusate Zinc Sulfate Po Ascorbic Acid Po Cholecalciferol P Multivitamin W/ M Rivaroxaban Ceftriaxone Iv Azithromycin Iv Furosemide Iv Pe	Po Sq Iv o Minerals Po	Y		s 000000000000000	Intravenous bolus	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case T	<u>ype</u>	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	180349	44 DIREC	Γ	Υ	(OT			70 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Glomerular Filtration R	Rate	Remdesivir		Υ		S	Intravenous (not				Gilead

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Decreased						otherwise specified)				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
16-Jul-2020	18034949	DIRECT	Υ		DE			64 YR	Male	USA
Preferred Term	Proc	duct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Agitation; Diarrhoea; Headache; Respiratory Distress	Dexa Love Furo Iohe	semide xol mine	Y		s c c c c c c	Intravenous bolus				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
16-Jul-2020	18034950	DIRECT	Y		DE			84 YR	Male	USA
Preferred Term	Proc	duct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Interaction; Hepa Failure	atic Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
	Asco	aban 5 Mg Po Bid orbic Acid 500 Mg Po Daily Food			C C	. ,				Not Reported Not Reported
	Cefti Chol Dapt Dexa Enox Escit Guai Levo Meto Zinc	nromycin 500 Mg Po Q24h riaxone 1 Gm Iv Daily lecalciferol 1,000 Iu Po Daily tomycin 450 Mg Iv Q24h amethaxone 6 Mg Iv Daily kaparin 90 Mg Sq Q12h talopram 10 Mg Po Daily ifenesin Er 600 Mg Po Bid oprolol 12.5 Mg Po Bid Sulfate 220 Mg Po Daily anyl 25 Mcg Iv Q1hr Prn			000000000000					Not Reported



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

						Detailed Ne	port				
		m Bicarbonate 150 000 Ml D5 Iv Solution 50			С						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18034951	DIRECT	Υ		ОТ				77 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration R Decreased	Rate Remde	esivir	Υ		S	Intravenous (not otherwise specified)	ı				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2020	18035164	DIRECT	Υ						91 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Creatinine Renal Clearance Decreased; Therapy Interrupted	ase Remde	əsivir			S	Intravenous (not otherwise specified)		Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	17878094	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470901)20-		57 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Death	Remde	esivir			S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	17878265	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0470883)20-		70 YR	Male	USA

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Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Covid-19 Pneumonia;		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Respiratory Failure		Hydroxychloroquine Actavis			С	. ,				Not Reported
		Acetaminophen			Č					Not Reported
		Amlodipine			Č					Not Reported
		Apixaban			Č					Not Reported
		Aspirin [Acetylsalicylic Acid]			Č					Not Reported
		Furosemide			Č					Not Reported
		Gabapentin			Č					Not Reported
		Insulin Glargine			Č					Not Reported
		Insulin Lispro			Č					Not Reported
		Isosorbide Mononitrate			C					Not Reported
		Metoprolol			C					Not Reported
		Rosuvastatin			C					Not Reported
		Sevelamer			C					Not Reported
		Sodium Polystyrene Sulfonate Plasma			C C					Not Reported Not Reported
					C					
		Oxygen								Not Reported
		Eliquis			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	179250	062 EXPEDITED (15-DAY)	C	E, HO	FR-PFIZER INC 2020238576	D-	80 YR	Male	FRA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Orug Ineffective For		Levofloxacin			S		Unk			Pfizer
Unapproved Indication	n; Off	Levofloxacin			S					Pfizer
abel Use		Meropenem			S		Unk			Pfizer
		Meropenem			S					Pfizer
		Tigecycline			S		Unk			Pfizer
		Tigecycline			S					Pfizer
		Isavuconazonium Sulfate			S		Unk			Unknown
		Isavuconazonium Sulfate			S					Unknown
		Remdesivir			S	Intravenous (not	200 Mg			Not Reported
					Ü	otherwise specified)				. ist itopolica
		Dame da air iir			S	,				Not Reported
		Remdesivir			0					Not Reponed

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							taned ite	POIL				
	Colimyc	ine [Colistin Sulfate]			S			Unk				Not Reported
	Colimyc	ine [Colistin Sulfate]			S							Not Reported
	Voricona				С			Unk				Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>		Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020 179	925759	EXPEDITED (15-DAY)			DE, HO, LT,	ОТ	US-GILEAD-20 0474420	20-		77 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Rout	<u>te</u>	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Blood Creatinine Increased; Blood	Remdes	ivir			S		enous (not wise specified)	200 Mg	ı, Once			Gilead
Potassium Increased; Blood Pressure Decreased; Death;	Remdes	ivir			S		renous (not wise specified)	100 Mg	ı, Qd			Gilead
Haematocrit Decreased;	Plasma				С			Unk				Not Reported
Haemoglobin Decreased; Thrombocytopenia; Vomiting	Acetami Chlorhe: Dexmed Docusat Fentany Haloperi Hydroco Insulin F Ketamin Levetira: Lorazep Metronic Midazola Milk Of I Pantopra Quetiapi Sodium Sodium	xidine letomidine e;Senna dol rtisone Regular Hm e cetam am dazole am Magnesia azole ne Bicarbonate Chloride Polystyrene Sulfonate ne Acid						Olik				Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	17951126	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0475719	20-		82 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Death	Remd	esivir			S	Intravenous (not otherwise specified)		g, Once		(Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 M	g, Qd		(Gilead
	Plasm Ceftria Emen Zofrar	axone d [Aprepitant] n [Ondansetron] azine [Prochlorperazine te]			000000					1 1 1 1	Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	Age	<u>Sex</u>	Country
17-Jul-2020	18020525	NON-EXPEDITED	<u>. 104111</u>		DE, OT	US-SA-2020SA		<u> </u>	<u>go</u>	Unknown	
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Subdural Haemorrhag	e Plavix				S	Unknown	Unk			5	Sanofi
	Acetyl	salicylic Acid			S	Unknown	Unk			1	Not Reported
	Low M	Nolecular Weight Heparin			S	Unknown	Unk			1	Not Reported
	Remd	esivir			S	Intravenous (not otherwise specified)	Unk			1	Not Reported
	Baricit	inib			S	Oral	Unk			1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18035516	DIRECT	Υ		ОТ				51 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	отс	Role	Route	Dosage	Text	Duration	N	<u> 1fr</u>

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Acute Kidney Injury; Lung	g Rem	desivir	Υ		S	Intravenous drip				Gilead
nfiltration	Vano Zosy	romycin comycin			C C C C	·				Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020 1	8035517	DIRECT	Υ	0	Т			70 YR	Male	AFG
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury;	Rem	desivir			S	Intravenous drip				Gilead
Disease Complication; Pneumonia	Zosy	romycin n medrol			C C C	·				Not Reported Not Reported Not Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020 1	8035597	DIRECT	Υ	0	Т			57 YR	Femal	e USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury	Rem	desivir	Υ		S	Intravenous drip				Gilead
	Solui	medrol			С	·				Not Reported
FDA Received Date C	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020 1	8035639	DIRECT	Υ					30 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferas Increased; Aspartate Aminotransferase	e Rem	desivir	Υ		S	Intravenous drip	Other Frequency:200mgx1,100r gx4;	n		Gilead
Increased	Onda Dexa Enox	aminophen 500mg Tab ansetron 4mg Iv amethasone 6mg Iv aparin 40mg Syringe nex Dm 600/30mg Tab Sr			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported



	Aceta	minophen 325mg Tab			С				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18035719	DIRECT	Υ	0	Γ			1 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased	Zosyn	ephin omycin	Y		S C C C	Intravenous drip			1 1 1	Gilead Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18035725	DIRECT	Υ	DE	≣				Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Disease Progression	Remd	esivir			S	Intravenous (not otherwise specified)			C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18035926	DIRECT	Υ	0	Γ			57 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Anxiety; Drug Hypersensitivity; Feelir	Remd ng	esivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		(Gilead
Abnormal; Headache; Pharyngeal Swelling;	Remd	esivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		(Gilead
Refusal Of Treatment Patient	Ascorl Azithro Ceftria Chole	calciferol nethasone aparin			0000000	outer mee openings,			1 1 1 1 1	Not Reported

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								<u> </u>			
		Zinc Sulfa	Guaifenesin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180359	933	DIRECT	Υ	C	T			89 YR	Female	e USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Infusion Related Reac Infusion Site Extravasation; Infusion Site Swelling		Remdesi	vir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180361	176	DIRECT	Υ	C	T			44 YR	Male	USA
Preferred Term		Product		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		Mfr
Covid-19 Pneumonia; Oxygen Saturation Decreased; Platelet Co Increased; Sars-Cov-2 Test Positive		Azithrom Benzona Ceftriaxo Enoxapa Famotidir Advair Hf Insulin Lie Spiriva 18 Vitamin C	vir sophen Q6h Prn Fever ycin 500mg Iv Daily tate 200mg Q8h ne 1g Iv Daily rin 30mg Subq Q12h ne 20mg Po Q12h ra 115/21 2 Puff Bid spro Sliding Scale Bmcg Inhaled Daily C 1000mg Po Daily ate 200mg Po Daily			s	Intravenous (not otherwise specified)	Other Frequency:200mg, 100mgx4d;	4 DAY		Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180361	194	DIRECT	Υ	C	T			50 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



							P			
Alanine Aminotransferas Increased; Aspartate	se Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Aminotransferase Increased; Sars-Cov-2 Test Positive	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
Test i ositive	Aceta	minophen			С					Not Reported
		methasone			С					Not Reported
	Docus	sate			С					Not Reported
	Enox	aparin			С					Not Reported
		trigine			C C					Not Reported
	Lithiu				С					Not Reported
		prazole			С					Not Reported
		ipexole			С					Not Reported
	Senna				С					Not Reported
	Trazo	done			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020 1	18036257	DIRECT	Υ	H	0			69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020 1	18036332	DIRECT	Υ	0	Т			63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferas Increased; Aspartate	se Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase	Aceta	minophen			С	• ,				Not Reported
Increased; Therapy	Amlo				С					Not Reported
Cessation	Azithr	omycin			С					Not Reported
		axone			С					Not Reported
		methasone			C					Not Reported
		edetomidine			С					Not Reported
		aparin			С					Not Reported
	Fenta				С					Not Reported
	Midaz	<u></u>			С					Not Reported

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	Norepinephrine Propofol Vasopressin			C C C Health Prof Outcomes Mfr Control # 503B						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18037300	EXPEDITED (15-DAY)			DE, OT	GB-IBIGEN-202	20.09028	84 YR	Male	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Livedo Reticularis	Oxygo Pipera	en acillin & Tazobactam			C S	Intravenous (not otherwise specified)	4.5 G, Tid			Not Reported Not Reported
	Atorva	urinol renadine astatin methasone			C C C S	Oral	6 Mg, Qd			Not Reported Not Reported Not Reported Not Reported
	Dalte	orazole parin omycin			C C S	Intravenous (not otherwise specified)	1 G, Bid			Not Reported Not Reported Not Reported
	Remo	desivir			S	Intravenous (not otherwise specified)	200, Stat			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
17-Jul-2020	18037988	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0483702	20-	54 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Cardiac Arrest; Hypotension	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Metfo Atorva Azithr	n (E.C.) rmin astatin romycin axone			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
		methasone			č					Not Reported

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	Enoxa Epinep Epopro Famoti Fentar Furose Lantus	hrine ostenol idine iyl emide			0000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	Insulin Midazo									Not Reported Not Reported
		nephrine lephrine			C C C					Not Reported Not Reported
	Propof	oĺ			Č					Not Reported
	Rocuro	onium n Bicarbonate			C C C					Not Reported Not Reported
	Vasop				C					Not Reported
	Vecuro	onium			С					Not Reported
	Tociliz	umab			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facil	<u>lity Age</u>	<u>Sex</u>	Country
17-Jul-2020	18038118 EXPEDITED (15-DAY)					US-GILEAD-20 0483220	20-		Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Overdose	Remde	esivir			S	Unknown	200 Mg, Once			Gilead
	Remde	esivir			S	Unknown	200 Mg, Once			Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facil	lity Age	<u>Sex</u>	Country
17-Jul-2020	18038968	EXPEDITED (15-DAY)		[DE, OT	GB-BAUSCH-B 020115	L-2020-	84 YR	Male	GBR
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Livedo Reticularis	Dexam	nethasone			S	Oral				Valeant
	Pipera	cillin And Tazobactam			S	Intravenous (not otherwise specified)				Not Reported
	Vanco	•			S	Intravenous (not otherwise specified)				Not Reported
	Remdesivir				S	Intravenous (not otherwise specified)	200, Stat			Not Reported



		Oxygen Allopurin Fexofena Atorvasta	adine atin			C C C	Unknown				Not Reported Not Reported Not Reported Not Reported
		Omepra	zole			С	Unknown				Not Reported
		Daltepar	in			С					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u> 503B Fa</u>	cility Age	<u>Sex</u>	Country
17-Jul-2020	180389	69	EXPEDITED (15-DAY)		I	DE, OT	US-GILEAD-20 0483273	020-	75 YR	Male	USA
Preferred Term		Product	i	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Cardio-Respiratory Arr Death	rest;	Remdes	ivir			S	Intravenous (not otherwise specified	100 Mg, Qd)			Gilead
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u> <u>503B Fa</u>	cility Age	<u>Sex</u>	<u>Country</u>
17-Jul-2020	180394	87	EXPEDITED (15-DAY)				US-GILEAD-20 0483949	020-	64 YR	Male	USA
Preferred Term		Product	<u>I</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Product Preparation Is	ssue	Remdes	ivir			S	Unknown				Gilead
FDA Received Date	Case #		Case Type	Health	Prof (Outcomes	Mfr Control	# <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
17-Jul-2020	180395	30	EXPEDITED (15-DAY)		(ОТ	US-GILEAD-20 0483230	020-	53 YR	Male	USA
Preferred Term		Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
International Normalise	ed	Remdes	ivir			S	Intravenous bolus	100 Mg, Qd			Gilead
Ratio Increased; Prothrombin Time		Remdes	ivir			S	Intravenous bolus	Unk			Gilead
Prolonged;		Remdes	ivir			S	Intravenous bolus	Unk			Gilead
Thrombocytopenia		Decadro	n [Dexamethasone]			С		6 Mg, Qd			Not Reported
		Actemra				С		Unk			Not Reported
						С					



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18040312	EXPEDITED (15-DAY)				US-GILEAD-20 0483260	20-	59 YR	Male	USA
Preferred Term	<u>P</u> 1	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Medication Error	Re	emdesivir			S	Intravenous (not otherwise specified)	100 Mg, Once			Gilead
	Az	rithromycin			С		Unk			Not Reported
	Ce	eftriaxone			С		Unk			Not Reported
	De	examethasone			С		Unk			Not Reported
	Er	noxaparin			С		Unk			Not Reported
	Combivent		С		С	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18040633	EXPEDITED (15-DAY)		[DE, OT	US-GILEAD-20 0483659	20-	85 YR	Male	USA
Preferred Term	<u>P</u> 1	oduct	Comp.	<u>otc</u>	Role	Route	Dosage Text	Duration		Mfr
Anuria; Blood Bilirubin Increased; Blood	Re	emdesivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
Creatinine Increased; Cardiac Arrest; Hypotension;	Re	emdesivir			S	Intravenous (not otherwise specified)	100 Mg			Gilead
Hypothermia; Respirat	O. <i>y</i>	examethasone			С		6 Mg, Qd			Not Reported
Arrest; Unresponsive 1 Stimuli	est; Unresponsive To Plasma Fresh Frozen				C C C		Unk			Not Reported Not Reported Not Reported
	Valsartan				С		Unk			Not Reported
		odium Chloride 0.9%			С		500 MI			Not Reported
		ormal Saline			С		75 MI/Hr			Not Reported
		bumin (Ljudski) 20%			С		Unk			Not Reported



FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18040850	EXPEDITED (15-DAY)		(OT	US-GILEAD-2 0483686	020-	88 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia	Remd	lesivir			S	Intravenous bolus	100 Mg, Once			Gilead
	Lisino	pril			С		Unk			Not Reported
	Dexar	methasone			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18042660	DIRECT	Υ					62 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferanceased	ase Remd	lesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18042664	DIRECT	Υ	ŀ	Ю			32 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	Tylend Azithr Dexar Enoxa Furos Levall Rocep	lesivir ol 650mg omycin 500mg methasone 6mg aparin 40mg emide 40mg outerol ohin 1gm hine 2mg			s ccccccc	Intravenous drip	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	•	Case Type	Health	Prof (<u> Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	18042688	DIRECT	Υ	(ТС			97 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Blood Creatinine		Remdesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
Increased		Carboxymethylcellulose			С					Not Reported
		Ophthalmic Drops Ceftaroline Premarin Vaginal Cream Enoxaparin			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	04 DIRECT	Υ					60 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Laboratory Test Abnormance Therapy Cessation	rmal;	Remdesivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	<u>Case Type</u>	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	11 DIRECT	Υ	Н)			82 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration F	Rate	Remdesivir			S	Intravenous drip		4 DAY		Gilead
Decreased		Atorvastatin Azithromcyin Dexamethasone Duloxetine Etomidate Famotidine Furosemide Heparin Insulin Lispro Ipratropium Levetiracetam Lorazepam Memantine Meropenem Oxybutynin Succinylcholine Propofol Gapabentin Fentanyl			000000000000000000000000000000000000000					Not Reported

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								-			
		Midazola Norepine				C C					Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	717	DIRECT	Υ					86 YR	Female	USA
Preferred Term		Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Creatinine Renal Clearance Decreased		Remdes	ivir			S	Intravenous drip		1 DAY	(Gilead
FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	722	DIRECT	Υ	0	ÞΕ			1 YR	Female	USA
Preferred Term		Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acidosis; Acute Kidney Injury; Cardiac Arrest;		Remdes	ivir	Υ		S	Intravenous (not otherwise specified)		(Gilead
Decreased Appetite; Encephalopathy; Letha Malaise; Nausea;	argy;	Azithron	scent Plasma nycin 500 Mg Iv Once			C C	·	,			Not Reported Not Reported
Pneumonia; Pyrexia; Respiratory Distress; Respiratory Failure; Se	eptic	Dexame	one 1 Gm Iv Once Dailly thasone 6 Mg Iv Once			C C					Not Reported Not Reported
Shock		Daily Enoxapa Daily	arin 40 Mg Sq Once			С				1	Not Reported
		Lasix 20	Mg Iv Bid 9a, 5p Mg Iv X 1			C C					Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	760	DIRECT	Υ	C	DΤ			62 YR	Male	USA
Preferred Term		Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury		Remdes	ivir			S	Intravenous (not otherwise specified)		(Gilead
			e thasone onated Heparin			C C C	,	•		1	Not Reported Not Reported Not Reported

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						Dotalioa 110	роп			
		Insulin Glargine Insulin Lispro Linezolid Mycophenolate Tacrolimus Dexmedetomidine Fentanyl Midazolam Norepinephrine Sodium Bicarbonate			000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	765 DIRECT	Υ					26 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasation; Pain; Peripheral Swelling; S Discolouration	kin	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	778 DIRECT	Υ	0	-			43 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Laboratory Test Abnor	rmal	Remdesivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180427	796 DIRECT	Υ	DE	Ē			72 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardio-Respiratory Art		Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Increased; Leukocytos Pneumonia Aspiration		Convalescent Plasma Hydroxychloroquine 400 Mg > Levetiracetam 500 Mg Iv Q12 Zosyn 3.375 Gm Iv Q8hr			C C C					Not Reported Not Reported Not Reported Not Reported



		Vancomycin 1250 Mg Iv Q18h			С					Not Reported
		Dexamethasone 20 Mg Iv Dail			С					Not Reported
		Amlodipine 5 Mg Po Once Dai	ily		С					Not Reported
		Aspirin 81 Mg Po Once Daily			C					Not Reported
		Atorvastatin 80 Mg Po Daily			C					Not Reported
		Donepezil 10 Mg Po W/			С					Not Reported
		Breakfast Enoxaparin 40 Mg Sq Once Daily			С					Not Reported
		Enoxaparin 100 Mg Sq Q12hr			С					Not Reported
		Enoxaparin 90 Mg Sq Q12hr			Ċ					Not Reported
		Fluoxetine 20 Mg Po Once Da	aily		С					Not Reported
		Metoprolol 25 Mg Po Q12hr	,		С					Not Reported
		Tamsulosin 0.4 Mg Po Once Daily			С					Not Reported
FDA Received Date	Case #	Case Type	<u>H</u>	ealth Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180428	00 DIRECT	Υ		DE			58 YR	Male	USA
Preferred Term		Product	Co	<u>тр.</u> <u>ОТ(</u>	Role	Route [<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
					_					
Hypotension; Hypoxia; Pulmonary Function To		Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
			Y			Intravenous (not otherwise specified)				
Pulmonary Function To		Azithromycin 500 Mg Iv X 1	·		С					Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once	·							
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily	e		C C					Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai	e		C C					Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once	e		C C					Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily	e		C C C					Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once	e		C C					Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once Daily	e		C C C					Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once	e		C C C					Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once Daily Methyprednisolone 60 Mg Iv Q12hr	e		C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once Daily Methyprednisolone 60 Mg Iv Q12hr Zinc Sulfate 220 Mg Po Bid	e		C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once Daily Methyprednisolone 60 Mg Iv Q12hr	e		C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To	est	Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once Daily Methyprednisolone 60 Mg Iv Q12hr Zinc Sulfate 220 Mg Po Bid Lantus 15 Units Sq Daily Lantus 20 Untis Sq Bid	e	ealth Prof	00 00 0 00		503B Facility	<u>Age</u>	Sex	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Pulmonary Function To Decreased	est	Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily Ceftriaxone 1 Gm Iv Once Dai Enoxaparin 40 Mg Sq Once Daily Enoxaparin 80 Mg Sq Once Daily Methyprednisolone 60 Mg Iv Q12hr Zinc Sulfate 220 Mg Po Bid Lantus 15 Units Sq Daily Lantus 20 Untis Sq Bid Case Type	e		00 00 0 000	otherwise specified)	503B Facility	Age 1 YR	<u>Sex</u> Male	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported



<u>Preferred Term</u>		Product	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Dyspnoea; Hypersensitivity; Rash	;	Remdesivir	Υ		S	Intravenous (not otherwise specified))			Gilead
Swelling		Azithromycin 500 Mg Iv X 1 Azithromycin 500 Mg Po Once Daily			C C	. ,				Not Reported Not Reported
		Ascorbic Acid 1000 Mg Po Q12 Ceftriaxone 1 Gm Iv Once Daily Diphenhydramine 25 Mg Iv X 1			C C C					Not Reported Not Reported Not Reported
		Stat Enoxaparin 60 Mg Sq Q12hrs Methylprednisolone 60 Mg Iv Q6hr			C C					Not Reported Not Reported
		Zinc Sulfate 220 Mg Po Bid			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control i	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180428	335 DIRECT	Υ						Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Liver Function Increased	Test	Remdesivir	Υ		S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>outcomes</u>	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2020	180428	345 DIRECT	Υ	D	E			71 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Fail Respiratory Failure	ure;	Remdesivir	Υ		S	Intravenous (not otherwise specified))			Gilead
		Convalescent Plasma Amlodipine 10 Mg Ascorbic Acid 1000 Mg Po Q12 Dexamethasone 10 Mg Iv Once			C C C	. ,				Not Reported Not Reported Not Reported Not Reported
		Daily Hydroxychloroquine 400 Mg Po Daily)		С					Not Reported
		Hydroxchloroquine 400 Mg Po Q12hrs			С					Not Reported

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							Dotanoa itt	5 1 1 1 1 1 1 1 1 1 1				
		Enoxaparin	50 Mg Sq Q12hrs			С					Not I	Reported
			100 Mg Sq Q12hrs			С					Not I	Reported
			100 Mg Sq Once			С						Reported
		Daily .	0 1									•
		Enoxaparin	80 Mg Sq Once			С					Not I	Reported
		Daily .	5 1									•
			70 Mg Sq Q12hrs			С					Not I	Reported
			n 1 Gm Q8hr			C						Reported
			n 500 Mg Q8hr			C						Reported
			n 1 Gm Iv Q12hrs			C						Reported
			n 750 Mg Iv Q12hrs			Č						Reported
			220 Mg Po Bid			Č						Reported
			nisolone 40 Mg Iv			Č						Reported
		Q12hr	modicine to mg m			Ü					1400	τοροποα
		Lantus 10 L	Inits Sa Bid			С					Not I	Reported
			24 Units Sq Bid			Č						Reported
			•									•
FDA Received Date	Case #	<u>Ca</u>	ase Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>		Country
17-Jul-2020	180428	48 DI	RECT	Υ	(OT			69 YR	Male		USA
11 Gai 2020	100120	.0 2.		·	`				00 111	maio		00/1
				_								
<u>Preferred Term</u>		<u>Product</u>		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>	
Laboratory Test Abno	rmal	Remdesivir				S					Gilea	ad
Laboratory Test Abrio	IIIIai	Remuesivii				<u> </u>	Intravenous bolus				Gilea	au
FDA Received Date	Case #	Ca	ase Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>		Country
17-Jul-2020	180428	73 DI	RECT	Υ	г	DE			65 YR	Female	_	USA
17-301-2020	100420	75 Di	KLOT	1		<i>)</i> _			03 110	i Gillaid	-	USA
Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>	
Brain Injury; Pulseless	3	Remdesivir		Υ		S					Not I	Reported
Electrical Activity												
FDA Received Date	Case #	Ca	ase Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>		Country
17-Jul-2020	180428	76 DI	RECT	Υ	г	DE			72 YR	Male		USA
17-JUI-ZUZU	100420	70 DI	NLO1	'	L	<i></i>			12 11	iviale		UUA
Preferred Term		Product		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>	
Pland Creatining		Domdooisis		V		c					Not !	Danartad
Blood Creatinine		Remdesivir		Υ		S						Reported
increased; Enterobact	reased; Enterobacter Actemra					С					NOT I	Reported



Pneumonia										
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2020	18038171	EXPEDITED (15-DAY)			DE, OT	GB-AUROBIND APL-2020-0352		84 YR	Male	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Livedo Reticularis	Piper	acillin+Tazobactam			S	Intravenous (not otherwise specified)	13.5 Gram, Once A Day (4.5 G, Tid)			Aurobindo
	Dexa	methasone			S	Oral	6 Milligram, Once A Day			Not Reported
	Vanc	omycin			S	Intravenous (not otherwise specified)	2 Gram, Two Times A Day (1 G, Bid)			Not Reported
	Remo	desivir			S	Intravenous (not otherwise specified)	Unk (200, Stat)			Not Reported
	Oxyg	en			С	Unknown	Unk			Not Reported
	Allopi	urinol			С	Unknown	Unk			Not Reported
	Fexof	enadine			С	Unknown	Unk			Not Reported
	Atorv	astatin			С	Unknown	Unk			Not Reported
	Omer	orazole			С	Unknown	Unk			Not Reported
	Dalte	parin			С	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2020	18042881	DIRECT	Υ		ОТ			74 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remo	lesivir	Υ		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2020	18042886	DIRECT	Υ					73 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>

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

Infusion Site Extravasation; Periphe Swelling		emdesivir			S					N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2020	18042888	B DIRECT	Υ						64 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Dialysis; Renal Failure	R	emdesivir			S	Intravenous bolus				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2020	18042948	3 DIRECT	Y	0	Т				62 YR	Female	USA
Preferred Term	<u>P</u>	<u>roduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Alanine Aminotransfer Increased	AAAABDEEFINBMQMINR	cetaminophne 650mg Q4h Prn scorbic Acid 1000 Mg Po Bid torvastatin 80 Mg Once Daily enzonatate 200 Mg Po Bid noxaparin 90 Mg Sc Q12h amotidine 20 Mg Iv/Po Q12h entanyl Iv Continuous Infusion isulin Glargine 40 Units Sc edtime lethylprednisolone 40 Mg Iv/6h lidazolam Iv Continuous fusion orepinephine Iv Continuous fusion ocuronium Continuous Iv fusion ertraline 50 Mg Po Daily hiamine Mononitrate 100 Mg o Daily inc Sulfate 220 Mg Po Bid			\$ CCCCCCCC C C C C C C	Intravenous bolus					ilead ot Reported

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

FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2020	1804289	DIRECT	Υ		ОТ			80 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B	lood	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
		Dexamethasone Cefepime Propofol Fentanyl Diltiazem Norepinephrine			C C C C C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2020	1804289	DIRECT	Υ		ОТ			40 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dyspnoea; Eye Irritatic Lacrimation Increased Photophobia	;	Remdesivir (Eua) 100 Mg In Sodium Chloride 0.9 % 250 Ml Ivpb Ceftriaxone 1g Q24h Doxycycline 100 Mg Bid Heparin 5000 Units Subq Bid Acetaminophen 1000 Mg Q8h Senna 17.2 Mg Dextromethorphan-Guaifenesin (Robitussin-Dm) 10-100 Mg/5 M Liquid 5 M	I		8 000000	Intravenous drip				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2020	1804292	21 DIRECT	Υ					42 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase	Remdesivir			S	Intravenous (not otherwise specified)				Not Reported

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							•				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2020	18042929	DIRECT	Υ		ОТ				48 YR	Female	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Liver Function Test Increased	Re	emdesivir			S	Intravenous (not otherwise specified)			(Gilead
	Mi No Pr	entanyl idazolam prepinephrine ropofol ecuronium			00000					 	Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2020	18042938	DIRECT	Υ						89 YR	Female	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Hypersensitivity; Lip Erythema; Lip Swelling] ;	emdesivir			S	Intravenous (not otherwise specified)			(Gilead
Lung Opacity; Oxygen Saturation Decreased; Sars-Cov-2 Test Positi	Er	examethasone Oral Tablet noxaparin 30 Mg Syringe			C C	·					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	17866588	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-2 0470040	020-		59 YR	Male	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	Duration	<u>N</u>	<u>lfr</u>
Septic Shock	Re	emdesivir			S	Intravenous (not otherwise specified		Mg, Once		(Gilead
	Re	emdesivir			S	Intravenous (not otherwise specified		Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	17976144	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0478171	020-		31 YR	Male	USA

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							Dotalloa 110	port			
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfera Increased	ase	Remdesivir				S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
		Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Dexamethason	ie			С		Unk			Not Reported
		Oxygen				С	Nasal	5 L, Q1minute			Not Reported
FDA Received Date	Case #	Case	Туре	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180442	292 DIRE	СТ	Υ		ОТ			26 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Heart Rate Decreased;	· ,	Remdesivir				S	Intravenous drip				Gilead
Liver Function Test Increased		Dexamethason Enoxaparin Sulfamethoxaz Acetaminopher	ole/Trimethoprim			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>Case</u>	Туре	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180442	297 DIRE	СТ	Υ		ОТ			84 YR	Male	USA
Preferred Term		Product		Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increas	sed	Remdesivir				S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
		Atorvastatin				С					Not Reported
		Dexamethason	ie			С					Not Reported
		Isosorbide				С					Not Reported
		Levothyroxine Potassium				C C					Not Reported
		Aspirin				C					Not Reported Not Reported
		Apixaban				C					Not Reported
		Ceftriaxone				C C					Not Reported
		Iohexol				Č					Not Reported
			•			Č					Not Reported
		Acetaminopher	1			()					NOI REDOILED

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		pime comycin			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044300	DIRECT	Υ		DE			69 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia; Metabolic Acidosis;	Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
Pulseless Electrical Activity; Respiratory Failure; Sepsis	Fenta Hepa Insul Mela Morp Ocul Ceftr Mida Nore Prop Albu	arin in Lispro tonin hine ar Lubricant iaxone zolam pinephrine ofol			000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044306	DIRECT	Υ					42 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased	Dexa	desivir Imethasone Iaparin			S C C					Gilead Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044312	DIRECT	Υ		DE			85 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
	lood Rem	desivir (Gs-574)			S					Gilead

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Creatinine Increased; Blood Urea Increased						otherwise specified)			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044317	DIRECT						40 YR	Male	USA
Preferred Term	P	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy	R	emdesivir	Υ		S	Intravenous (not otherwise specified)			Gilead
Interrupted	Ad	cetaminophen 650 Mg			С	•	,			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044322	DIRECT	Υ		НО			42 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased	rase Ro	emdesivir			S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044453	DIRECT	Υ					76 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Transaminases Increa	sed R	emdesivir			S	Intravenous drip				Not Reported
		examethasone ivaroxaban			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18044487	DIRECT	Y		ОТ			67 YR	Female	USA
Preferred Term	P	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>∕/fr</u>
Acute Kidney Injury; L		emdesivir	Υ		S	Intravenous drip	Other Frequency:Once;			Gilead
Function Test Increase	Ai	torvastan zithromycin			C C	·	, ,			Not Reported Not Reported

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Note: If the field is blank, there is no data.



		Ceftriaxor Norephine Fentanyl Pitressin Propofol	ephrine Drip Drip			C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180445	22	EXPEDITED (15-DAY)		[DE, OT	US-GILEAD-20 0484016)20-		64 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Renal Failure; Respira Failure; Septic Shock	·	Cefepime Ascorbic Azithromy	ednisolone Acid vcin Omeprazole]			s C C C C C	Unknown	200 M	g, Once			Gilead Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180445	35	EXPEDITED (15-DAY)		ŀ	НО	US-GILEAD-20 0483671)20-		29 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase	Remdesiv	⁄ir			S	Intravenous (not otherwise specified)		g, Once			Gilead
Aminotransferase Increased; Hepatic		Acetamin	ophen			С		Unk				Not Reported
Enzyme Increased		Guaifenes	sin			С		Unk				Not Reported
		Multivitan	nin			С		Unk				Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180452	26	EXPEDITED (15-DAY)		ŀ	HO, OT	US-GILEAD-20 0483668)20-		66 YR	Male	USA
Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blood Remdesivir Bilirubin Increased; Liver					S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead	

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Function Test Increased	t	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180452	38 EXPEDITED (15-DAY)			DE, OT	GB-PFIZER IN0 2020274304)-	84 YR	Male	GBR
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	Duration	<u> </u>	<u>Mfr</u>
C-Reactive Protein Increased; Hypotension	ι;	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid 3x/Day			Pfizer
Livedo Reticularis; Whit Blood Cell Count Decreased	e	Vancomycin Hcl			S	Intravenous (not otherwise specified)	2 G, 2x/Day			Pfizer
200100000		Dexamethasone			S	Oral	6 Mg, Qd (Daily)			Not Reported
		Remdesivir			S	Intravenous (not otherwise specified)	200 Unk (Stat)			Not Reported
		Oxygen			С		Unk			Not Reported
		Allopurinol			С		Unk			Not Reported
		Fexofenadine			С		Unk			Not Reported
		Atorvastatin			С		Unk			Not Reported
		Omeprazole			С		Unk			Not Reported
		Dalteparin			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180455	38 EXPEDITED (15-DAY)				US-GILEAD-20 0483336	20-		Unknow	n USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u> </u>	<u>Mfr</u>
Product Preparation Iss	ue	Remdesivir			S	Unknown				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	180457	88 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0483629	20-	74 YR	Male	USA
Preferred Term		Product	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>

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Glomerular Filtration Ra	ate Remd	lesivir			S	Unknown	Unk				Gilead
Decreased	Propo	ofol			С		Unk				Not Reported
	Tylend	ol			С		Unk				Not Reported
	Azithr	omycin			С		Unk				Not Reported
	Ceftria	axone			С		Unk				Not Reported
	Famo	tidine			С		Unk				Not Reported
	Atorva	astatin			С		Unk				Not Reported
	Enoxa	aparin			С		Unk				Not Reported
	Pipera	acillin / Tazobactam			С		Unk				Not Reported
	Hepar	rin			С		Unk				Not Reported
	Zofrar	n [Ondansetron]			С		Unk				Not Reported
	Calqu	ence			С		Unk				Not Reported
	Lasix	[Furosemide]			С		Unk				Not Reported
	Potas	sium Chloride			С		Unk				Not Reported
	Sodiu	m Chloride			С		Unk				Not Reported
	Fenta	nyl			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18045905	EXPEDITED (15-DAY)		(DΤ	US-GILEAD-20 0483722	20-		88 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Remd	lesivir			S	Intravenous (not otherwise specified)	100 M	lg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047692	DIRECT	Υ						76 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Product Prescribing Err Wrong Product Administered	or; Remd	lesivir			S	Intravenous (not otherwise specified)					Gilead

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Note: If the field is blank, there is no data.



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047736	DIRECT	Υ	Н)			61 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypotension	Remo	desivir	Υ		S	Intravenous bolus				Gilead
	Plavi: Dexa Insuli Lasix Lisino	methasone n opril prolol XI n Ix nox			000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047739	DIRECT	Υ	RI				28 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Intentional Dose Omission; Liver Functi Test Increased		desivir	Y		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047771	DIRECT	Υ					80 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Hepatic Failure;		desivir			S	Intravenous bolus				Gilead
International Normalis Ratio Increased; Ischaemic Hepatitis	ed Mero	penem			С					Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047777	DIRECT	Υ					87 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Extra Dose Administer Product Prescribing Er		desivir			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047781	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
	Dipriv	<i>r</i> an			С	,				Not Reported
	Hepa				С					Not Reported
	Verse				C C					Not Reported
	Zemu Subli				C					Not Reported Not Reported
		ım Chloride 0.45%			Č					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047785	DIRECT	Υ		ОТ			53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Alanine Aminotransfer Increased	ase Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;			Gilead
	Remo	desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Tocili	zumab			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047790	DIRECT	Υ		ОТ			59 YR	Male	USA

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>Mfr</u>	•
Transaminases Increa	sed Remo	lesivir 200mg			S	Intravenous bolus	200mg X1 Then 100mg Daily X4		Gil	ead
	Atorva	astatin			С				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047806	DIRECT	Υ	L7				75 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial	Remo	lesivir			S	Intravenous drip			Gil	ead
Infarction	Famo Rocui Midaz Propo	methasone 6 Mg Po tidine 20 Mg Po conium 50 Mg Iv colam 2 Mg Iv ofol nylcholine 100 Mg Iv			00000				No No No No	at Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047826	DIRECT	Υ	0	Γ				Unknown	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfera Increased; Internationa Normalised Ratio Increased		lesivir			S				No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047831	DIRECT	Υ	0	Γ			52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Blood Pressure Decreased	Remo	lesivir			S	Intravenous (not otherwise specified)		Gil	ead

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18047838	DIRECT	Υ						44 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	ļ	<u>Mfr</u>
Infusion Site Discomfo Infusion Site Extravasation; Infusion Site Pain	,	ndesivir	Υ		S	Intravenous (not otherwise specified)					Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2020	18048292	DIRECT	Υ		ОТ				46 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	ļ	<u>Mfr</u>
Atrioventricular Block Second Degree	Rer	ndesivir			S	Intravenous (not otherwise specified)					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	17872381	EXPEDITED (15-DAY)			но, от	US-GILEAD-20 0469304	20-		79 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration	ļ	<u>Mfr</u>
International Normalise Ratio Increased; Liver		ndesivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
Function Test Increase	ed Plac	quinol			С	Oral	Unk				Not Reported
	Cef	triaxone			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Dox	xycycline			С	Oral	Unk				Not Reported
	Var	ncomycin			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Vita	min C [Ascorbic Acid]			С		Unk				Not Reported
	Tor	semide			С	Oral					Not Reported
	0	dizem Cd			С	Oral					Not Reported

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						Detailed Ne	port			
		Lipitor [Atorvastatin]			С	Oral				Not Reported
		Protonix [Omeprazole] Metoprolol Prednisone			C C C					Not Reported Not Reported Not Reported
		Prednisone				Intravenous (not otherwise specified)	Unk			·
		Actemra			С	Intravenous (not otherwise specified)	400 Mg			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1797523	34 EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-20 0477746	20-	61 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		Mfr
Infection; Liver Functio Test Increased	on	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
		Dexamethasone			С	Intravenous (not otherwise specified)	6mg			Not Reported
		Enoxaparin			С	Subcutaneous	70 Mg, Bid			Not Reported
		lohexol			С	Intravenous (not otherwise specified)	90ml			Not Reported
		Multivitamins;Minerals			С	Oral	Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1797928	39 EXPEDITED (15-DAY)		C	T	US-GILEAD-20: 0478652	20-	77 YR	Female	e USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Pressure Increa	sed	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Remdesivir			S	,	Unk			Gilead
		Amlodipine			С		Unk			Not Reported
		Azithromycin			С		Unk			Not Reported
		Carvedilol			С		Unk			Not Reported
		Ceftriaxone			С		Unk			Not Reported

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		Cefurox	kime			С		Unk				Not Reported
		Clopido	grel			С		Unk				Not Reported
		Dexam	ethasone			С		Unk				Not Reported
		Enoxap	arin			С		Unk				Not Reported
		Humalo	og			С		Unk				Not Reported
			ic [Bifidobacterium ;Lactobacillus nilus]			С		Unk				Not Reported
		Lisinop	ril			С		Unk				Not Reported
		Potassi	um Chloride			С		Unk				Not Reported
		Pravast	tatin			С		Unk				Not Reported
		Acetam	inophen			С		Unk				Not Reported
		Haldol [[Haloperidol]			С		Unk				Not Reported
		Hydrala	azine			С		Unk				Not Reported
		Effer K				С		Unk				Not Reported
		Magnes	sium			С		Unk				Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	180486	88	DIRECT	Υ						53 YR	Male	USA
Preferred Term		Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransfer ncreased	rase	Remde	sivir			S	Intravenous (not otherwise specified	(b				Gilead
		Remde	sivir			С						Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	180486	91	DIRECT	Υ						41 YR	Female	USA
Preferred Term		Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Alanine Aminotransfer	rase	Remde	sivir			S	Intravenous drip					Gilead
Increased		Acetam	iinophen ol			C C	aronous unp					Not Reported Not Reported



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

		natate xone ne-Guaifenasin nethasone parin dine			0000000				1 1 1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18048696	DIRECT	Υ	(DΤ			71 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfera	ase Remde	esivir			S	Intravenous bolus			(Gilead
Increased; Pulseless Electrical Activity		l acurium nephrine			C C C				1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18048902	DIRECT		[DE			55 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Anxiety; Blood Fibrinog Increased; Blood Lacta		esivir	Υ		S				,	Cilead
Dehydrogenase Increased; Covid-19; Diarrhoea; Drug Withdrawal Syndrome; Fibrin D Dimer Increas Nausea; Pulseless Electrical Activity; Respiratory Distress; Serum Ferritin Increas Vomiting	ed;		•		C	Intravenous drip				Gilead
Increased; Covid-19; Diarrhoea; Drug Withdrawal Syndrome; Fibrin D Dimer Increas Nausea; Pulseless Electrical Activity; Respiratory Distress; Serum Ferritin Increas Vomiting	ed;	Case Type		Prof (<u>Outcomes</u>	Intravenous drip Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>N</u>	<u>lfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Therapy Cessation	ase Remo	desivir			S	Intravenous drip		5 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049335	DIRECT	Υ	(DT			60 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Drug Eruption	Remo	lesivir			S				ľ	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049365	DIRECT	Υ	(DT			83 YR	Male	PRI
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Electrocardiogram Qt Prolonged; Hepatic Enzyme Increased	Doxyo	methasone cycline binephrine bime colam			S C C C C C	Intravenous (not otherwise specified)			! ! !	Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049368	DIRECT	Υ	(T			59 YR	Male	USA
<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Liver Function Test Increased	Remo	lesivir			S	Intravenous (not otherwise specified)			(Gilead
	Azithr	omycin			С	, ,			ı	Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049671	DIRECT	Υ	С	т			20 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransfer	ase Rem	desivir	Υ		S	Intravenous drip			Gil	lead
Increased	Cefti Dexa Enox	aromycin 500mg Iv Q24h riaxone 2g Iv Q24h amethasone 6mg Po Q24h kaparin 40mg Sq Q24h izumab 400mg Iv Once			0000				No No No	ot Reported of Reported of Reported of Reported of Reported of Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049679	DIRECT	Υ	D	S, HO			39 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Cerebral Artery Occlus Cerebral Infarction	sion; Rem	desivir			S	Intravenous bolus		5 DAY	Gil	lead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049688	DIRECT	Υ					33 YR	Female	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Chills	Rem	desivir	Υ		S	Intravenous bolus			Gil	lead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049743	DIRECT		Н	0			79 YR	Female	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased	Rem	desivir			S	Intravenous bolus	Other Frequency:Once;		Gil	lead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049788	DIRECT			ОТ			64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Albur Decreased	Simv	desivir astatin			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18049795	DIRECT	Υ		DS			52 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury	Remo	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;		C	Gilead
	Remo	desivir	Υ		S	Intravenous (not otherwise specified))		C	Gilead
		in 81 Mg			С					Not Reported
		pyridinium Chloride			С					Not Reported
		hexidine			C					Not Reported
		racurium methasone			C C					Not Reported
		Petrolatum-Mineral Oil			C					Not Reported Not Reported
		halmic Ointment			C				ľ	voi Reported
	Diltia:				С				N	Not Reported
		aparin			Č					Not Reported
		otidine			Ċ					Not Reported
	Fenty	/nal			С				N	Not Reported
		semide			С					Not Reported
	Hepa				C					Not Reported
		n Lispro			С					Not Reported
		vitamin With Iron-Mineral			С					Not Reported
	Mupii				C C					Not Reported
		ethylene Glycol Packet osides			C					Not Reported Not Reported
	Unjur				C					Not Reported Not Reported

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		Midazolam Norepinephrine Propofol				CCC					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type		Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	180504	438 EXPEDITE	D (15-DAY)		(ЭТ	US-GILEAD-20 0483985	20-	22 YR	Female	e USA
Preferred Term		<u>Product</u>	<u>0</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Maternal Exposure Du	ıring	Remdesivir				S	Intravenous drip	200 Mg, Once			Gilead
Pregnancy; Transaminases Increa	hazı	Remdesivir				S	Intravenous drip	100 Mg, Qd			Gilead
Transaminases merea	1300	Dexamethasone				С		Unk			Not Reported
		Ceftriaxone				С		Unk			Not Reported
		Albuterol [Salbutamo	l Sulfate]			С		Unk			Not Reported
		Fluticasone				С		Unk			Not Reported
		Azithromycin				С		Unk			Not Reported
		Plasma				С		Unk			Not Reported
FDA Received Date	Case #	<u>Case Type</u>		<u>Health</u>	Prof (Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	180505	599 EXPEDITE	D (15-DAY)		I	DE, OT	US-GILEAD-20 0484234	20-	58 YR	Male	USA
Preferred Term		<u>Product</u>	2	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Hypertension; Hypoxia; Pulmonary		Remdesivir				S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Function Test Decreas	sed	Azithromycin				С	Intravenous (not otherwise specified)	500 Mg			Not Reported
		Azithromycin				С	Oral	500 Mg, Qd			Not Reported
		Ceftriaxone				С	Intravenous (not otherwise specified)	1 G, Qd			Not Reported
		Enoxaparin				С	Subcutaneous	40 Mg, Qd			Not Reported
		Enoxaparin				С	Subcutaneous	80 Mg, Qd			Not Reported
		Methylprednisolone				С	Intravenous (not otherwise specified)	60 Mg			Not Reported

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						Detailed Ne	port				
	Zinc S	ulfate			С	Oral	220 M	g, Bid			Not Reported
	Lantus	5			С	Subcutaneous	15 Uni	ts			Not Reported
	Lantus	3			С	Subcutaneous	20 Uni	ts			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18050743	EXPEDITED (15-DAY)			DE, HO	BE-SEBELA IR LIMITED- 2020SEB00086			68 YR	Female	BEL
<u>Preferred Term</u>	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Hepatitis Toxic;	Imura	n			S		Unk				Sebela
Respiratory Failure	Remd	esivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Remd	esivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
	Rituxii	mab			S		Unk				Not Reported
	Aldact	one			С		Unk				Not Reported
	Calciu	m Carbonate			С		Unk				Not Reported
	Cetriz	ine			С		Unk				Not Reported
	Domp	eridone			С		Unk				Not Reported
	Livial				С		Unk				Not Reported
	Thyro	xine			С		Unk				Not Reported
	Medro	l			С		Unk				Not Reported
	Omep	razole			С		Unk				Not Reported
	Xanax				С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18050980	EXPEDITED (15-DAY)			НО	US-GILEAD-20 0484178)20-		15 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Covid-19	Remd	esivir			S	Intravenous (not otherwise specified)	Unk)				Gilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1805210	0 EXPEDITED (15-DAY)			НО	US-GILEAD-20 0484063)20-		Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Covid-19	F	Remdesivir			S	Unknown				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1805235	0 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484228)20-	67 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased	ase F	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
	٦	Tylenol			С		650 Mg			Not Reported
	A	Albuterol Hfa			С		Unk			Not Reported
	(Ceftriaxone			С		1 G			Not Reported
	1	Ns			С		Unk			Not Reported
	A	Azithromycin			С		500 Mg			Not Reported
	H	Heparin			С	Subcutaneous	7500 Unit			Not Reported
	[Dextromethorphan;Guaifenesin			С		20 Mg			Not Reported
	L	evothyroxin			С		137 Mcg			Not Reported
	(Ondansetron			С		4 Mg			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1805334	2 DIRECT	Υ		ОТ			75 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase F	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053359	DIRECT	Υ	R	1				59 YR	Male	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Cardiogenic Shock; Haemodialysis; Paraly Renal Failure; Sepsis; Therapy Cessation	vsis; Ca Ca Da Er Fa	emdesivir alcium Chloride efepime examethasone noxaparin amotidine antus			8000000					N N N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053364	DIRECT	Υ	D	E				73 YR	Female	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hypotension	Lo At Pr Pr Zo Pe Mo Lio Fe Ep	emdesivir ovenox orvastatin ropofol nytonadione osyn eg orphine docaine entanyl oinephrine urosemide			s 00000000000	Oral					Gilead Jot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053368	DIRECT	Υ	D	E, HO, LT				84 YR	Female	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransferanceased; Aspartate	ase Re	emdesivir			S					Ν	lot Reported

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Aminotransferase

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053390	DIRECT	Υ					64 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
International Normalise	ed Rem	ndesivir	Υ		S	Intravenous bolus				Gilead
Ratio Increased	Riva	roxaban			S	Oral			,	Janssen
	Asco Azitl Ceft Cho Gab Insu Pan Risp Tioti	nterol Inhaler orbic Acid nromycin riaxone lecalciferol apentin lin toprazole eridone ropium Sulfate			0000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053433	DIRECT	Υ	(ОТ			82 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Infusion Site Extravasation; Skin	Rem	ndesivir Eua 100mg			S	Intravenous (not otherwise specified))			Gilead
Disorder		amethasone Iv xaparin Sq			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053436	DIRECT	Υ		DE			97 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Creatinine Renal	Rem	ndesivir			S	Intravenous drip	Other Frequency:Once;		(Gilead

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ADIVI	THE STREET					Detailed Re	eport			
Clearance Decreased		oxymethylcellulose halmic Drops			С				N	lot Reported
		aroline			С				N	lot Reported
		narin Vaginal Cream			С					lot Reported
		amethasone			С					lot Reported
	Enox	aparin			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18053466	DIRECT	Υ	Н)			83 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Asthenia; Blood Gluco: Decreased; Dysarthria Dyspnoea; Hyperglycaemia; Letha	; argy;	desivir			S	Intravenous (not otherwise specified)			G	Bilead
Lung Infiltration; Menta Status Changes; Pyrex White Blood Cell Coun Increased	kia;									
FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
21-Jul-2020	18054434	DIRECT	Y	DE	Ī			59 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	<u>Role</u>	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Arrhythmia; Cardiac Arrest; Heart Rate	Rem	desivir Solution 100mg Vial	Υ		S	Intravenous (not otherwise specified)	Frequency: Once		G	Bilead
Decreased	Rem	desivir Solution 100mg Vial	Υ		S	Intravenous (not otherwise specified)	1		G	Bilead
	Aceta	aminophen			С					lot Reported
	Albut				С					lot Reported
	Apixa				C					lot Reported
	Aspii				С					lot Reported
		/astatin			С					lot Reported
		zonatate			C C					lot Reported
	Calci				C					lot Reported
		iaxone			С					lot Reported
		rhexidine			C C					lot Reported
	Clop	idogrel			C				<u> </u>	lot Reported



							<u>•</u>			
		examethasone			С					Not Reported
		Piphenhydramine			C					Not Reported
		poetin Alfa-Epbx			C C C					Not Reported
		luconazole			С					Not Reported
		urosemide			С					Not Reported
		nsulin Detemir			С					Not Reported
		nsulin, Regular			С					Not Reported
		sosorbide Mononitrate			C C C					Not Reported
		<i>l</i> elatonin			С					Not Reported
		1etolazone			С					Not Reported
		1idodrine			C C C					Not Reported
		<i>l</i> upirocin			С					Not Reported
		lorepinephrine			C C C					Not Reported
		Ondansetron			C					Not Reported
		² antoprazole			C					Not Reported
		Propafenone			C					Not Reported
		Sevalamer Carbonate			C					Not Reported
		erazosin			C					Not Reported
		razodone			C					Not Reported
		/ancomycin			00000					Not Reported
		'enlafaxine			C					Not Reported
		Clortimazole			C					Not Reported
		nsuline Aspart			С					Not Reported
	IN.	Metroprolol Succinate			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1805489	4 DIRECT	Υ	RI				67 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	F	Remdesivir (Eua) (Remdesivir			S					Not Reported
		Eau))								'
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	1805494	3 DIRECT	Υ					83 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate		Remdesivir (Eua) (Remdesivir Eau))			S	Intravenous (not otherwise specified)			Not Reported



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

Aminotransferase

Increased; Liver Function

Test Increased										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18054997	DIRECT	Υ					51 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Infusion Site Extravas	ation Rem (Eau	desivir (Eua) (Remdesivir))			S	Intravenous (not otherwise specified))			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18055037	DIRECT	Υ	F	RI			79 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Hepatic Enzyme Increased; Therapy Interrupted	rase Rem (Eau	desivir (Eua) (Remdesivir))			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2020	18055038	DIRECT	Υ	0	ÞΕ			89 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Disease	a (Eau	desivir (Eua) (Remdesivir))			S	Intravenous (not otherwise specified)				Not Reported
Progression; Glomeru Filtration Rate Decrea Renal Impairment										
Progression; Glomeru Filtration Rate Decrea	sed;	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	Age	<u>Sex</u>	Country

Note: If the field is blank, there is no data.



Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Disease Progression; Glomerul Filtration Rate Decreas Renal Failure	lar	Remdesivir (Eua) (Remdesivir (Eau))			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	<u>Case Type</u>	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	17925	133 EXPEDITED (15-DAY)			DE, LT, OT	US-GILEAD-20 0474418	20-	78 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Respiratory Fail Covid-19; Dyspnoea	ure;	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Plasma			С		Unk			Not Reported
		Acetaminofen			С		Unk			Not Reported
		Ipratropium Bromide/Albuterol Sulfate			С		Unk			Not Reported
		Aspirin [Acetylsalicylic Acid]			С		Unk			Not Reported
		Azithromycin			С		Unk			Not Reported
		Bisacodyl			С		Unk			Not Reported
		Carvedilol			С		Unk			Not Reported
		Cefazolin			С		Unk			Not Reported
		Ceftriaxone			С		Unk			Not Reported
		Cholecalciferol			С		Unk			Not Reported
		Clopidogrel			С		Unk			Not Reported
		Folic Acid			С		Unk			Not Reported
		Furosemide			С		Unk			Not Reported
		Heparin			С		Unk			Not Reported
		Lidocaine			С		Unk			Not Reported



						Detailed Ne	port			
	Meto	prolol			С		Unk			Not Reported
	Scop	olamine [Hyoscine]			С		Unk			Not Reported
	Tams	sulosin			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	17952578	EXPEDITED (15-DAY)				US-GILEAD-20 0476285	20-	52 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration]	<u>Mfr</u>
Medication Error	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18015900	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0480805	20-	73 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Aspartate Aminotransferase	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Increased	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Aspir	in			С		Unk			Not Reported
	Azith	romycin			С		Unk			Not Reported
	Ceftr	iaxone			С		Unk			Not Reported
	Cisat	racurium			С		Unk			Not Reported
		dron [Dexamethasone]			С		Unk			Not Reported
	Digo: Fenta				C C		Unk			Not Reported Not Reported
		r [Furosemide] arin [Heparin Sodium]			C C		Unk			Not Reported Not Reported
	Nore	pinephrine			С		Unk			Not Reported
	Dipriv	van			С		Unk			Not Reported
	Herce Perje				C C					Not Reported Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18054154	DIRECT	Υ	0	Г			65 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18054171	DIRECT	Υ	0	Γ			80 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
	Ertap	enem			С	. ,				Not Reported
		axone			С					Not Reported
		romycin			C C					Not Reported
		ulosin			C					Not Reported
		emide			С					Not Reported
	Morp	minophen			C					Not Reported Not Reported
		nsetron			C C					Not Reported
		odone			Č					Not Reported
		aparin			С					Not Reported
	Famo	tidine			С					Not Reported
		sonide			С					Not Reported
		methasone			С					Not Reported
	Finas				С					Not Reported
		astatin			C C					Not Reported
		alopram								Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18054175	DIRECT	Υ	CA	A			31 YR	Female	USA
<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Foetal Death; Materna	I Remo	lesivir			S					Not Reported

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Drugs Affecting Foetus; Maternal Exposure Timing Unspecified	Fentar Loven Ceftria Nimbe	n Drip nyl Drip ox xone x nethasone			0000000						Not Reported
FDA Received Date Ca	ase#	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	<u>#</u> <u>50</u> :	3B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 18	3054179	DIRECT	Υ	DE	Ξ				68 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>ct</u>	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	e Remde	esivir			S	Intravenous (not otherwise specified))		7 DAY		Gilead
Aminotransferase Increased; Blood Creatinine Increased; Cardio-Respiratory Arrest Hypotension	Zinc S Multivi	tamin alciferol ol nyl			00000000						Not Reported
FDA Received Date Ca	ase#	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Control #	<u> 50</u> :	3B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 18	3054194	DIRECT	N							Prefer no disclose	ot to USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Tex	<u>ct</u>	Duration	ļ	<u>VIfr</u>
Blood Creatinine Increased	Remde	esivir			S						Gilead
FDA Received Date Ca	ase #	Case Type	Health	Prof O	utcomes	Mfr Control #	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 18	3054412	DIRECT	Υ	0	Γ				66 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Tex	<u>«t</u>	<u>Duration</u>		<u>Mfr</u>



Alanine Aminotransferase Increased	Remd	esivir	Υ		S	Intravenous (not otherwise specified)			C	Gilead
	Albute	rol			С					Not Reported
		rol-Ipratropium			Č					Not Reported
		oic Acid			Č					Not Reported
		omycin			Č					Not Reported
		calciferol			Č					Not Reported
		nethasone			Č					Not Reported
	Doxyo				Ċ					Not Reported
	Famo				C					Not Reported
	Melato	onin			C					Not Reported
		sium Chloride			C					Not Reported
	Ceftria	ixone			С					Not Reported
	Thiam	ine			С				N	Not Reported
	Zinc S	ulfate			С				N	Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 180)54585	DIRECT						66 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransferase ncreased	Remd	esivir			S	Intravenous (not otherwise specified)			C	Gilead
	Dexar	nethasone			С				١	Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 180)54623	DIRECT	Υ	1	ОТ			43 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
iver Function Test	Remd	esivir	Υ		S	Intravenous (not otherwise specified)			C	Gilead
		statin			С	outorwide opcomedy				Not Reported Not Reported
		minophen			С				1.	voi reported
FDA Received Date Cas	Aceta	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country

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Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased	Remdesivir			S	Intravenous bolus	Other Frequency:Once Dose;			Gilead
FDA Received Date Case	# Case Type	Health	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 18054	1800 DIRECT	Υ					30 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Therapy	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once- Loading Dose;			Gilead
Cessation	Vancomycin Levofloxacin Azithromycin Dexamethasone			C C C	. ,	G			Not Reported Not Reported Not Reported Not Reported
FDA Received Date Case	# Case Type	Health	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020 18054	1852 DIRECT	Υ					66 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Alkaline	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Phosphatase Increased; Blood Bilirubin Increased	Tocilizumab Amiodarone Drip Atorvastatin Azithromycin Cisatracurium Drip Diltiazem Drip Enoxaparin Epoprostenol Neb Ketamine Drip Lorazepam Inj			000000000					Not Reported
	Methylprednisolone Sod Succ Ir Midazolam Drip Norepinephrine Drip	j 		C C					Not Reported Not Reported Not Reported

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		Pantoprazole Inj Piperacillin-Tazobactam Ivpb Rivaroxaban			C C C						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180549	27 EXPEDITED (15-DA)	()		ОТ	US-GILEAD-20 0484197	20-		37 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase	Remdesivir			S	Intravenous (not otherwise specified)	Unk				Gilead
		Benzonatate Dexamethasone Enoxaparin Ceftriaxone Bio-K Plus			C C C C						Not Reported Unknown Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180549	37 DIRECT	Υ						63 YR	Female	e USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransfer	ase	Remdesivir			S	Intravenous (not otherwise specified)					Gilead
Increased; Therapy Cessation		Piperacillin-Tazobactam Cholecalciferol Dexamethasone Vitamin C Zinc Gluconate Lovenox Insulin			0000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180550	94 DIRECT	Υ		ОТ				77 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased		Remdesivir			S	Intravenous (not					Gilead

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						otherwise specified)				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055099	DIRECT	Υ	D	E			64 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Drug Ineffective	Remo	desivir			S	Intravenous drip			(Silead
	Remo	desivir			S	Intravenous drip			(Gilead
	Dime	thicone			С	•			١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055100	DIRECT	Υ	D	E			71 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>fr</u>
Acute Kidney Injury; Glomerular Filtration R		desivir			S	Intravenous (not otherwise specified))		(Gilead
Decreased; Renal Impairment	Chole Azith Piper Amio Atorv Cicat Dexn Epop Fenta Nore	pinephrine oprazole			000000000000				1 1 1 1 1 1 1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055115	DIRECT	Υ	D	E			80 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>



Death	R	emdesivir			S	Intravenous (not otherwise specified)				Gilead
	_	onvalascent Plasma examethasone			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055119	DIRECT	Υ					49 YR	Male	USA
Preferred Term	<u>P</u>	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased; Transamina Increased	ases D	emdesivir examethasone ovenox	Y		S C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	1805512	1 DIRECT	Υ		ОТ			82 YR	Female	e USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase R	emdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;			Gilead
	А	zithromycin			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055167	7 EXPEDITED (15-DAY)		ОТ	US-GILEAD-20 0484150)20-	40 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme	R	emdesivir			S	Intravenous bolus	200 Mg, Once			Gilead
Increased	R	emdesivir			S	Intravenous bolus	100 Mg, Qd			Gilead
	R	ocephine			С	Intravenous (not otherwise specified)				Not Reported
	A	zithromycin			С	Intravenous (not otherwise specified)	Unk			Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control:	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055195	DIRECT	Υ		ОТ				61 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Alanine Aminotransfera Increased	ase Remd	esivir			S	Intravenous (not otherwise specified)	1				Gilead
	Dexar Enoxa Famoi Mycop Nifedi	n natate nethasone parin			000000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	Sex	Country
22-Jul-2020	18055197	DIRECT	Υ		ОТ				45 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	отс	Role	Route	Dosage	e Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury	Remd	esivir	Υ		S	Intravenous bolus					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055237	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484419)20-		59 YR	Male	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>n</u>	<u>Mfr</u>
Death; Liver Function Increased	Γest Remd	esivir			S	Intravenous (not otherwise specified)	Unk				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055242	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484409)20-		65 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	отс	Role	Route	Dosage	e Text	Duration	r	<u>//fr</u>

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Brain Injury; Death; Pulseless Electrical Activity	Rem	desivir			S	Intravenous (not otherwise specified)	Unk		Gilead			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country	
22-Jul-2020	18055247	DIRECT	Υ		DE				73 YR	Male	USA	
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OT(</u>	C Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	
Alanine Aminotransfer Increased	Tocil Chol Vitar Zinc Dexa Azith Ceftr Cefe Amlo Atory Bude Cary Enox	desivir izumab 800 Mg Iv ecalciferol nin C amethasone 6 Mg Iv Daily iromycin riaxone pime odipine vastatin esonide edilol caparin steride semide			8000000000000000						Gilead Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country	
22-Jul-2020	18055254	DIRECT	Υ		ОТ				58 YR	Male	USA	
Preferred Term	Proc	luct	Comp.	OTO	C Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	Acet Asco Dexa Enox Pant	desivir aminophen orbic Acid amethasone caparin opraxole Sulfate			s c c c c						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055312	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484440	20-		71 YR	Male	USA
Preferred Term	Produ	ct	Comp.	OTO	Role	Route	Dosage	Text	<u>Duration</u>		<u>Mfr</u>
Death	Remde	esivir			S	Intravenous (not otherwise specified)	100 M	g, Bid			Gilead
	Plasma	a			С		Unk				Not Reported
	Amlod	ipine			С		Unk				Not Reported
	Ascorb	oic Acid			С		Unk				Not Reported
	Dexam	nethasone			С		Unk				Not Reported
	Hydrox	kychloroquine			С		Unk				Not Reported
	Enoxa	parin			С		Unk				Not Reported
	Merop	enem			С		Unk				Not Reported
	Vanco	mycin			С		Unk				Not Reported
	Zinc S	ulfate			С		Unk				Not Reported
	Methyl	prednisolone			С		Unk				Not Reported
	Lantus	1			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>!</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055323	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484424	20-		72 YR	Male	USA
Preferred Term	Produ	ct	Comp.	OTO	Role	Route	Dosage	Text	Duration		<u>Mfr</u>
Blood Creatinine Increased; Death;	Remde	esivir			S	Intravenous (not otherwise specified)	Unk				Gilead
Enterobacter Pneumo	nia Actem	ra			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18055324	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0484475	20-		79 YR	Female	e USA
Preferred Term	Produ	ct	Comp.	OTO	Role	Route	Dosage	Text	<u>Duration</u>		<u>Mfr</u>

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Death		Remdesivir			S		Intravenous (not otherwise specified)	100 Mg	Qd			Gilead
		Oxygen Plasma			C			Unk				Not Reported Not Reported
		Azithromycin			С			Unk				Not Reported
		Ceftriaxone			С			Unk				Not Reported
		Dexamethasone			С			Unk				Not Reported
		Enoxaparin			С			Unk				Not Reported
		Lasix [Furosemide]			С			20 Mg,	Bid			Not Reported
		Lasix [Furosemide]			С			40 Mg,	Once			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcon	<u>nes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180554	EXPEDITED (15-DAY)		DE, OT		US-GILEAD-202 0484435	20-		72 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	C Ro	<u>ole</u>	Route	Dosage '	<u> Fext</u>	Duration		<u>Mfr</u>
Death; Hepatic Enzym Increased; Hypoxia;		Remdesivir			S		Intravenous (not otherwise specified)	100 Mg	Qd			Gilead
Leukocytosis; Pneumo Aspiration	onia	Remdesivir			S		Intravenous (not otherwise specified)	100 Mg	Qd			Gilead
		Remdesivir			S		Intravenous (not otherwise specified)	100 Mg	Qd			Gilead
		Hydroxychloroquine			С			400 Mg				Not Reported
		Dexamethasone			С		Intravenous (not otherwise specified)	20 Mg,	Qd			Not Reported
		Plasma			С			Unk				Not Reported
		Vancomycin			С		Intravenous (not otherwise specified)	1250 M	9			Not Reported
		Zosyn			С		Intravenous (not otherwise specified)	3.375 G	, Q8h			Not Reported
		Levetiracetam			С		Intravenous (not otherwise specified)	500 Mg	Bid			Not Reported
		Amlodipine			С		Oral	5 Mg, Q	d			Not Reported

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		Aspirin 8	1			С	Oral	81 Mg, Qd			Not Reported
		Atorvasta	atin			С	Oral	80 Mg, Qd			Not Reported
		Donepez	il			С	Oral	10 Mg			Not Reported
		Enoxapa	rin			С	Subcutaneous	40 Mg, Qd			Not Reported
		Enoxapa	rin			С	Subcutaneous	100 Mg, Bid			Not Reported
		Enoxapa	rin			С	Subcutaneous	90 Mg, Bid			Not Reported
		Fluoxetin	ie			С	Oral	20 Mg, Once			Not Reported
		Metoprol	ol			С	Oral	25 Mg, Bid			Not Reported
		Tamsulo	sin			С	Oral	0.4 Mg, Qd			Not Reported
		Epinephr	ine			С					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180563	373	NON-EXPEDITED			DE, OT	US-SA-2020SA	\189495		Unkno	wn USA
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Subdural Haemorrhage	е	Plavix				S	Unknown				Sanofi
		Acetylsal	licylic Acid			S	Unknown				Not Reported
		Heparin ((Salt Not Specified)			S	Unknown				Not Reported
		Remdesi	vir			S	Intravenous (not otherwise specified)	Unk)			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control #	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180565	545	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484152)20-	57 YR	Male	USA
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Bilirubin Increas Blood Creatinine	·	Remdesi	vir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
ncreased; Inflammato Marker Increased; Live Function Test Increase	er	Remdesi	vir			S	Intravenous (not otherwise specified)	100 Mg, Qd)			Gilead
Pneumonia	,	Azithrom	ycin			С		Unk			Not Reported
Staphylococcal		Carbama				С		Unk			Not Reported



						2010111001110	P 0 : 0			
		Ceftriaxone			С		Unk			Not Reported
		Dexamethasone			С		Unk			Not Reported
		Enoxaparin			С		Unk			Not Reported
		Famotidine			С		Unk			Not Reported
		Fentanyl			С		Unk			Not Reported
		Meropenem			С		Unk			Not Reported
		Midazolam			С		Unk			Not Reported
		Propofol			С		Unk			Not Reported
		Risperidone			С		Unk			Not Reported
		Tocilizumab			С		Unk			Not Reported
		Vancomycin			С		Unk			Not Reported
		Vitamin C [Ascorbic Acid]			С		Unk			Not Reported
		Zinc Sulfate			С		Unk			Not Reported
		Clonazepam Metformin Metoprolol Tartrate			C C C					Not Reported Not Reported Not Reported
DA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
2-Jul-2020	180565	97 EXPEDITED (15-DAY)			ОТ	US-GILEAD-202 0484192	20-	72 YR	Male	USA
referred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
anine Aminotransfera creased; Aspartate	ase	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
ninotransferase creased		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Enoxaparin			С	Subcutaneous	30 Mg			Not Reported
		Famotidine			С	Oral	20 Mg			Not Reported
		Culturelle			С	Oral	1 Dosage Form, Qd			Not Reported
		Vitamin C Acid			С	Oral	1 G, Qd			Not Reported
		Zinc Sulfate			С	Oral	220 Mg, Qd			Not Reported
		Dexamethasone			С		.			Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18056841	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484422	020-		55 YR	Female	e USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Anxiety; Death; Diarrh Drug Withdrawal	oea; Remo	desivir			S	Intravenous (not otherwise specified	100 Mg)	, Bid			Gilead
Syndrome; Nausea; Oxygen Saturation	Enox	aparin			С	•	Unk				Not Reported
Decreased; Pulseless Electrical Activity; Vomiting	Oxyg	en			С	Nasal	12 L Hiç Cannula	gh Flownasal a			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18056972	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484177	020-		69 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Bilirubin Increas Pneumonia Pseudomo Systemic Candida		desivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18057091	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484405	020-		63 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	rase Remo	desivir			S	Intravenous (not otherwise specified	100 Mg)	, Qd			Gilead
Aminotransferase ncreased	Aceta	aminophen			С		Unk				Not Reported
	Amlo	dipine			С		Unk				Not Reported
		romycin iaxone			C C		Unk				Not Reported Not Reported
	Dexa	methasone			С		Unk				Not Reported
	Dexm	nedetomidine			С		Unk				Not Reported

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		Fentany	1			С		Unk			Not Reported
		Midazol	am			С		Unk			Not Reported
		Norepin	ephrine			С		Unk			Not Reported
		Propofo	I			С		Unk			Not Reported
		Vasopre	essin			С		Unk			Not Reported
FDA Received Date	Case #		Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	180571	10	EXPEDITED (15-DAY)		C	т	US-GILEAD-20 0484418	20-	69 YR	Male	USA
Preferred Term		<u>Produc</u>	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Laboratory Test Abnormal		Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	1805712	23	EXPEDITED (15-DAY)		C	т	US-GILEAD-20 0484429	20-	50 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase	Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Aminotransferase Increased		Remdes	sivir			S	Intravenous (not otherwise specified)	100 Mg, Once			Gilead
		Acetami	nophen			С		Unk			Not Reported
		Dexame	ethasone			С		Unk			Not Reported
		Docusat	te			С		Unk			Not Reported
		Enoxapa	arin			С		Unk			Not Reported
		Lamotriç Lithium Pantopr				C C C		Unk			Not Reported Not Reported Not Reported
		Pramipe Senna	exole			C C		Unk			Not Reported Not Reported

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	Trazodone OA Received Date				С					١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18057147	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484437)20-		43 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role Role	Route	Dosage 7	<u> Fext</u>	Duration	<u>M</u>	<u>fr</u>
Platelet Count Increase	ed Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd		C	Bilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18057167	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484479)20-		59 YR	Female	USA
<u>Preferred Term</u>	Pro	<u>oduct</u>	Comp.	OTO	Role	<u>Route</u>	Dosage 1	<u> </u>	Duration	<u>M</u>	<u>fr</u>
Cardiac Arrest	Ren	ndesivir			S	Intravenous (not otherwise specified)	200 Mg,	Once		C	Silead
	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd		C	Silead
		etaminophen uterol [Salbutamol]			C C		Unk				lot Reported lot Reported
	Apix	xaban			С		Unk			N	lot Reported
	Ator	oirin [Acetylsalicylic Acid] rvastatin nzonatate			C C		Unk			N	lot Reported lot Reported lot Reported
	Cald	citriol			С		Unk			١	lot Reported
	Ceff	triaxone			С		Unk			N	lot Reported
	Chlo	orhexidine			С		Unk			N	lot Reported
		pidogrel trimazole			C C		Unk				lot Reported lot Reported
	Dex	amethasone			С		Unk			N	lot Reported
	Dipl	henhydramine			С		Unk			N	lot Reported
	Epo	petin Alfa Epbx			С		Unk			١	lot Reported
	Fluc	conazole			С		Unk			N	lot Reported

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	Furose Insulin				C C		Unk				Not Reported Not Reported
	Insulin	Detemir			С		Unk				Not Reported
	Insulin	Regular [Insulin Porcine]			С		Unk				Not Reported
	Isosorb Melato	ide Mononitrate nin			C C		Unk				Not Reported Not Reported
	Metola: Metopr Midodr Mupiro	olol Succinate ine			C C C		Unk				Not Reported Not Reported Not Reported Not Reported
	Norepi	nephrine			С		Unk				Not Reported
	Ondan	setron			С		Unk				Not Reported
	Pantop Propafe Sevela				C C C		Unk				Not Reported Not Reported Not Reported
	Terazo Trazod Vancor	one			C C C		Unk				Not Reported Not Reported Not Reported
	Venlafa	axine			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	Sex	Country
22-Jul-2020	18057283	EXPEDITED (15-DAY)		C	T	US-GILEAD-20 0484715	020-		59 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Transaminases Increa	sed Remde	sivir			S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead
	Remde	sivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058379	DIRECT	Υ	C	T				70 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>



Aspartate Aminotransferase Increased	Remdesivir Y S Intravenous bolus						(Gilead		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058380	DIRECT	Υ		LT			29 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Bradycardia	Remo	lesivir			S	Intravenous drip			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058418	DIRECT	Υ					63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury	Remo	lesivir			S	Intravenous (not otherwise specified)			(Gilead
		calciferol methasone in C			C C C	outor mod spasmas,			1	Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058424	DIRECT	Υ					22 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Hypertension; Infusion Related Reaction; Oxy Saturation Decreased; Pyrexia	rgen	lesivir For Injection			S	Intravenous (not otherwise specified)			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058427	DIRECT	Υ		DE, LT			91 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>

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

Alanine Aminotransfer Increased	rase Remo	desivir			S	Intravenous (not otherwise specified)	Other Frequency:Once - Loading Dose;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058431	DIRECT	Υ	Н	Ю			53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased		desivir astatin 40 Mg			S C	Intravenous drip	Other Frequency:Once;	1 DAY		Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058438	DIRECT	Υ	D	DE			81 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Fail		desivir			S	Intravenous bolus				Gilead
Hypotension; Hypoxia Mental Status Change Oxygen Saturation Decreased	es; Comb	methasone 6 Mg bivent romycin 500 Mg Iv axone 1 Gm Iv			C C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058451	DIRECT	Υ					56 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Alkaline Phosphatase Increase Liver Function Test Increased		desivir	Y		S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058454	DIRECT	Υ					67 YR	Male	USA

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Preferred Term	ferred Term Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase Rem	ndesivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	<u>503B Fac</u>	cility Age	<u>Sex</u>	Country
22-Jul-2020	18058458	DIRECT	Υ					50 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Rem	ndesivir			S	Intravenous (not otherwise specified))			Gilead
	Dex Vitar Zinc Azitl Ceft Cisa Dex Eno Fen Gab Keta Nore Pan	lecalciferol amethasone min C inromycin riaxone atracurium medetomidine axaparin tanyl apentin amine epinephrine toprazole oofol awatatin			0000000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	<u>503B Fac</u>	cility Age	<u>Sex</u>	Country
22-Jul-2020	18058463	DIRECT	Υ		ОТ			39 YR	Female	uSA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	Dex Leve	ndesivir amethasone ofloxacin nromycin			S C C	Intravenous drip				Gilead Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058472	DIRECT	Υ					45 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfer Increased	ase Remo	lesivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058478	DIRECT	Υ					86 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Incorrect Drug Administration Rate; Product Preparation Is		lesivir	Υ		S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058482	DIRECT	Υ					82 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remo	lesivir For Injection			S	Intravenous (not otherwise specified)		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18058488	DIRECT	Υ	I	DE			33 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Paralysis; Respiratory	Remo	desivir			S	Intravenous bolus			G	ilead
Failure	Dexai Famo Metro	oime 2 Gm Iv methasone 2 Mg tidine 20 Mg nidazole 500 Mg omycin Iv			C C C C				Ne Ne Ne	ot Reported ot Reported ot Reported ot Reported ot Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058493	DIRECT	Υ	C	T			59 YR	Femal	e USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Rash Macular; Rash	Rem	desivir			S	Intravenous drip				Gilead
Maculo-Papular	Cipro	floxacin			S	Intravenous drip				Not Reported
	Dival Docu Atorv Aspir Pante Halop Aceta Enox	a 8.6mg proex 500mg Dr sate Sodium 250mg rastatin 10mg in 81mg prazole 20mg Tablet peridol 5mg Tablet aminophen 500mg Tablet aparin 40mg Sc prolol 50mg Ir			0000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058500	DIRECT	Υ	F	Ю			34 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Rem	desivir	Y		S	Intravenous (not otherwise specified)			Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058507	DIRECT	Υ	C	T			71 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Remo Atorv Asco	desivir desivir rastatin 40 Mg Oral Daily rbic Acid 3000 Mg Oral Bid ecalciferol 25 Mcg Oral			s s c c	Intravenous drip Intravenous drip	Other Frequency:Once;	1 DAY		Gilead Gilead Not Reported Not Reported Not Reported

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						Dotanoa No	port			
	Furos	methasone 6 Mg Daily Iv semide 40 Mg Iv Bid 220 Mg Daily Oral			C C C				N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058533	DIRECT	Υ					47 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfer Increased	rase Remo	desivir	Y		S	Intravenous (not otherwise specified)			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jul-2020	18058540	DIRECT	Υ	(OT			67 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Chills	Remo	desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	17914969	EXPEDITED (15-DAY)		[DE, LT, OT	US-GILEAD-20 0473383	20-	51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Cardiac Arrest; Genera Physical Health	al Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		G	ilead
Deterioration; Pneumothorax; Respiratory Failure	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
, respiratory i amare	Ascoi	bic Acid			С	Intravenous (not otherwise specified)	1500 Mcg		N	ot Reported
	Atorv	astatin			С	Oral	10 Mg		N	ot Reported
	Aztre	onam			С	Intravenous bolus	2 G		N	ot Reported
	Bisac	odyl			С	Oral	5 Mg			ot Reported
	Buspi				С	Oral	10 Mg			ot Reported
	Carbi	dopa-Levodopa-B			С	Oral	25 Mg - 100 Mg		N	ot Reported

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			<u> </u>	
Celebrex	С	Oral	100 Mg	Not Reported
Clonazepam	С	Oral	0.5 Mg	Not Reported
Digoxin	С	Oral	62.5 Mcg	Not Reported
Depakote Lovenox Hp	C C	Subcutaneous	60 Mg	Not Reported Not Reported
Fentanyl 3 Day Hmt	С		200 Mcg	Not Reported
Guaifenesin	С	Oral	600 Mg	Not Reported
Metoprolol Propofol	C	Intravenous (not otherwise specified)	10 Mcg	Not Reported Not Reported
Risperidone	С	Oral	0.5 Mg	Not Reported
Oxygen Albuterol [Salbutamol]	C	Respiratory (inhalation)	360 Mcg	Not Reported Not Reported
Cetirizine	С	Oral	10 Mg	Not Reported
Peridex [Chlorhexidine Gluconate]	С	Oral	15 MI	Not Reported
Cyanocobalamin	С	Oral	500 Mcg	Not Reported
Decadron [Dexamethasone Acetate]	С	Intravenous (not otherwise specified)	4 Mg	Not Reported
Senokot S	С	Oral	1 Dosage Form	Not Reported
Pepcid [Famotidine]	С	Intravenous (not otherwise specified)	20 Mg	Not Reported
Fluticasone	С	Respiratory (inhalation)	220 Mcg	Not Reported
Magnesium Citrate	С		30 MI	Not Reported
Solu-Medrol	С	Intravenous (not otherwise specified)	30 Mg	Not Reported
Midodrine	С	Oral	5 Mg	Not Reported
Montelukast	С	Oral	10 Mg	Not Reported
Pyridoxine	С	Oral	20 Mg	Not Reported
Sodium Bicarbonate	С	Intravenous (not otherwise specified)	50 Meq	Not Reported

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	Thia	ımine			С	Intravenous bolus	200 Mg			Not Reported
	Zan	aflex			С	Oral	4 Mg			Not Reported
		zodone acon			C C	Intravenous (not otherwise specified)	150 Mg			Not Reported Not Reported
	Van	comycin			С	Intravenous (not otherwise specified)	750 Mg			Not Reported
	Effe	xor Sr			С	Oral	150 Mg			Not Reported
		inal [Acetylsalicylic l;Butalbital;Caffeine]			С		Ç			Not Reported
	Dex	medetomidine			С	Intravenous (not otherwise specified)	400 Mcg			Not Reported
	Epir	nephrine			С	Intravenous (not otherwise specified)	4 Mg			Not Reported
	Nor	epinephrine			С	Intravenous (not otherwise specified)	15 Mg			Not Reported
	Vas	opressin			С	Intravenous (not otherwise specified)	40 Units			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18000931	EXPEDITED (15-DAY)			ОТ	US-GILEAD-202 0480838	20-	60 YR	Male	USA
Preferred Term	<u>Pro</u>	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Leukopenia	Ren	ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Amr	nonium Lactate			С	Topical	1 App			Not Reported
	Clor	nazepam			С	Oral	0.5 Mg, Bid			Not Reported
	Dex	amethasone			С	Oral	6 Mg, Qd			Not Reported
	Diva	alproex Sodium			С	Oral	125 Mg, Tid			Not Reported
	Leve	etiracetam			С	Oral	1000 Mg			Not Reported
	Mirt	azapine A			С	Oral	15 Mg			Not Reported
	Lact	ulose			С	Oral	40 G, Bid			Not Reported

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	Me	elatonin			С	Oral	15 Mg			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
23-Jul-2020	18058096	EXPEDITED (15-DAY)				US-GILEAD-20 0484800	20-	57 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Product Preparation E	rror Re	emdesivir			S	Unknown				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18058774	EXPEDITED (15-DAY)			DE, OT	GB-MYLANLAE 2020M1064915		84 YR	Male	GBR
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Livedo Reticularis	Pip	peracillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid			Not Reported
	Re	emdesivir			S	Intravenous (not otherwise specified)	200, Stat			Mylan
	Va	ncomycin			S	Intravenous (not otherwise specified)	1 G, Bid			Mylan
	De	examethasone			S	Oral	6 Mg, Qd			Mylan
	Ox	kygen			С		Unk			Mylan
	All	opurinol			С		Unk			Mylan
	Ato Or	exofenadine orvastatin meprazole alteparin			C C C C		Unk			Mylan Mylan Mylan Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18059145	DIRECT	Υ		ОТ			63 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Decreased; Aspartate Aminotransferase	ase Re	emdesivir			S	Intravenous (not otherwise specified)		4 DAY		Gilead

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Decreased; Hepatotoxicity	Tamsulosin 0.4 Mg Daily Metoprolol Succinate 25 M Daily	1g		C C					ot Reported ot Reported
	Insulin Glargine & Lispro			С				Ne	ot Reported
	Lisinopril 5 Mg Daily			Č					ot Reported
	Enoxaparin 30 Mg Q12h			Č					ot Reported
	Aspirin 325 Mg Daily			Č					ot Reported
	Allopurinol 300 Mg Daily			С					ot Reported
	Acetaminophen 650 Mg Q (1 Dose Given)	4h Prn		С				No	ot Reported
	Àtorvastatin 80 Mg Daily			С				No	ot Reported
FDA Received Date Cas	e# Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020 180	59208 EXPEDITED (15	-DAY)			US-GILEAD-20 0484718	020-		Male	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Incorrect Product Administration Duration	Remdesivir			S	Unknown			G	ilead
FDA Received Date Cas	e # Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020 1809	59300 DIRECT	Υ	0	ÞΕ			82 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Hypoxia; Oxygen Saturation Decreased;	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	ilead
Sars-Cov-2 Test Positive	Aspirin			С	' '	•		No	ot Reported
	Atorvastatin			Č					ot Reported
	Azithromycin			С					ot Reported
	Ceftriaxone			С				No	ot Reported
	Clopidogrel			С					ot Reported
	Dexamethasone			C					ot Reported
	Donepizil .			С					ot Reported
	Enoxaparin			С					ot Reported
	Furosemide Isosorbide			C C					ot Reported
				C					ot Reported ot Reported
	Lorazonam								
	Lorazepam Metoprolol			C					ot Reported



							•			
		hine peridol ansetron			C C C				N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18059532	DIRECT	Υ					47 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Alanine Aminotransfera		desivir Imethasone			S C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18059728	DIRECT	Υ	Н)			17 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Liver Function Test Increased	Rem	desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18059746	DIRECT	Υ					34 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>'r</u>
Alanine Aminotransfera	ase Rem	desivir	Υ		S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18059811	DIRECT	Υ					87 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Liver Funct Test Increased		desivir	Y		S	Intravenous drip	Other Frequency:Once;		G	ilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	<u># 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18059877	DIRECT	Υ						55 YR	Female	USA
Preferred Term	Pr	roduct	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Liver Funct Test Increased		emdesivir	Y		S	Intravenous drip					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	<u># 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18059882	DIRECT	Υ						75 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage T	ext	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Re	emdesivir	Υ		S	Intravenous drip					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	<u># 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	18060296	DIRECT	Υ	(TO				49 YR	Female	USA
Preferred Term	<u>Pr</u>	roduct	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	No	emdesivir orco cetaminophen			S C C						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	<u> </u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18060302	DIRECT	Υ	(OT				46 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage T	ext	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Transfusion	n Ac	emdesivir cetaminophen evophed			S C C						Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061063	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484797			91 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	Duration		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Death	ase Remde	esivir			S	Intravenous (not otherwise specified		g, Once			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061107	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484795	020-		64 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remde	esivir			S	Intravenous (not otherwise specified	100 M	g, Qd			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified	100 M	g, Qd			Gilead
	Dimeth	nicone			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061137	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484791	020-		80 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	Duration		Mfr
Death	Remde	esivir			S	Intravenous (not otherwise specified	200 M	g, Qd			Gilead
	Plasma Dexam	a nethasone			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061316	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484733	020-		84 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	отс	Role	Route	Dosage	Text	Duration		Mfr

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Transaminases Increased	Remdes	sivir			S	Intravenous (not otherwise specified)	200 Mg	ı, Qd			Gilead
	Dexame	ethasone			С		Unk				Not Reported
	Isosorbi	de			С		Unk				Not Reported
	Levothy	roxine			С		Unk				Not Reported
	Potassi	um			С		Unk				Not Reported
	Aspirin	[Acetylsalicylic Acid]			С		Unk				Not Reported
	Apixaba	n			С		Unk				Not Reported
	Ceftriax	one			С		Unk				Not Reported
	Iohexol				С		Unk				Not Reported
	Acetam	inophen			С		Unk				Not Reported
	Furoser	nide			С		Unk				Not Reported
	Cefepin	ne			С		Unk				Not Reported
	Vancom	nycin			С		Unk				Not Reported
FDA Received Date Cas	se #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020 180	61558	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484363	20-		62 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		Mfr
Acute Kidney Injury	Remdes	sivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
	Cefepin	ne			С		Unk				Not Reported
	Dexame	ethasone			С		Unk				Not Reported
	Unfracti	onated Heparin			С		Unk				Not Reported
	Insulin (Glargine			С		Unk				Not Reported
	Insulin L	₋ispro			С		Unk				Not Reported
	Linezoli	d			С		Unk				Not Reported
	Mycoph	enolate			С		Unk				Not Reported
	Tacrolin	nus			С		Unk				Not Reported
	Dexmed				С						Not Reported



							<u> </u>			
	Fenta	nyl			С		Unk			Not Reported
	Midaz	olam			С		Unk			Not Reported
	Norep	inephrine			С		Unk			Not Reported
	Sodiu	m Bicarbonate			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control a	503B Facilit	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061613	EXPEDITED (15-DAY)		(DΤ	US-GILEAD-20 0482969	20-	89 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasa	ation Remo	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Control a	503B Facilit	ty <u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061654	EXPEDITED (15-DAY)		(DΤ	US-GILEAD-20 0484374	20-	61 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypersensitivity	Remo	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Azithr	omycin			С		Unk Mg			Not Reported
	Azithr	omycin			С		Unk			Not Reported
	Ascor	bic Acid			С		Unk			Not Reported
	Ceftria	axone			С		Unk			Not Reported
	Diphe	nhydramine			С		Unk			Not Reported
	Enoxa	aparin			С		Unk			Not Reported
	Methy	Iprednisolone			С		Unk			Not Reported
	Zinc S	Sulphate			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Control	503B Facilit	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18061839	EXPEDITED (15-DAY)		(OT	ES-ASTELLAS 2020US023406		22 YR	Male	ESP
Preferred Term	Produ	ict	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Hypokalaemia;	Ar	mphotericin B, Liposome			S	Unknown	Unk Unk, Unknown Freq.			Astellas
Hypotensive Crisis; Nausea; Vomiting	Re	emdesivir			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.			Not Reported
	Li	nezolid			С	Unknown	Unk Unk, Unknown Freq.			Not Reported
	М	eropenem			С	Unknown	Unk Unk, Unknown Freq.			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064217	DIRECT	Υ					62 YR	Male	USA
Preferred Term	P	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Ro	emdesivir	Y		S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064224	DIRECT	Υ					39 YR	Female	USA
<u>Preferred Term</u>	<u>P</u>	roduct	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Ro	emdesivir			S	Intravenous (not otherwise specified)	1			Gilead
	Fa Al No Ac Th As Lo	azodone amotidine buterol orco cetaminophen niamine scorbic Acid ovenox examethasone			000000000	•				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064231	DIRECT	Υ		DE, HO, LT			68 YR	Male	USA
Preferred Term	P	roduct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>

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Liver Function Test	Remd	esivir	Υ		S	Intravenous drip			(Gilead
ncreased	Amiod Azithro Chlorh Dexan Famot Hepar Insulin Pipera Thiam Norep Propo Vasop Fentar Midaz	arone omycin nexidine nethasone idine in Glargine cillin-Tazobactam ine inephrine fol ressin			0000000000000000	muavenous unp				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064238	DIRECT	Υ	D	ÞΕ			62 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Acute Kidney Injury; A Respiratory Distress Syndrome; Anuria; Candida Infection; Pneumonia Pseudomo Septic Shock; Streptococcal Infection	onal;	esivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064294	DIRECT	Υ	D	E, OT			73 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
					S	Introveneus (not			(Gilead
Haemodialysis; Renal Impairment	Remd	esivir For Injection			3	Intravenous (not otherwise specified)			·	Silcad



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

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064343	DIRECT	Υ		DE			90 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Pain; Respiratory Failure; Sedation	Remo	desivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> 503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064778	DIRECT	Υ		RI			52 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Flushing; Hyperhidrosi Hypertension; Oxygen		desivir 200mg			S	Intravenous (not otherwise specified)	1			Gilead
Saturation Decreased	Remo	desivir 100mg			S	Intravenous (not otherwise specified)				Gilead
		urium			C					Not Reported
		n Glargine hexidine Gluconate			C C					Not Reported
		osides			C					Not Reported Not Reported
	Docu				C					Not Reported
	Albut				č					Not Reported
	Rocu	ronium			C					Not Reported
		methasone Sodium phate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2020	18064943	DIRECT	Υ		RI			47 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remo	desivir 100mg			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)				Gilead

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		Remdesivir 100mg			S	Intravenous (not	<u> </u>				Gilead
		Ç				otherwise specified	d)				
		Rocephin			С						Not Reported
		Azithromycin			С						Not Reported
		Dexamethasone Sodium			С						Not Reported
		Phosphate Fentanyl			С						Not Reported
		Magnesium Sulfate			Č						Not Reported
		Norepinephrine			Č						Not Reported
		Pantoprazole			С						Not Reported
		Potassium Chloride			С						Not Reported
FDA Received Date	<u>Case</u> :	<u>Case Type</u>	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	17971	419 EXPEDITED (15-DAY)		I	DE, HO, LT	FR-AUROBIN APL-2020-03			80 YR	Male	FRA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Drug		Levofloxacin			S	Unknown	Unk				Aurobindo
Ineffective For Unapproved Indication	. 0#	Levofloxacin			S						Aurobindo
Unapproved indication Label Use	, Oli	Meropenem			S	Unknown	Unk				Aurobindo
Laber 030		Meropenem			S						Aurobindo
		Voriconazole			S	Unknown	Unk				Aurobindo
		Colimycine [Colistin Sulfate]			S	Unknown	Unk				Not Reported
		Colimycine [Colistin Sulfate]			S						Not Reported
		Isavuconazonium Sulfate			S	Unknown	Unk				Not Reported
		Isavuconazonium Sulfate			S						Not Reported
		Tigecycline			S	Unknown	Unk				Not Reported
		Tigecycline			S						Not Reported
		Remdesivir			S	Intravenous drip	200 M Dose)	illigram (Loading			Not Reported
		Remdesivir			S	Unknown	Unk				Not Reported
		Remdesivir			S						Not Reported
FDA Received Date	<u>Case</u> :	<u>Case Type</u>	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	17996	635 EXPEDITED (15-DAY)		(ОТ	US-GILEAD-2 0478717	2020-		63 YR	Male	USA

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Preferred Term	<u> </u>	Product	Comp.	OTO	Role Role	Route	Dosage 1	<u>「ext</u>	Duration		<u>Mfr</u>
Bradycardia	F	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg,	Qd			Gilead
	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Unk				Gilead
	[Dexamethasone			С	Oral	6 Mg, Q	d			Not Reported
	F	Plasma			С		Unk				Not Reported
	E	Enoxaparin			С		40 Mg, 0	Qd			Not Reported
	E	Enoxaparin			С	Subcutaneous	40 Unk				Not Reported
	A	Acetaminophen			С	Oral	650 Mg,	Q4hr, As Needed			Not Reported
		Omeprazole Famsulosin			C C	Oral	0.4 Mg,				Not Reported Not Reported
	F	Pantoprazole			С	Oral	20 Mg, 0	Qd			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806255	5 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485076	20-		20 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>Text</u>	Duration		<u>Mfr</u>
Alanine Aminotransfera	ase F	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg,	Qd			Gilead
	F	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg,	Qd			Gilead
	A	Azithromycin			С		Unk				Not Reported
	(Ceftriaxone			С		Unk				Not Reported
	Г	Dexamethasone			С		Unk				Not Reported
	Е	Enoxaparin			С		Unk				Not Reported
	٦	ocilizumab			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	Sex	Country
24-Jul-2020	1806258	9 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20. 0485054	20-		51 YR	Male	USA

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<u>Preferred Term</u>	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Blood Creatinine	R	Remdesivir			S	Intravenous drip	100 Mg Daily		G	Silead
Increased	F	Rocephin [Ceftriaxone]			С	•	Unk		N	lot Reported
	Д	zithromycin			С		Unk		N	lot Reported
	٧	ancomycin/			С		Unk		N	lot Reported
	Z	losyn			С		Unk		N	lot Reported
		Dexamethasone			С		Unk		N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806542	6 DIRECT	Υ		НО			1 YR	Male	USA
Preferred Term	Ē	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Inappropriate Antidiure Hormone Secretion	etic R	Remdesivir			S	Intravenous (not otherwise specifie	d)		N	lot Reported
	R	Remdesivir			С		·		١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806549	6 DIRECT	N						Unknown	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Heart Rate Decreased	d R	Remdesivir			S				١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806558	6 DIRECT	Υ					20 YR	Male	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer	ase R	Remdesivir			S	Intravenous bolus			G	Silead
Increased; Aspartate Aminotransferase Increased		razadone 25 Mg Dexamethasone 6 Mg Acetaminophen			C C C				N	lot Reported lot Reported lot Reported

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Product Remdesives 065617 Product Remdesives	Case Type DIRECT vir Case Type	Y Comp.	OTC Prof Ou	Role S utcomes	Route Mfr Control #	Dosage Text 503B Facility Dosage Text	Duration Age Duration	<u>Sex</u> Male	USA Mfr Not Reported Country USA Mfr
Remdesive see #	Case Type DIRECT vir Case Type	Health Y Comp.	Prof Ou	S sutcomes	Mfr Control #	503B Facility	Age	<u>Sex</u> Male	Not Reported Country USA
Product Remdesivase #	Case Type DIRECT vir Case Type	Y Comp.		Role		•		Male	Country USA
Product Remdesiv	vir Case Type	Y Comp.		<u>Role</u>		•		Male	USA
Product Remdesiv	vir <u>Case Type</u>	Comp.	OTC		Route	<u>Dosage Text</u>	<u>Duration</u>		
Remdesiv	Case Type	-	OTC		Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
ise #	Case Type	Health		0					
		Health		S					Not Reported
065620			Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	DIRECT	Υ	01	Γ			64 YR	Male	USA
Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Remdesiv	<i>y</i> ir	Υ		S	Intravenous drip				Gilead
Rocephin				C C C					Not Reported Not Reported Not Reported
nse #	Case Type	Health	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
065740	DIRECT	Υ	DE	Ē			80 YR	Male	USA
Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Vancomy Apixaban	cin			S C C C					Not Reported Not Reported Not Reported Not Reported
ase #	Case Type	Health	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
065824	DIRECT	Υ	01	Γ			78 YR	Female	USA
30	Remdesiv Azithromy Rocephin Dexametl Se # 065740 Product Remdesiv Vancomy Apixaban Cefepime	Remdesivir Azithromycin Rocephin Dexamethasone Se # Case Type 065740 DIRECT Product Remdesivir Vancomycin Apixaban Cefepime Se # Case Type	Remdesivir Y Azithromycin Rocephin Dexamethasone Se # Case Type Health 065740 DIRECT Y Product Comp. Remdesivir Vancomycin Apixaban Cefepime Se # Case Type Health	Remdesivir Y Azithromycin Rocephin Dexamethasone Se # Case Type Health Prof Out Product Comp. OTC Remdesivir Vancomycin Apixaban Cefepime Se # Case Type Health Prof Out Health Prof Out Health Prof Out Health Prof Out	Remdesivir Y S Azithromycin C Rocephin C Dexamethasone C Se # Case Type Health Prof Outcomes 065740 DIRECT Y DE Product Comp. OTC Role Remdesivir S Vancomycin C Apixaban C Cefepime C Se # Case Type Health Prof Outcomes	Remdesivir Y S Intravenous drip Azithromycin C Rocephin C Dexamethasone C Se # Case Type Health Prof Outcomes Mfr Control # 065740 DIRECT Y DE Product Comp. OTC Role Route Remdesivir S Vancomycin C Apixaban C Cefepime C Se # Case Type Health Prof Outcomes C Mfr Control #	Remdesivir Y S Intravenous drip Azithromycin Rocephin Dexamethasone C Se # Case Type Health Prof Outcomes Product Remdesivir Vancomycin Apixaban Cefepime Case Type Health Prof Outcomes Route Dosage Text S Vancomycin Apixaban Cefepime Case Type Health Prof Outcomes Mfr Control # 503B Facility Mfr Control # 503B Facility Mfr Control # 503B Facility S Vancomycin C C C C Se # Case Type Health Prof Outcomes Mfr Control # 503B Facility	Remdesivir Y S Intravenous drip Azithromycin C C Rocephin C C Dexamethasone C Se # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age 065740 DIRECT Y DE 80 YR Product Comp. OTC Role Route Dosage Text Duration Remdesivir S Vancomycin C Apixaban C C Cefepime C C Se # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age	Remdesivir Y S Intravenous drip Azithromycin C C Rocephin C C Dexamethasone C C Se # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex 065740 DIRECT Y DE 80 YR Male Product Comp. OTC Role Route Dosage Text Duration Remdesivir Vancomycin Apixaban C C Apixaban C C Cefepime C C Se # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex

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<u>Preferred Term</u>	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Erythema	; Remo	desivir	Υ		S	Intravenous drip				Gilead
Infusion Site	Thian	nine 100 Mg			С	·				Not Reported
Extravasation; Infusion		cosin 1 Mg			Č					Not Reported
Site Swelling		capine 2.5 Mg In Am And			Č					Not Reported
	5mg l				Ū					rtot rtoportou
		itin Powder			С					Not Reported
		zapine 15 Mg			Ċ					Not Reported
		n Lispro			Č					Not Reported
		Acid 1mg			Č					Not Reported
		aparin 40 Mg Qc			Č					Not Reported
		pazil 10 Mg Daily			Č					Not Reported
		methasone 6mg Oral Tab			Č					Not Reported
		dine 0.1 Mg Every 12h			Č					Not Reported
		pram 20mg			С					Not Reported
		ecalciferol 1000 Units Po			С					Not Reported
		ppion XI 300mg			С					Not Reported
		astatin 20mg			С					Not Reported
	Aspiri	n Ec 81mg			С					Not Reported
	Alpra	zolam 0.5mg Bid			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066173	DIRECT	Υ	D	E			86 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dyspnoea; Hypoxia; Oxygen Saturation	Remo	desivir			S	Intravenous drip	Other Frequency:Once Then 100mg Da;			Gilead
Decreased	Ascoi	bic Acid			С					Not Reported
		aparin			C					Not Reported
		utidine			С					Not Reported
		semide			С					Not Reported
	Loraz	epam			С					Not Reported
		oenem			С					Not Reported
	Doxy	cycline			С					Not Reported
	Methy	/ĺprednisolone			С					Not Reported
		omycin			С					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control i	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066227	DIRECT	Υ		ОТ				60 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Acute Kidney Injury;	Remo	lesivir			S	Intravenous drip				G	ilead
Hypovolaemic Shock	Amioo Amloo Aspiri Atorva Azithr Carve Ceftri Dexa Fenta Furos Hepa Insulii Lanso Vaso Potas	n astatin comycin edilol axone methasone myl emide rin prazole pressin sium Chloride pyl			00000000000000000000					N N N N N N N N N N N N N N N N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066233	DIRECT	Υ						69 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Therapy Interrupted	Remo	lesivir			S	Intravenous (not otherwise specified))			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066239	DIRECT	Υ						60 YR	Female	USA
Preferred Term	Prod	uct	Comp.	ОТС	Role	Route	Dosage	e Text	Duration	Mf	r

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Therapy Interrupted	Re	mdesivir			S	Intravenous (not otherwise specified)				Gilead
	Too	cilizumab			С	,				Not Reported
		c Sulfate			Č					Not Reported
		xamethasone			Č					Not Reported
		corbic Acid			Č					Not Reported
	ASI	COIDIC ACIO								Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066243	DIRECT	Y	D	E			81 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Pulse Absent; Respira Arrest; Sars-Cov-2 Te Positive		mdesivir			S					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066285	DIRECT	Υ					71 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Product Administration	n Re	mdesivir			S	Intravenous (not otherwise specified)				Gilead
	De	xamethasone			С					Not Reported
		c Sulfate			Č					Not Reported
		corbic Acid			Č					Not Reported
					C					Not Reported
	EII	oxaparin			<u> </u>					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18066287	DIRECT	Y	0	Т			80 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Transaminases Increa	ased Re	mdesivir			S	Intravenous (not otherwise specified)				Gilead
	De	xamethasone			С	. ,				Not Reported
		c Sulfate			Č					Not Reported
		corbic Acid			C					Not Reported
	ASC	JUI DIU AUIU			$\overline{}$					INUL INEPULLED

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							1			
	(E F L L E	Azithromycin Ceftriaxone Enoxaparin Pravastatin Lisinopril Levothyroxine Bisoprolol Aspirin Pantoprazole			00000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806629	0 DIRECT	Υ					66 YR	Female	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Alanine Aminotransfer Increased	ase F	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Not Reported
	L () () () () () () () () () () () () ()	Montelukast 10 Mg Lisinopril Combivent Respimat Insulin Lispro Gabapentin 300 Mg Enoxaparin Duloxetine 60 Mg Dexamethasone 6 Mg Symbicort Atorvastatin Aspirin Chewable Amlodipine			000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806629	7 DIRECT	Υ	DE	≣			89 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Breath Sou Absent; Pulse Absent		Remdesivir			S					Gilead

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806630	0 DIRECT	Υ	D	E				78 YR	Male	USA
Preferred Term	E	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Ac Respiratory Distress		Remdesivir			S	Intravenous (not otherwise specified	d)				Gilead
Syndrome; Cardiac Arr	. L	examethasone			С						Not Reported
Hypoxia		ocilizumab			С						Not Reported
	S	Sodium Bicarbonate Infusion			С						Not Reported
		asopressin/			С						Not Reported
		Phenylephrine			C C						Not Reported
		lorepinephrine			С						Not Reported
		Propofol			С						Not Reported
		entanyl			С						Not Reported
		miodarone			С						Not Reported
		zithromycin			С						Not Reported
		pinephrine			С						Not Reported
		lbumin 25%			C						Not Reported
		Cefepime			C C						Not Reported
		'ancomycin			C						Not Reported
		leparin Sq			C						Not Reported
		noxaparin Treatment Dosing			C						Not Reported
		noxaparin Ppx Dosing			C C C						Not Reported
	-	amotidine									Not Reported
		nsulin			C						Not Reported
	F	urosemide			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806630	5 DIRECT	Υ						69 YR	Male	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Anxiety; Throat Tightne	ess R	Remdesivir	Υ		S	Intravenous (not otherwise specified	d)				Not Reported
	А	cetaminophen			С						Not Reported
		spirin			Č						Not Reported
		Clonidine			Č						Not Reported
		Dexamethasone			Č						Not Reported
	L	revaluelliasone			U						Mot Izebouen

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							tuiiou itt	spo. c					
	Insuli Isoso Levot Metoj Oxyb Panto Polye Rosu Senn	alazine n Lispro rbide Mononitrate hyroxine orolol Succinate XI utynin oprazole Ec othylene Gylcol vastatin			00000000000							Not I Not I Not I Not I Not I Not I Not I Not I	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>		Country
24-Jul-2020	18067776	EXPEDITED (15-DAY)			DE, HO, LT	, OT	US-GILEAD-20 0485221	020-		84 YR	Female	Э	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Rou	<u>te</u>	Dosage	<u>Text</u>	Duration		<u>Mfr</u>	
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Cardiac Art		desivir			S	Unkn	own	Unk				Gilea	ad
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>		Country
24-Jul-2020	18068101	EXPEDITED (15-DAY)					US-GILEAD-20 0484476	020-			Unkno	wn	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Rou	<u>te</u>	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>	
Product Storage Error	Remo	desivir			S		renous (not wise specified)				Gilea	ad
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>		Country
24-Jul-2020	18068860	EXPEDITED (15-DAY)			DS, HO, OT	-	US-GILEAD-20 0484987	020-		39 YR	Male		USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Rou	<u>te</u>	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>	
Cerebral Artery Occlus	ebral Artery Occlusion Remdesivir				S	Intrav	enous bolus	100 M	g, Qd			Gilea	ad



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806886	EXPEDITED (15-DAY)		ОТ	US-GILEAD-2 0485562	020-		63 YR	Male	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	OTO	Role Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	ŀ	Remdesivir			S	Intravenous (not otherwise specified	100 Mg)	, Qd			Gilead
	1	Cholecalciferol Dexamethasone /itamin C [Ascorbic Acid] Zinc			C C C						Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1806886	9 EXPEDITED (15-DAY)		ОТ	US-GILEAD-2 0485223	020-		65 YR	Male	USA
Preferred Term	!	<u>Product</u>	Comp.	<u>OT(</u>	Role	Route	Dosage	<u>Text</u>	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased; Blood Alkal	line	Remdesivir			S	Intravenous (not otherwise specified	200 Mg	, Once			Gilead
Phosphatase Increase Blood Bilirubin Increas		Remdesivir			S	Intravenous (not otherwise specified	100 Mg)	, Qd			Gilead
		Госіlizumab			C						Not Reported
		Amiodarone			C C						Not Reported
		Atorvastatin Azithromycin			C						Not Reported Not Reported
		Cisatracurium			C						Not Reported
		Diltiazem			Ç						Not Reported
		Enoxaparin			C C						Not Reported
		Epoprostenol			Ċ						Not Reported
		Ketamine			C						Not Reported
		_orazepam			С						Not Reported
	ı	Methylprednisolone			С						Not Reported
		Midazolam			С						Not Reported
	1	Norepinephrine			С						Not Reported
		Pantoprazole			С						Not Reported
		Piperacillin & Tazobactam Rivaroxaban			C C						Not Reported Not Reported



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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	Age	Sex	Country
24-Jul-2020	18068870		<u></u>		ОТ	US-GILEAD-20 0485506	•	62 YR	Male	USA
<u>Preferred Term</u>	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	rase R	emdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18070936	6 DIRECT	Υ		ОТ			44 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	A C D D E A B	emdesivir Lyophilized Powder Ibuterol/Ipratropium eftriaxone examethasone oxycycline noxaparin cetaminophen enzonatate shexol	Y		8 00000000	Intravenous bolus	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18070943	3 DIRECT	Υ		ОТ			77 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	J	<u>Mfr</u>
Respiratory Arrest	R	emdesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
		lethylprednisolone 60 Mg Iv 12h			С	•	. , ,			Not Reported
	D	examethasone 6mg Po Daily noxpararin 1 Mg/Kg Sc Bid			C C					Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u> #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18070950	DIRECT	Υ						61 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Rem	desivir			S	Intravenous bolus			4 DAY		Gilead
Increased; Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase	line Hepa Doxa ed Dexa Clop	oprolol 12.5 Mg arin 500 Sq azosin 2 Mg amethasone 6 Mg idogrel rin 81			C C C C C						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18070955	DIRECT	Υ	DI	≣				73 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<u>Duration</u>		<u>Mfr</u>
Acute Myocardial Infarction	Acet Eton Prop Roci Lora Mida Fent Lans Meth Insu Nore Asco Eno: Carv Toci Amlo Losa Aspi	uronium zapam azolam anyl soprazole nylprednisolone lin spinephrine orbic Acid (Iv) kaparin redilol lizumab odipine urtan rin semide			%0000000000000000000000000000000000000						Not Reported

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	ľ	Metolazone			С				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1807098	9 DIRECT	Υ					51 YR	Female	USA
Preferred Term	!	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Liver Function Test Increased	F	Remdesivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1807105	2 DIRECT	Υ	С	DΕ			67 YR	Female	USA
Preferred Term	1	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	r
Blood Calcium Decreas Blood Chloride Increas	,	Remdesivir	Υ		S	Intravenous (not otherwise specified)			G	ilead
Blood Creatinine Increased; Blood Gluco		Convalescent Plasma X 2 Un At Other Hosp	its		С				N	ot Reported
Increased; Blood Magnesium Increased;	. 7	Focilizumab 800 Mg X 1 At Other Hosp			С				N	ot Reported
Blood Phosphorus Increased; Blood	A	Amiodarone 200 Mg Po Q12h Azithromycin 500 Mg Feed To			C C					ot Reported ot Reported
Potassium Increased; Blood Urea Increased;	[Daily Dexamethasone 10 Mg Iv On			С					ot Reported
Carbon Dioxide Decreased; Cardiac	[Daily								·
Arrest; Glomerular	F	Dexamethasone 6 Mg Iv Dail Enoxaparin 100 Mg Sq Q12h			C C					ot Reported ot Reported
Filtration Rate Increase Haematocrit Decrease	ea; F	Famotodine 20 Mg Iv Bid			С					ot Reported
Red Blood Cell Count	^{u,} l	antus Up To 20 Untis Sq Bio			С				N	ot Reported
Decreased; Sars-Cov-2										
Test Positive; White Blo Cell Count Increased	ood									
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	1807107	8 DIRECT	Υ					49 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mf	

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						Dotanoa itt	port			
Alanine Aminotransfera Increased; Liver Function		desivir (Eua)			S	Intravenous (not otherwise specified)	1		G	ilead
Test Increased	Mcg/1	nedetomidine In Ns 400 I 00 MI (4 Mcg/MI) Iv Prem edex In	ix		С	,			N	ot Reported
		inyl (Pf) In Ns 10 Mcg/MI I	/		С				N	ot Reported
	Hepa	rin (Porcine) In D5w 25,00 250 MI(100 Unit/MI) Iv ix	0		С				N	ot Reported
		n Regular Human Sliding Inj (Humulin R/Novolin R)			С				N	ot Reported
	Ipratro	opium 17 Mcg/Actuation Puff (Atrovent Hfa)			С				N	ot Reported
	Melat	onin Rap Dis Tablet 10 M	ר		С				N	ot Reported
		nidazole In Nacl Iv Premix			Č					ot Reported
		/indazole in Naci iv i reiniz /lg (Flagyl)	•		O				11	ot reported
		colam In Ns 1 Mg/Ml Iv So	ln		С				N	ot Reported
		bic Acid Ivpb 1,500 Mg			Č					ot Reported
					C C					
		ylephrine 100 Mg In	_		C				IN	ot Reported
		m Chloride 0.9% 250 MI I	/							
	Soln									
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020	18071081	DIRECT	Υ	[DE			45 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> f	<u>r</u>
Death	Remo	desivir			S	Intravenous (not otherwise specified))		G	ilead
	Tylen	ol			С				N	ot Reported
		omycin			Č					ot Reported
		axone			C					ot Reported
					C					
	Nimbe				C C				N	ot Reported
	Ryand				C					ot Reported
	Lover				C C					ot Reported
	Insulii									ot Reported



FDA Received Date	Case #	Case Ty	<u>pe</u>	Health	<u>Prof</u>	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
24-Jul-2020	180710	87 DIRECT		Υ		DE				81 YR	Male	USA	
Preferred Term		<u>Product</u>		Comp.	ОТС	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>		<u>Mfr</u>	
Blood Creatinine Increased; Blood Gluc	ose	Remdesivir		Υ		S	Intravenous (not otherwise specified))				Gilead	
Increased; Blood Urea Increased; Glomerular		Dexamethasone 5 Daily	Mg Iv Once			С						Not Reported	
Filtration Rate Decreas	sea	Carvedilol 3.125 N				С						Not Reported	
		Valproate Sodium Ticagrelor 90 Mg I				C C						Not Reported Not Reported	
		Thiamine 100 Mg				C						Not Reported	
		Spironolactone 25				Č						Not Reported	
		Entresto 24/26 Po				Ċ						Not Reported	
		Pantoprazole 40 N	/Ig Po Once			С						Not Reported	
		Daily Megestrol 400 Mg	Po Bid			С						Not Reported	
		Furosemide 40 Mg				С						Not Reported	
		Fluconazole 100 N	Mg Po Once			С						Not Reported	
		Daily Ezetimibe 10 Mg I	Po Once Daily			С						Not Reported	
		Enoxaparin 80 Mg	Sq Q12hr			С						Not Reported	
		Atorvastatin 80 Mg				C C						Not Reported	
		Asa 81 Mg Po On				С						Not Reported	
		Albuterol Mdi Rt B				С						Not Reported	
		Clinimix E 2.75%-	5%			С						Not Reported	
		Tpn Custom				С						Not Reported	
FDA Received Date	Case #	Case Ty	<u>pe</u>	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
24-Jul-2020	180716	57 DIRECT		Υ						53 YR	Male	USA	
Preferred Term		Product		Comp.	OTC	<u>Role</u>	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>		Mfr	
Blood Creatinine		Remdesivir				S						Not Reported	
Increased; Glomerular		Cyclosporine				Ċ						Not Reported	
Filtration Rate Decrease Therapy Cessation		Decadron				С						Not Reported	



FDA Received Date Cas	se #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2020 180	073245	DIRECT	Υ		ОТ			86 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Agitation; Alanine Aminotransferase	Remd	esivir 100mg/MI			S	Intravenous (not otherwise specified)	Frequency: Once			Gilead
Increased; Aspartate	Aceta	minophen			С					Not Reported
Aminotransferase	Ascor	bic Acid			С					Not Reported
Increased; Bacterial Infection; Blood Creatinine	Flutica				С					Not Reported
Increased; Creatinine	Budes	sonide Neb			С					Not Reported
Renal Clearance	Vitam				С					Not Reported
Decreased; Disease	Zinc S				С					Not Reported
Progression; Procalcitonin		mazole			С					Not Reported
Increased; Respiratory	Cenna				С					Not Reported
Failure: White Blood Cell		omycin			С					Not Reported
Count Increased		icysteine			С					Not Reported
Count increased	Omni				С					Not Reported
		prednisolone			C					Not Reported
	Thiam				С					Not Reported
	Enoxa				C					Not Reported
	Famo				C					Not Reported
		astatin			C					Not Reported
		omycin			С					Not Reported
	Aspiri				C					Not Reported
	Melate	onin			С					Not Reported
FDA Received Date Cas	se #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2020 180	071093	DIRECT	Υ		ОТ			62 YR	Femal	e USA
Preferred Term	Produ	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
White Blood Cell Count Decreased	Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
		erol-Ipratropium methasone			C C	. ,				Not Reported Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2020	1807109	8 DIRECT	Υ		OT			35 YR	Female	e USA
Preferred Term	ļ	Product	Comp.	отс	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase F	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once As	i		Gilead
		Acetaminophen 650 Mg Po Q6h Prn			С	. ,				Not Reported
		Albuterol 2 Puff Q4h			С					Not Reported
		Ascorbic Acid 1000 Mg Po Daily			Ċ					Not Reported
	(Clozapine 100 Mg Po Bid			С					Not Reported
		Robitussin Ac 10 Ml Po Q8h Prn Cough			С					Not Reported
		Dexamethasone 6 Mg Iv Bid			С					Not Reported
		Ouloxetine 30 Mg Po Daily			С					Not Reported
		noxaparin 40 Mg Sc Bid			С					Not Reported
		amotidine 20 Mg Po Bid			С					Not Reported
		abetalol 100 Mg Po Bid			С					Not Reported
		isinopril 10 Mg Po Daily			С					Not Reported
		Spironolactone 25 Mg Po Daily			C					Not Reported
		Thiamine Mononitrate 100 Mg Po Daily			С					Not Reported
		opiramate 100 Mg Po Bedtime			С					Not Reported
	2	Zinc Sulfate 220 Mg Po Daily			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2020	1807110	3 DIRECT	Υ		ОТ			83 YR	Male	USA
Preferred Term	<u> </u>	<u>Product</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	F	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
	A	Alfuzosin			С					Not Reported
	Amlodipine			Ċ					Not Reported	
		Enoxaparin			Ċ					Not Reported
		Hydralazine			C					Not Reported
		nsulin			Ċ					Not Reported
		Melatonin			С					Not Reported



		ylprednisolone nosides			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2020	18071109	DIRECT	Υ	C	T			41 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Dexr Epop Enox Famo Keta Ceftr Azith Levo Nore	semide nedetomidine orostenol caparin otidine mine iaxone romycin floxacin pinephrine ylprednisolone Case Type	Health	Prof C	C C C C C C C C	Mfr Control #	503B Facility	Age	Sex	Not Reported
25-Jul-2020	18071115	DIRECT	Υ	С	ÞΕ			84 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rem	desivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2020	18071156	DIRECT	Υ					53 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Asthenia; Infusion Rela	ated Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
	Rem	desivir			С					Not Reported

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							1			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2020	18071160	DIRECT	Υ					65 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferancreased	ase Ren	ndesivir			S	Intravenous (not otherwise specified)				Gilead
	Eno. Gua Keto	irin amethasone xaparin fenisin orolac nadol			00000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jul-2020	18071165	DIRECT	Υ	0	T			52 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Rem	ndesivir			S	Intravenous (not otherwise specified)				Gilead
	Rem	ndesivir			С	. ,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jul-2020	18072868	DIRECT	Υ	D	E			81 YR	Female	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Pulse Absent; Respira Arrest; Subcutaneous	tory Rem	ndesivir Solution 100mg Vi	al Y		S	Intravenous (not otherwise specified)	Frequency: Once			Gilead
Emphysema	Rem	ndesivir Solution 100mg Vi	al Y		S	Intravenous (not otherwise specified)	Other Route:Iv			Gilead
	Ace	taminophen			С	Oral				Not Reported
	Albu	iterol			С		Other Dose:2 Puffs;Other Frequency:Q6-8 Hr;			Not Reported
	Asc	orbic Acid (Vitamin C)			С	Oral	<u>-</u>			Not Reported

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			•	
Atorvastatin	С	Oral		Not Reported
Azithromycin	С		Other Route:Iv	Not Reported
Azithromycin	С	Oral		Not Reported
Cefazolin	С		Other Route:Iv	Not Reported
Cefepime	С		Other Route:Iv	Not Reported
Chlorhexidine	С	Oral		Not Reported
Cholecalciferol (Vitamin D3)	С	Oral	Other Frequency:Once Or Bid;	Not Reported
Dexamethasone	S		Other Frequency:Q 12-24 Hr;Other Route:Iv	Not Reported
Donepezil	С	Oral		Not Reported
Enoxaprin	S	Subcutaneous	Other Dose:40-60 Mg;Other Frequency:Q 12- 24 Hr;	Not Reported
Fentanyl	С		Other Frequency:Continuous;Oth er Route:Iv	Not Reported
Furosemide	С		Other Frequency:X 3 Doses;Other Route:Iv	Not Reported
Guaifenesin	С	Oral		Not Reported
Hydrocodone- Acetaminophen	С	Oral	Other Frequency:Q 6-12 Hr;	Not Reported
Insulin Aspart	С	Subcutaneous	Other Dose:0-10 Units;Other Frequency:Ac & Hs Prn;	Not Reported
Insulin Detemir	С	Subcutaneous	Other Dose:8-25 Units;	Not Reported
Insulin, Regular	С	Subcutaneous	Other Dose:0-10 Units;Other Frequency:Q 4 Hr Prn;	Not Reported
Losartan	С	Oral		Not Reported
Meclizine	С	Oral		Not Reported
Melatonin	С	Oral		Not Reported
Methylprednisolone Sodium	С		Other Dose:40-125	Not Reported
Methylprednisolone Sodium	С		Other Dose:40-125	Not Reported

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	Succ	inate					Mg;Other Route:Iv			
	Mupi	rocin			С	Nasal				Not Reported
	Nore	pinephrine			С		Other Dose:0.02-0.16 Mcg/Kg/M;Other Frequency:Continuous;0 er Route:Iv	Oth		Not Reported
	Onda	ansetron			С		Other Route:Iv			Not Reported
	Prop	ofol			С		Other Frequency:Continuous; er Route:Iv	Oth		Not Reported
	Senr	a - Docusate 8.5 - 50			С	Oral				Not Reported
	Vano	comycin			С		Other Frequency:Intermittent Dosin;Other Route:Iv			Not Reported
	Zinc	Sulfate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	17868186	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-2 0469280	2020-	85 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Hepatic Enzyme Increased	Rem	desivir			S	Intravenous (not otherwise specified	200 Mg d)			Gilead
	Tyler Zosy				C C		Unk			Not Reported Not Reported
	Doxy	rcycline			С		Unk			Not Reported
	Pant	oprazole			С		Unk			Not Reported
	Enox	aparin			С		Unk			Not Reported
	Clop	idogrel			С		Unk			Not Reported
	Albut	erol [Salbutamol]			С		Unk			Not Reported
	Albu	erol [Salbutamol]			С	Respiratory (inhalation)	Unk			Not Reported
	Aceta	aminophen			С		Unk			Not Reported
	Albu				С		Unk			Not Reported

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						Dotalloa No	PO. 1				
	Amin	o Acids Nos			С		Unk				Not Reported
	Asco	rbic Acid			С		Unk				Not Reported
		um & Vitamin D ium;Colecalciferol]			С		Unk				Not Reported
		Emulsions			С		Unk				Not Reported
	Furo	semide			С		Unk				Not Reported
	Halo	peridol			С		Unk				Not Reported
	Insul	in Regular Hm			С		Unk				Not Reported
	Leva	lbuterol [Levosalbutamol]			С		Unk				Not Reported
	Meto	prolol			С		Unk				Not Reported
	Multi	vitamin And Mineral			С		Unk				Not Reported
	Ns				С		Unk				Not Reported
	Pota	ssium Chloride			С		Unk				Not Reported
	Sodi	um Chloride			С		Unk				Not Reported
	Sodi	um Phosphate			С		Unk				Not Reported
		Amino Acids Carbohydrates			С		Unk				Not Reported
	Nos;	Minerals Nos;Vitamins Nos] Sulfate			С		Unk				Not Reported
	Kine	/ac			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	Sex	Country
27-Jul-2020	17882674	EXPEDITED (15-DAY)			LT, OT	US-GILEAD-20 0469816	20-		63 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation	Rem	desivir			S	Intravenous (not otherwise specified)		X 1, 100mg X 1			Gilead
	Rem	desivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
	Ceftr	tonin ochlorothiazide iaxone aparin			C C C						Not Reported Not Reported Not Reported Not Reported



		Morphine Pantoprazole Insulin Zinc Ascorbic Acid Sucralfate Decadron [Dexamethasone] Decadron [Dexamethasone]			000000000		Unk Unk Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	178826	697 EXPEDITED (15-DAY	()		ОТ	US-GILEAD-202 0469673	20-	74 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Afr</u>
Acute Kidney Injury; Covid-19 Pneumonia;		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Hypovolaemia; Pneumonia Staphylococcal; Renal		Remdesivir			S	Intravenous (not otherwise specified)	100 Unk			Gilead
Tubular Necrosis; Seps Septic Shock	sis;	Norepinephrine			S	Intravenous (not otherwise specified)	Unk			Not Reported
		Enoxaparin			С	Subcutaneous	30 Mg			Not Reported
		Etomidate			С	Intravenous (not otherwise specified)	20 Mg			Not Reported
		Famotidine			С	Intravenous (not otherwise specified)	20 Mg			Not Reported
		Furosemide			С	Intravenous (not otherwise specified)	40 Mg			Not Reported
		Furosemide			С	Intravenous (not otherwise specified)	40 Mg			Not Reported
		Heparin			С	Subcutaneous	7500 Units			Not Reported
		Lorazepam			С	Oral	4 Mg			Not Reported
		Metoclopramide			С	Intravenous (not otherwise specified)	10 Mg			Not Reported
		Vecuronium			С	Intravenous (not	10 Mg			Not Reported

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						otherwise specified)				
	Azi	thromycin			С	Intravenous (not otherwise specified)	500 Mg			Not Reported
	Cet	azolin			С	Intravenous (not otherwise specified)	2 G			Not Reported
	Cet	epime			С	Intravenous (not otherwise specified)	2 G			Not Reported
	Dex	kmedetomidine			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Dilt	iazem			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Me	toprolol			С	Intravenous (not otherwise specified)	2.5 Mg			Not Reported
	Pro	pofol			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Var	ncomycin			С	Intravenous (not otherwise specified)	1750 Mg			Not Reported
	Pot	assium Chloride			С	Intravenous (not otherwise specified)	40 Meq			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18040153	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-202 0483271	20-	90 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Death	Rei	mdesivir			S	Intravenous (not otherwise specified)	Unk			Gilead
	Rei	mdesivir			S	Intravenous (not otherwise specified)	Unk			Gilead
	Lev	rophed			С	. ,	Unk			Not Reported
	Pre	cedex			С		Unk			Not Reported
	Pro	pofol			С		Unk			Not Reported
	Fer	ntanyl			С		Unk			Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18045095	EXPEDITED (15-DAY)		DE	E, OT	US-GILEAD-20 0484021	020-	77 YR	Femal	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Bradycardia; Death	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Oxyg	en			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control:	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072744	DIRECT	Y	O	Г			53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Asthenia; Hypersensiti	Insuli Atorv Panto	desivir Eua n Nph 5 Units astatin 20mg prazole 40mg n 81mg	Υ		S C C C					Gilead Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072756	DIRECT	Υ	07	Γ			44 YR	Male	USA
<u>Preferred Term</u>	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury	Remo	desivir	Υ		S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072768	DIRECT	Υ					70 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Death	Remo	desivir 100mg	Υ		S	Intravenous (not otherwise specified)				Gilead
	Remo	desivir 100mg	Υ		S	Intravenous (not				Gilead

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						otherwise specified)				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072778	DIRECT	Υ		ОТ			46 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	desivir			S	Intravenous drip				Gilead
Increased	Enox Azith	methasone aparin romycin iaxone			0000					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072790	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	ase Remo	desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Levo	phed			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072809	DIRECT	Υ		ОТ			77 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	Remo	desivir			S	Intravenous drip				Gilead
Increased	Atorv	astatin			С	·				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072842	DIRECT	Υ		ОТ			77 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not				Gilead

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						otherwise specified)				
	Gam Insul Meth	otidine munex in Lispro lylprednisone ssium Chloride			C C C C				Not Reported Not Reported Not Reported Not Reported Not Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072846	DIRECT						76 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Rem	desivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18072852	DIRECT	Υ	Н	0			56 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Creatinine Renal Clearance Increased;	Rem	desivir			S	Intravenous (not otherwise specified)				Gilead
Therapy Interrupted		amethasone 6 Mg Iv valescent Plasma			C C	,				Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18072951	DIRECT	Υ	D	E, OT			67 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypertension; Slow Response To Stimuli;	Rem	desivir 100mg/20ml			S	Intravenous (not otherwise specified)				Gilead
Tachycardia	Rem	desivir 100mg Injection			S	Intravenous (not otherwise specified)	Frequency Daily X 4 Day	ys 4 DAY		Gilead
					C C C					Not Reported Not Reported Not Reported Not Reported
	Diltia	zem			С					Not Reported

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Hydralazine Labetalol Metoprolol			C C C								Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18073621	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0485716	20-		71 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
	Chole Azith Piper Amio Atorv Cisat Dexn Epop Fenta Nore Prope	pinephrine oprazole ofol			0000000000000						Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18074246	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485069	20-			Femal	e USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Angioedema; Bradyca Fluid Overload	rdia; Remo	desivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
	Propo	ofol			С		Unk				Not Reported
	Verse	ed			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18076581	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486049	20-		72 YR	Male	USA

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Preferred Term			Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Myocardial	arction; Covid-19 Acetaminophen				S	Unknown	Unk			Gilead
iniarction; Covid-19	Acetai Etomio Propo	date			C C C					Not Reported Not Reported Not Reported
	Rocur	onium			C C C					Not Reported
	Loraze				C					Not Reported
	Midaz Fentai				C					Not Reported Not Reported
		prazole			C					Not Reported
		Iprednisolone			0000000					Not Reported
	Insulin				Č					Not Reported
	Norep	inephrine			С					Not Reported
		oic Acid			С					Not Reported
	Enoxa	parin			С					Not Reported
	Carve				С					Not Reported
	Tociliz				C					Not Reported
	Amlod				С					Not Reported
	Losart				С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077392	EXPEDITED (15-DAY)			DE, OT	US-GILE/ 0485708	ND-2020-	73 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Alanine Aminotransfe	rase Remd	esivir			S	Unknown	100 Mg, Qd			Gilead
Increased		cumab calciferol n C [Ascorbic Acid]			C C C		-			Not Reported Not Reported Not Reported
		nethasone			C C C					Not Reported Not Reported
	Azithro Ceftria	omycin axone			С					Not Reported Not Reported
	Cefep				С					Not Reported
	Amlod				С					Not Reported
	Atorva				C C					Not Reported
	-	onida			С					Not Reported
	Budes									
	Budes Carve Enoxa	dilol			C C					Not Reported Not Reported

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		steride semide			C C		-				Not Reported Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	Age	Sex	Country
27-Jul-2020	18077503	EXPEDITED (15-DAY)				US-GILEAD 0479527	-2020-		64 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	Duration	<u>N</u>	<u>lfr</u>
Product Storage Error; Product Temperature Excursion Issue	Rem	desivir			S	Intravenous (not otherwise specific	ed)			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077545	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD 0486092	-2020-		62 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; Ad Respiratory Distress		desivir			S	Unknown		pleted An Extended ay Course In 2020		(Gilead
Syndrome; Septic Shoo	ck Dexa	amethasone			С			pleted A 10 Day se In 2020		1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077663	EXPEDITED (15-DAY)			ОТ	SK-BAUSC 021078	H-BL-2020-		38 YR	Male	SVK
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Liver Disorder	Dexa	amethasone			S	Oral				,	/aleant
	Meta	mizol (Metamizole)			S	Oral				1	Not Reported
	Moxi	floxacin			S	Oral				1	Not Reported
	Rem	desivir			S	Intravenous (not otherwise specific	ed)			1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077728	EXPEDITED (15-DAY)			DE, OT	US-GILEAD 0485681	-2020-		45 YR	Female	USA

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<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>M1</u>	<u>ir</u>
Death	Remo	lesivir			S	Unknown	Unk		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077754	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485067)20-	57 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Covid-19 Pneumonia	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		G	ilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Solu-I	Medrol			С	Intravenous (not otherwise specified)	200 Mg, Qd		N	ot Reported
	Solu-I	Medrol			С	Intravenous (not otherwise specified)	100 Mg, Qd		N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077843	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485590)20-	43 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Liver Function Test Increased	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead
	Atorva	astatin			С		Unk		N	ot Reported
	Aceta	minophen			С		Unk		N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18077932	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485701)20-	63 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Acute Kidney Injury; Alanine Aminotransfer Increased	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	ilead

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							, po. 1			
	Pip	eracillin And Tazobactam			С		Unk			Not Reported
	Ch	olecalciferol			С		Unk			Not Reported
	De	xamethasone			С		Unk			Not Reported
	Vit	amin C Flavour			С		Unk			Not Reported
	Zin	c Gluconate			С		Unk			Not Reported
	Lo	venox [Enoxaparin Sodium]			С		Unk			Not Reported
	Ins	ulin			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078185	DIRECT	Υ		ОТ			26 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alka Phosphatase Increase Therapy Cessation	line	mdesivir			S			3 DAY		Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078194	DIRECT	Υ		ОТ			74 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase Re	mdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Onco	е		Gilead
	To	cilizumab			С	,				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078205	DIDEOT	Υ		HO, LT			51 YR	Female	USA
	10070203	DIRECT	'		,					
Preferred Term		oduct	Comp.	OTC		Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



	Rem	ndesivir			S	Intravenous drip				Gilead
	Tocil Amb Levo Fioro Solu Acet Cefti Doxy Aton Robi Leve Albu Cyar Pota Oxyt Cital	alol poclopramide lizumab pien pothyroxine petMedrol paminophen priaxone pycycline pyastatin pitussin Ac pemir peterol phocobalamin pissium Chloride putynin popram			000000000000000000000000000000000000000					Not Reported
FDA Received Date		Case Type	Health	Prof (Outcomes	Mfr Control #	# 503B Facility	Age	Sex	Country
27-Jul-2020	18078218	DIRECT	Y		HO, LT		-	27 YR	Female	-
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia	Rem Acet Albu Sodi Azith Love Cefe Solu Leve Nove	um Chloride nromycin enox epime -Medrol emir			s s cccccccc	Intravenous drip Intravenous drip	Other Frequency:Once;			Gilead Gilead Not Reported



						Dotalloa IX	эрогг			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078228	DIRECT			DE				Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Respiratory Failu		esivir			S	Intravenous bolus				Gilead
Cardiac Arrest; Conditi Aggravated; Septic Sho	ock Cisatr Norep Midaz	methason acurium vinephrine volam Infusion edetomidine nyl			C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078249	DIRECT	Y		DE			73 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Respiratory Failo Anxiety; Bilevel Positivo Airway Pressure; Respiratory Failure; Unresponsive To Stimo	е	lesivir			S	Intravenous bolus				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078277	DIRECT	Υ		НО			34 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Renal Failure	Remd	esivir	Υ		S	Intravenous bolus				Gilead
		ncomycin eracillin-Tazobactam			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078287	DIRECT	Υ		ОТ			91 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	Mfr_

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Blood Creatinine		ndesivir	Υ		S	Intravenous drip			G	ilead
ncreased; Glomerular Filtration Rate Decreas Renal Failure	sed; Lov Glin Irbe Iver	amethamethsone enox nepiride sartan mectin hromycin			C C C C C				N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078366	DIRECT	Υ					9 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Product Administration Error; Product Prepara Issue		ndesivir			S	Intravenous (not otherwise specified)			N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078376	DIRECT	Υ					89 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Therapy Cessation	ase Ren	ndesivir			S	Intravenous drip		3 DAY	G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078388	DIRECT	Υ	(ОТ			51 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Chest Pain; Therapy Cessation	Ren	ndesivir			S	Intravenous (not otherwise specified)			G	ilead
		enox adron			C C					ot Reported ot Reported



FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078397	DIRECT	Υ					83 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Therapy Cessation	rase Remd	lesivir			S	Intravenous drip		3 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078408	DIRECT	Υ		НО			68 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	Remd	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Furos Aceta Albute Times Ascor Times Budes Ceftria Chole	omycin 500mg Iv Daily emide 40mg Iv Twice Daily minophen As Needed erol/Ipratropium Neb Four s Daily bic Acid 500mg Oral Three s Daily sonide Neb axone 2gm Ivpb Daily ecalciferol 1,000units Daily			0000 0 000					Not Reported
	Daily Enoxa Fenta	eycline 100mg Ivpb Twice aparin 40mg Sub Q Daily nyl Infusion //prednisolone 60mg Ivp			С С С					Not Reported Not Reported Not Reported Not Reported
	Midaz Norep Panto Thiam	colam Infusion binephrine Infusion prazole 40mg Iv Daily hine 200mg Iv Daily conium Infusion			C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported

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

	Zin Da	c Sulfate 220mg Oral Twice ily			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078420	DIRECT	Υ						46 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Infusion Site Erythema Infusion Site Swelling; Injection Site Extravasation	-,	mdesivir	Y		S	Intravenous (not otherwise specified)					Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078433	DIRECT	Υ		НО				78 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Glomerular Filtration R Decreased; Therapy	Rate Re	mdesivir			S	Intravenous (not otherwise specified)					Gilead
Interrupted	Alb	etaminophen As Needed outerol/Ipratropium Neb 4 nes Daily			C C						Not Reported Not Reported
	Am As	nlodipine 10mg At Bedtime corbic Acid 500mg Tablet ice Daily			C C						Not Reported Not Reported
	Ası	pirin 81mg Daily			С						Not Reported
	Ato	enolol 50mg Tablet Daily orvastatin 40mg Daily desonide 0.5mg Neb Twice			C C						Not Reported Not Reported Not Reported
	Clo En	opidogrel 75mg Tablet Daily oxaparin 40mg Sub Q Daily			C C						Not Reported Not Reported
	Fai Da	motidine 20mg Tablet Twice ily			С						Not Reported
	Fei Fui Lad	ntanyl Infusion rosemide 40mg Iv Twice Dail ctobacillus 1 Capsule Daily	У		C C						Not Reported Not Reported Not Reported
		ezolid 600mg Iv Q12h ropenem 1g Iv Q12h			C C						Not Reported Not Reported

Note: If the field is blank, there is no data.



							1 -			
		Methylprednisolone 40mg Iv			С					Not Reported
		Q6h Midazolam Infusion			С					Not Reported
		Thiamine 200mg Iv Twice Daily			Č					Not Reported
		Zinc Sulfate 220mg Po Twice			Č					Not Reported
		Dialy			Ü					Hot Hoponou
		Norepinephrine Infusion			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	1807844	1 DIRECT	Υ		ОТ			66 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	I	Remdesivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Increased		Apixaban 5mg Bid			С					Not Reported
		Buproprion 50mg Tid			Ċ					Not Reported
		Duloxetine 30mg Daily			C					Not Reported
		Apripirazole 5mg Bid			C C					Not Reported
		nsulin Glargine 15units Hs			С					Not Reported
		Levothyroxine 100mcg Daily			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	1807845	50 DIRECT	Υ					70 YR	Male	USA
27 001 2020	1007010	DINCEOT	•					70 110	IVIGIO	00/1
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase	Remdesivir			S	Intravenous (not otherwise specified)				Gilead
		Azithromycin 500 My Po Daily			С					Not Reported
		Ceftriaxone 1 Gm Iv Q24h			C					Not Reported
		Enoxaparin 40 Mg Sq Q12h			C					Not Reported
		Furosime 20 Mg Ivpush Daily			Ċ					Not Reported
		Methylprednisolone 20 Mg Iv			Č					Not Reported
		Q6h			•					
		Prednisone 40 Mg Daily			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	1807847	0 DIRECT	Υ		OT			61 YR	Femal	e USA
			-					2		

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<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage Text</u>	Duration	<u>N</u>	<u>//fr</u>
Renal Injury	Remo	lesivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
	Propo	l Drip binephrine Drip ofol Drip onium Drip			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078474	DIRECT	Υ	0	Т			44 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Afr</u>
Alanine Aminotransfel Increased; Aspartate Aminotransferase Increased	rase Remo	lesivir			S	Intravenous (not otherwise specified	Other Frequency:Once;	1 DAY		Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078481	DIRECT		0	Т			78 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Renal Failure	Remo	lesivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18078538	DIRECT	Υ	0	Т			23 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Liver Function Test	Remo	lesivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Increased	Famo	omycin 250mg Daily tidine 20mg Bid axone 1gm Q 24h			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country

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						, p			
Preferred Term I	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
	Remdesivir			S	Intravenous drip				Gilead
Ratio Increased F	Rivaroxaban			S	Oral		1 YR		Janssen
	Remdesivir Rivaroxaban			C C	ora.				Not Reported
									Not Reported
FDA Received Date Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020 1807927	0 DIRECT	Υ	DE	≣			77 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death; Confusional State;	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	Frequency: Once			Gilead
Fatigue; Lethargy; Myasthenia Gravis Crisis; Pulse Absent	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)	1			Gilead
A	Acetaminophen			С					Not Reported
	Alprazolam			С					Not Reported
-	Dexamethasone Dexmedetomidine			C C					Not Reported Not Reported
-	Dexmedetomidine Diphenhydramine			C					Not Reported
	Enoxaparin			C					Not Reported
	-urosemide			C					Not Reported
	Hydrocortisone Sodium			C					Not Reported
	Succinate			C					Not Reported
	Mupirocin			С					Not Reported
	Mycophenolate			C					Not Reported
	Norepinephrine			C					Not Reported
	vorepriirie Vitamin D			C					Not Reported
FDA Received Date Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020 1807940	DIRECT	Y	DE	Ξ			82 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aggravated; Oxygen	Remdesivir Solution 100mg Vial	Y		S	Intravenous (not otherwise specified)				Gilead
Saturation Decreased F	Remdesivir Solution 100mg Vial	Υ		S	Intravenous (not				Gilead

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						otherwise specified)				
	Aceta	minophen			С					Not Reported
	Albute	erol			C C					Not Reported
	Alpraz	olam			С					Not Reported
	Amloc	lipine			С					Not Reported
	Ascorl	bic Acid (Vitamin C)			С					Not Reported
	Atorva				C C					Not Reported
		nexidine			С					Not Reported
		cciferol (Vitamin D3)			С					Not Reported
	Clonic				С					Not Reported
		nethasone			C C					Not Reported
		nhydramine			С					Not Reported
	Enoxa				С					Not Reported
	Famo				С					Not Reported
	Gabar				C C					Not Reported
	Hydra				С					Not Reported
	Levofl				С					Not Reported
	Loraze				С					Not Reported
	Mupiro				C C					Not Reported
		nsetron			С					Not Reported
		mer Calcium Sorbitex			С					Not Reported
		m Bicarbonate			С					Not Reported
		m Bicarbonate In Dextrose			С					Not Reported
	5%				•					N. B.
	Sucra				С					Not Reported
		ol Maleate 0.5%			С					Not Reported
	Zinc S	sulfate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2020	18079480	DIRECT	Υ	D	E			74 YR	Male	USA
<u>Preferred Term</u>	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remd	esivir Solution 100 Mg Via	ΙΥ		S	Intravenous (not otherwise specified)	Frequency: Once			Gilead
	Remd	esivir Solution 100 Mg Via	ΙΥ		S	Intravenous (not otherwise specified)				Gilead
	Bupro				С					Not Reported
		nexidine			С					Not Reported
	Citalo	pram			С					Not Reported



Dexamethasone C Not Repo Diphenhydramine C Not Repo Enoxaparin C Not Repo Furosemide C Not Repo Insulin, Regular C Not Repo Melatonin C Not Repo Mupirocin C Not Repo Nifedipine C Not Repo Quetiapine C Not Repo Tamsulosin C Not Repo Tamsulosin C Not Repo Zolpidem C Not Repo	orted
FDA Bossived Bets Coos # Coos Turns Health Bref Cutanana Mfr Control # F00B Fooility Are Court	
FDA Received Date	untry
27-Jul-2020 18085061 DIRECT Y OT 71 YR Male USA	Α
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr	
Bradycardia; Remdesivir S Not Repo Electrocardiogram Abnormal	orted
FDA Received Date	untry
28-Jul-2020 17931173 EXPEDITED (15-DAY) DE, OT US-GILEAD-2020- 67 YR Female USA 0474765	А
<u>Preferred Term</u> <u>Product</u> <u>Comp. OTC</u> <u>Role</u> <u>Route</u> <u>Dosage Text</u> <u>Duration</u> <u>Mfr</u>	
Acute Respiratory Distress Remdesivir S Intravenous (not 200 Mg otherwise specified) Gilead otherwise specified)	
Pulseless Electrical Activity; Respiratory Disorder Remdesivir S Intravenous (not 100 Mg, Qd otherwise specified) Gilead Otherwise specified)	
Azithromycin C Unk Not Repo	orted
Diltiazem C Unk Not Repo	orted
	orted
Enoxaparin C Subcutaneous 40 Mg Not Repo	
Enoxaparin C Subcutaneous 40 Mg Not Repo Lorazepam C Intravenous (not 1.5 Mg Not Repo otherwise specified)	
Lorazepam C Intravenous (not 1.5 Mg Not Repo	orted

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						otherwise specified)				
	Po	otassium Chloride			С		Unk			Not Reported
	Sc	odium Chloride 0.9%			С		Unk			Not Reported
	Ну	ydralazine			С	Intravenous (not otherwise specified)	10 Mg			Not Reported
	Mo	orphine			С	Intravenous (not otherwise specified)	4 Mg			Not Reported
	Ve	ecuronium			С		Unk			Not Reported
	Εp	oinephrine			С		Unk			Not Reported
	Ph	nenylephrine			С		Unk			Not Reported
	Pr	ropofol			С		Unk			Not Reported
	Sc	odium Bicarbonate			С		100 Meq			Not Reported
	Ce	efepime			С	Intravenous (not otherwise specified)	2 G			Not Reported
	Pa	antoprazole			С	Intravenous (not otherwise specified)	40 Mg			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date 28-Jul-2020	<u>Case #</u> 17933655		Health		itcomes , DS, OT	Mfr Control # US-GILEAD-202 0474767		Age 77 YR	<u>Sex</u> Male	<u>Country</u> USA
	17933655		Health Comp.		·	US-GILEAD-202 0474767				
28-Jul-2020	17933655	EXPEDITED (15-DAY)		DE	E, DS, OT	US-GILEAD-202 0474767	20-	77 YR		USA
28-Jul-2020 Preferred Term	17933655 <u>Pr</u> eath Re	EXPEDITED (15-DAY)		DE	E, DS, OT	US-GILEAD-202 0474767 Route Intravenous (not	Dosage Text	77 YR		USA Mfr
28-Jul-2020 Preferred Term	17933655 Pr eath Re	EXPEDITED (15-DAY) roduct emdesivir		DE	Role S	US-GILEAD-202 0474767 Route Intravenous (not otherwise specified) Intravenous (not	Dosage Text 200 Mg, Qd	77 YR		USA Mfr Gilead
28-Jul-2020 Preferred Term	17933655 Pr eath Re Re	EXPEDITED (15-DAY) roduct emdesivir emdesivir		DE	Role S	US-GILEAD-202 0474767 Route Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Dosage Text 200 Mg, Qd 100 Mg, Qd	77 YR		USA Mfr Gilead Gilead
28-Jul-2020 Preferred Term	17933655 Pr eath Re Er Du	EXPEDITED (15-DAY) roduct emdesivir emdesivir noxaparin		DE	Role S S C	US-GILEAD-202 0474767 Route Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Respiratory	200- Dosage Text 200 Mg, Qd 100 Mg, Qd 40 Mg	77 YR		USA Mfr Gilead Gilead Not Reported
28-Jul-2020 Preferred Term	17933655 Pr eath Re Er Du	EXPEDITED (15-DAY) roduct emdesivir emdesivir noxaparin uoneb antoprazole odium Chloride		DE	Role S C C C	US-GILEAD-202 0474767 Route Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Respiratory (inhalation)	Dosage Text 200 Mg, Qd 100 Mg, Qd 40 Mg 3 MI	77 YR		USA Mfr Gilead Gilead Not Reported Not Reported Not Reported Not Reported Not Reported
28-Jul-2020 Preferred Term	17933655 Pr eath Re Er Du	emdesivir emdesivir enoxaparin uoneb antoprazole		DE	Role S S C C C	US-GILEAD-202 0474767 Route Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Respiratory (inhalation)	Dosage Text 200 Mg, Qd 100 Mg, Qd 40 Mg 3 MI	77 YR		USA Mfr Gilead Gilead Not Reported Not Reported Not Reported



								•			
		Cefepime			С		venous (not rwise specified)	2 G			Not Reported
		Albuterol [Salbutamol]			С		piratory alation)	2 Puffs			Not Reported
		Insulin			С		venous (not rwise specified)	10 Units			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	179710	034 EXPEDITED (15-DAY)			DE, HO, LT	, OT	US-GILEAD-20 0477731	20-	54 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role Role	Ro	<u>ute</u>	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; H Rate Decreased; Hepa		Remdesivir			S		venous (not rwise specified)	200 Mg, Qd			Gilead
Enzyme Increased; Hypotension; Liver Disorder; Pulseless		Remdesivir			S		venous (not rwise specified)	100 Mg, Qd			Gilead
Electrical Activity; Ren Tubular Necrosis	al	Amiodarone			S		venous (not rwise specified)	0.5 Mg, Q1minute			Not Reported
		Ivermectin			С			Unk			Not Reported
		Tocilizumab			С			Unk			Not Reported
		Plasma Calcium Gluconate Ceftriaxone Clinimix E Norepinephrine Phenylephrine Propofol Sodium Bicarbonate Vasopressin Acetaminophen Albuterol Hfa Ascorbic Chlorhexidine			00000000000000						Not Reported
		Cholecalciferol Enoxaparin Epinephrine Etomidate Famotidine			00000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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	Meto Petro Ond Roca Kaye	arin ı-Medrol oprolol olatum/Mineral Oil lansetron uronium exalate : Sulfate			0000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	17992213	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0479521)20-		50 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 M	g, Qd			Gilead
	Azith	hromycin			С						Not Reported
		riaxone			C C						Not Reported
	Dexa	amethasone			С						Not Reported
	Eno	xaparin			0000						Not Reported
		lin Lispro			С						Not Reported
		nopril			С						Not Reported
		oprolol			С						Not Reported
		toprazole			C						Not Reported
	Van	comycin			С	Intravenous (not otherwise specified)					Not Reported
	Cisa	atracurium			С						Not Reported
	Sodi	ium Bicarbonate			C C C						Not Reported
	Epin	nephrine			С						Not Reported
		prostenol			С						Not Reported
		romorphone			С						Not Reported
		azolam			С						Not Reported
		epinephrine			C						Not Reported
		opressin			00000						Not Reported
		taminophen			C						Not Reported
		iterol [Salbutamol]			С						Not Reported
		azolam			С						Not Reported
	Benz	zonatate			С						Not Reported



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18014563	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0482006)20-	61 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase Increased; Cardiac Ari	Insulir Cefep Rocep Dexar Loven Metop Furos	ox [Acetazolamide] on Human ime ohine methasone ox [Enoxaparin Sodium] orolol emide			8 00000000	Intravenous (not otherwise specified)	100 Mg, Qd		No No No No No No	t Reported
FDA Received Date		zolamide	Lloolth	Drof	C Outcomes	Mfr Control	# FOOD Facility	Ago		t Reported
		Case Type DIRECT	<u>neaith</u> Y		Outcomes	WIII CONTROL	503B Facility	Age	<u>Sex</u>	Country
28-Jul-2020	18078490	DIRECT	Y		OI			87 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>Mfr</u>	
Bradycardia	Remd	esivir	Υ		S	Intravenous (not otherwise specified)		5 DAY	No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18078499	DIRECT	Υ		ОТ			63 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Alanine Aminotransfer		esivir			S	Intravenous bolus	Other Frequency:Once;		Gil	ead
Increased; Cardiac Ari Liver Function Test Increased	rest; Remd	esivir			S	Intravenous bolus			Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18078998	EXPEDITED (15-DAY)			DS, OT	US-GILEAD-20 0485015	020-	51 YR	Male	USA

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Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Cetylpyridinium Chloride			С		Unk			Not Reported
		Chlorhexidine			С		Unk			Not Reported
		Cisatracurium			С		Unk			Not Reported
		Dexamethasone			С		Unk			Not Reported
		White Petrolatum			С		Unk			Not Reported
		Diltiazem			С		Unk			Not Reported
		Enoxaparin			С		Unk			Not Reported
		Famotidine			С		Unk			Not Reported
		Fentanyl			С		Unk			Not Reported
		Furosemide			С		Unk			Not Reported
		Heparin			С		Unk			Not Reported
		Insulin Lispro			С		Unk			Not Reported
		Multivitamin Iron			С		Unk			Not Reported
		Mupirocin			С		Unk			Not Reported
		Polyethylene Glycol 3350			С		Unk			Not Reported
		Sennosides			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180811	04 EXPEDITED (15-DAY)		D	E	IE-PFIZER INC 2020280589	-	43 YR	Male	IRL
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Orug Ineffective For Jnapproved Indication		Vancomycin Hcl			S	Intravenous (not otherwise specified)	Unk			Pfizer
abel Use; Product Use; Product Use; Inapproved Indication		Meropenem			S		1 G, 3x/Day			Pfizer
pp.o.ca maioanoi		Piperacillin & Tazobactam			S		4.5 G, 4x/Day			Not Reported

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		Co-Am	oxiclave			S	Intravenous (not otherwise specified)	1.2 G, 3x/Day			Not Reported
		Clarithr	omycin			S	. ,	500 Mg, 2x/Day			Not Reported
		Remde	sivir			S		Unk			Not Reported
		Salbuta	amol			С		Unk (Inhaler)			Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18081	722	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0486573	020-	86 YR	Male	USA
Preferred Term		Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Agitation; Alanine Aminotransferase		Remde	sivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Increased; Aspartate Aminotransferase		Acetam	inophen			С		Unk			Not Reported
Increased; Blood		Ascorb	ic Acid			С		Unk			Not Reported
Creatinine Increased; Death; Respiratory		Methylp	orednisolone			С		Unk			Not Reported
Disorder; Superinfection	on	Thiamir	n [Thiamine]			С		Unk			Not Reported
Bacterial		Enoxap	parin			С		Unk			Not Reported
		Famotio	dine			С		Unk			Not Reported
		Atorvas	statin			С		Unk			Not Reported
		Azithro	mycin			С		Unk			Not Reported
		Aspirin	[Acetylsalicylic Acid]			С		Unk			Not Reported
		Melator	nin			С		Unk			Not Reported
		Fluticas	sone			С		Unk			Not Reported
		Budesc	onide			С		Unk			Not Reported
		Vitamin	D [Colecalciferol]			С		Unk			Not Reported
		Zinc Su	ılfate			С		Unk			Not Reported
		Methim	azole			С		Unk			Not Reported
		Ceftriax	cone			С		Unk			Not Reported
		Vancon	nycin			С		Unk			Not Reported
		Acetylc	ysteine			С		Unk			Not Reported



	Omni	paque			С		Unk				Not Reported
	Plasm Oxyge				C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18082608	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0485063	2020-		70 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>!</u>	<u>Mfr</u>
Renal Impairment	Remd	esivir			S	Intravenous drip	200 Mg	g, Qd			Gilead
	Remd	esivir			S	Intravenous drip	100 Mg	g, Qd			Gilead
	Zosyn				С		Unk				Not Reported
	Solum	edrol			С		Unk				Not Reported
	Azithr	omycin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18082610	EXPEDITED (15-DAY)			CA, OT	US-GILEAD-2 0486085	2020-		31 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	!	<u>Mfr</u>
Endotracheal Intubation	•	esivir			S	Unknown	Unk				Gilead
Foetal Death; Maternal Exposure During	l Hepar	in			С		Unk				Not Reported
Pregnancy	Fenta	nyl			С		Unk				Not Reported
	Loven	ox [Levofloxacin]			С		Unk				Not Reported
	Ceftria	axone			С		Unk				Not Reported
	Nimbe	ex [Nimesulide]			С		Unk				Not Reported
	Dexar	nethasone			С		Unk				Not Reported
	Prece	dex			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18082674	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0485073	2020-		1 YR	Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	ОТС	Role	Route	Dosage	Text	<u>Duration</u>		<u>Mfr</u>

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Acute Kidney Injury; Alanine Aminotransfera		ndesivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
Increased; Aspartate Aminotransferase Increased	Rei	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
morodood	Roo	cephin [Ceftriaxone Sodium]			С		Unk				Not Reported
	Roo	cephin [Ceftriaxone Sodium]			С		Unk				Not Reported
	Zos	yn			С		Unk				Not Reported
	Azi	hromycin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18083224	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485103	20-		67 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		Mfr
Acute Kidney Injury	Rei	ndesivir			S	Intravenous (not otherwise specified)	200 Mg	, Once			Gilead
		ndesivir rvastatin			S C		Unk				Gilead Not Reported
	Azi	hromycin			С		Unk				Not Reported
	Cef	triaxone			С		Unk				Not Reported
	Noi	epinephrine			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Pitr	essin [Vasopressin]			С	Intravenous (not otherwise specified)	Unk				Not Reported
	Pro	pofol			С	,	Unk				Not Reported
	Fer	tanyl Citrate			С	Intravenous (not otherwise specified)	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18084069	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0485112	20-		39 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Transaminases Increa	sed Rei	ndesivir			S	Intravenous (not	100 Mg	, Qd			Gilead

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						otherwise specifi	ed)				
		zithromycin evofloxacin			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18084128	EXPEDITED (15-DAY)			ОТ	US-GILEAD 0486098)-2020-		49 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase R	emdesivir			S	Unknown	Unk				Gilead
Increased	No	orco			С		7 Dose	es			Not Reported
	Ad	cetaminophen			С		500 M	g, 2 Doses			Not Reported
	0:	xygen			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18084211	EXPEDITED (15-DAY)			HO, OT	US-GILEAD 0486110)-2020-		46 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Ro	emdesivir			S	Intravenous (not otherwise specific					Gilead
	Ad	cetaminophen			С		Unk				Not Reported
	Le	evophed			С		Unk				Not Reported
	To	ocilizumab			С		Unk				Not Reported
	PI	asma			С		Unk				Not Reported
	Az Ro	examethasone zithromycin ocephin xygen			C C C						Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18084673	EXPEDITED (15-DAY)			DE, OT	US-GILEAD 0486571)-2020-		81 YR	Female	USA
Preferred Term	P	roduct	Comp.	OTC	Role	Route	Dosage	Text	Duration		<u>Mfr</u>



Covid-19 Pneumonia; Subcutaneous Emphysema

Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)	Gilead
Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)	Gilead
Acetaminophen	С		Unk	Not Reported
Albuterol [Salbutamol]	С		Unk	Not Reported
Ascorbic Acid	С		Unk	Not Reported
Atorvastatin	С		Unk	Not Reported
Azithromycin	С		Unk	Not Reported
Cefazolin	С		Unk	Not Reported
Cefepime	С		Unk	Not Reported
Chlorhexidine	С		Unk	Not Reported
Cholecalciferol	С		Unk	Not Reported
Dexamethasone	С		Unk	Not Reported
Donepezil	С		Unk	Not Reported
Enoxaparin	С		Unk	Not Reported
Fentanyl	С		Unk	Not Reported
Furosemide	С		Unk	Not Reported
Guaifenesin	С		Unk	Not Reported
Hydrocodone/Acetaminophen	С		Unk	Not Reported
Insulin Aspart	С		Unk	Not Reported
Insulin, Regular	С		Unk	Not Reported
Losartan	С		Unk	Not Reported
Meclizine [Meclozine]	С		Unk	Not Reported
Melatonin	С		Unk	Not Reported
Methylprednisolone Sodium Succinate	С		Unk	Not Reported
Mupirocin	С		Unk	Not Reported
Norepinephrine	С		Unk	Not Reported
Ondansetron	С		Unk	Not Reported



							-			
	Prop	ofol			С		Unk			Not Reported
		na-S [Docusate um;Sennoside A+B]			С		Unk			Not Reported
		comycin			С		Unk			Not Reported
	Zinc	Sulfate			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085150	DIRECT	Υ	D	E			73 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspergillus Infection; Hepatic Failure; Renal Failure; Staphylococca Infection; Staphylococ Infection	l al	desivir			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085180	DIRECT	Υ	D	E			59 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rem	desivir			S	Intravenous (not otherwise specified)			Gilead
		amethasone caparin			C C	cancer and appearance	,			Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085188	DIRECT	Υ	C	т				Unkno	wn USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Cardio-Respiratory Art Hepatic Function Abnormal; Renal Impairment	rest; Rem	desivir			S					Not Reported



							- P			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085199	DIRECT	Υ	DI	E			54 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Condition Aggravated; Palliative Care	Remo	desivir			S				٨	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085208	DIRECT	Υ	DI	Ē			73 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Covid-19 Pneumonia; Respiratory Distress	Docus Lover Insuli Insuli Wiht I Lantu Ativar Losar Morpl Morpl Proto Senna Thian Prece	desivir sate 100 Mg Po Bid nox 70 Mg Iv Bid n Sliding Scale n Aspart 7 Units Sub Q Tid Meals s Subq 17 Units Nightly n 1 Mg Iv X1 tan 25 Mg Po Daily nine 1 Mg Iv X1 nine 4 Mg Iv X1 nix 20 Mg Iv Daily a 1 Tablet Nightly nine 100 Mg Iv Daily edex Titrated nine Pca			%0000 000000000					lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085231	DIRECT	Y					59 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer	ase Remo	desivir			S	Intravenous bolus			Ν	lot Reported
Increased; Aspartate Aminotransferase Increased	Cefep Dexa	oime methasone			C C					lot Reported lot Reported

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		nsetron omycin rin			C C C				1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085362	DIRECT	Υ	D	E			29 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Brain Injury; Cardiac Arrest; Haemodialysis; Hypotension; Mental Status Changes; Rena Failure; Respiratory Failure; Tachycardia		lesivir			S				I	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085373	DIRECT	Υ	Н	10			72 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Liver Function Test Increased	Remo Remo		Υ		S C	Intravenous drip	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085406	DIRECT	Υ	Н	IO, OT			42 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatinine Increased; Glomerular Filtration Rate Decreas		lesivir	Y		S				(Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085562	DIRECT	Υ	Н	Ю			69 YR	Unknowr	n USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	N	<u>lfr</u>



Acute Kidney Injury	Rem	desivir	Υ		S	Intravenous drip	Other Frequency:Once;			Gilead
	Rem	desivir			С		, , ,			Not Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020 1	8085591	DIRECT	Υ		ОТ			50 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferas	e Rem	desivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
Increased; Aspartate Aminotransferase	Rem	desivir			S	Intravenous bolus	• •			Gilead
Increased	Aspi Aton Bude Fluti Furo Guai Hydr Lora Losa Mela Zinc Iverr Thia Vand Asco Azith Cefe	vastatin esonide Neb casone Nasal semide ifenesin ralazine Inj rzepam artan atonin Sulfate mectin min comycin odipine orbic Acid Iv aromycin epime otidine			00000000000000000000					Not Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020 1	8085602	DIRECT	Υ		DE			56 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated;	Rem	desivir	Υ		S	Intravenous bolus				Gilead
Liver Disorder; Shock;	Cisa	tracurium			С					Not Reported

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							-			
Staphylococcal Sepsis		Norepinephrine Nafcillin Midazolam Drip Fentanyl Drip			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180856	61 DIRECT	Υ	C	T			63 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase	Remdesivir			S	Intravenous bolus				Gilead
Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Ra Decreased		Gabapentin 300mg Ti Insulin Glargine 35 Un Pantoprozole 40mg D	its Bid		C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180856	72 DIRECT	Υ	D	E, OT			60 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Glomerular Filtration Ra Decreased		Remdesivir Amiodarone Ivpb Azithromycin 500mg Q Enoxaparin 73mg Q12			S C C C	Intravenous bolus	Other Frequency:Once;			Gilead Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180856	83 DIRECT	Υ	Н	Ю			54 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Delirium		Remdesivir Dexamethasone	Υ		S C					Gilead Not Reported



							•			<u> </u>
FDA Received Date Ca	ise#	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020 18	085716	DIRECT	Υ	07	Γ			74 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; Ecchymosis; Infusion Site Bruising; Infusion Site Extravasation; Infusion Site Pain; Localised Oedema	Remde Ceftria		Y		S C	Intravenous drip				Gilead Not Reported
FDA Received Date Ca	ıse#	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020 18	085726	DIRECT	Υ	01	Г			58 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased	Remde Dexam Enoxaj	ethasone			S C C					Gilead Not Reported Not Reported
FDA Received Date Ca	ise#	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020 18	085736	DIRECT	Υ	DE	Ē			59 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acinetobacter	Remde	esivir	Υ		S	Intravenous bolus				Gilead
Bacteraemia; Device Related Thrombosis; General Physical Health Deterioration; Haemofiltration; Hypotension; Klebsiella Bacteraemia; Pulmonary Embolism; Shock; Therapy Interrupted; Transaminases Increased	Fentan Midazo Epopro Norepi Cisatra	ethasone yl Infusion olam Infusion ostenol Nebulization nephrine Infusion ocurium Infusion			00000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported



						•			
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020 18085	747 DIRECT	Υ					60 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Acute Kidney Injury; Transaminases Increased	Remdesivir	Y		S	Intravenous bolus				Gilead
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
28-Jul-2020 18085	776 DIRECT	Υ	DE	Ē			78 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Cardio-Respiratory	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Arrest; General Physical Health Deterioration; Hypotension;	Remdesivir	Y		S	Intravenous (not otherwise specified)				Gilead
Unresponsive To Stimuli	Ascobic Acid			С					Not Reported
	Cholesclciferol			С					Not Reported
	Dexamehasone			С					Not Reported
	Enoxaparin			С					Not Reported
	Humulin 70/30			C C					Not Reported
	Insulin Lispro Sliding Scale			C					Not Reported Not Reported
	Pantoprazole Zinc			C					Not Reported
	ZIIIC			<u> </u>					Not Reported
FDA Received Date Case		·	Prof Ou		Mfr Control #		<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020 18085	784 EXPEDITED (15-DA	AY)	DE	, OT	US-GILEAD-20 0486567	20-	77 YR	Female	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia; Death; Myasthenia Gravis	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)			Gilead
Crisis	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)			Gilead
				С					Not Reported

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						Detailed Ne	port			
	Alpra	azolam			С		Unk		N	lot Reported
	Dexa	amethasone			С		Unk		١	lot Reported
		medetomidine enhydramine			C C		Unk			lot Reported lot Reported
	Enox	kaparin			С		Unk		١	lot Reported
	Furo	semide			С		Unk		N	lot Reported
		ocortisone Sodium cinate			С		Unk		١	lot Reported
	Mupi	irocin			С		Unk		١	lot Reported
	Мусс	ophenolate			С		Unk		١	lot Reported
	Nore	pinephrine			С		Unk		١	lot Reported
	Vitar	nin D [Colecalciferol]			С		Unk		١	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085785	DIRECT	Υ	0	Т			45 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Eye Irritation; Eye Pair Infusion Related Reac	•	desivir			S	Intravenous (not otherwise specified)			C	Gilead
Infusion Site Erythema Infusion Site Swelling; Lacrimation Increased Rash Erythematous; Therapy Interrupted; Vision Blurred	Kem	desivir			С	,			١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085795	DIRECT	Υ	0	Т			57 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Bradycardia	Rem	desivir			S	Intravenous drip			١	lot Reported
	Dom	desivir			S	Intravenous drip				lot Reported
	Keiii	UCSIVII			-	IIIII avelluus uliu				



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	180858	d49 DIRECT	Υ	Н	0			69 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Pancreatitis		Remdesivir			S	Intravenous (not otherwise specified)		No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2020	180858	59 DIRECT	Υ	Н	0			49 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	Mf	<u>r</u>
Liver Function Test Increased		Remdesivir			S	Intravenous (not otherwise specified)		Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180858	76 DIRECT	Υ	D	Е			89 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	ŗ
Alanine Aminotransfera	ase	Remdesivir	Υ		S	Intravenous drip			Gi	lead
Increased; Aspartate Aminotransferase Increased; Blood Albur	min	Convalescent Plasma Dexamethasone 6 Mg Iv Once Daily	•		C C					ot Reported ot Reported
Decreased; Blood Bilir Increased; Blood Calci		Amiodarone Iv Drip			С					ot Reported
Decreased; Blood	iuiii	Amlodopine 5 Mg Po Bid	il.		C C					ot Reported
Creatinine Increased; Blood Glucose Increas	sed;	Aspirin 81 Mg Ec Po Once Da Atorvastatin 40 Mg Po Daily A Hs			C					ot Reported ot Reported
Blood Lactate		Cefepime 2 Gm Iv			С				No	ot Reported
Dehydrogenase Increased; Blood		Ceftoloazane/Tazobactam 0.7 Gm lv	5		С				No	ot Reported
Magnesium Increased Blood Phosphorus	,	Clopidogrel 75 Mg Po Once Daily			С				No	ot Reported
Increased; Blood Potassium Increased;		Enoxaparin 60 Mg Sq Q 12hr			С					ot Reported
Blood Sodium Decreas	sed:	Ezetimibe 10 Mg Po Daily			С					ot Reported
	- 1	Famotidine 20 Mg Po Daily			С				NO	ot Reported

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

C-Reactive Protein
Increased; Haemoglobin
Decreased;
Hyperphosphatasaemia;
Pneumonia Pseudomonal;
Procalcitonin Increased;
Protein Total Decreased;
Red Blood Cell Count
Decreased; Red Blood
Cell Sedimentation Rate
Increased; Refusal Of
Treatment By Relative;
Renal Impairment;
Somnolence; White Blood

Cell Count Increased

Meropenem Iv Renally Adjusted Metoprolol 25 Mg Po Q8hr Pravastatin 20 Mg Po Once Daily C C Not Reported Not Reported Not Reported

Cell Court Increased										
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085898	DIRECT	Υ	НС)			71 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Glomerular	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Filtration Rate Decreas	Aspini				С					Not Reported
	Atracu Chlork	ırıum nexidine			C C					Not Reported Not Reported
	Famo				C					Not Reported
	Fenta				C					Not Reported
	Insulir Midaz				C C					Not Reported Not Reported
		inephrine			C					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	18085938	DIRECT	Υ	ОТ				89 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
	Ampio	cillin/Sulbactam			С					Not Reported

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		Dexamethasone Famotidine Heparin 5000u			C C C						Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Control #	1	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180859	17 DIRECT	Y	[DE				63 YR	Male	USA
<u>Preferred Term</u>		Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Haemodialysis;		Remdesivir	Υ		S	Intravenous (not otherwise specified)					Gilead
Hypotension; Hypoxia; Metabolic Acidosis; Multiple Organ		Convalescent Plasma Dexamethasone 6 Mg Iv Once Daily			C C	,					Not Reported Not Reported
Dysfunction Syndrome Respiratory Failure	;	Ascorbic Acid 1000 Mg Po Q12h Aspirin 81 Mg Po Daily			C						Not Reported Not Reported
		Atorvastatin 80 Mg Po Hs Azithromycin 500 Iv X 1, Then 250 Mg Po Once Daily			C C						Not Reported Not Reported
		Cefepime 1 Gm Iv Q6hr Cholecalciferol 2, 0000 Units Po Daily			C C						Not Reported Not Reported
		Clopidogrel 75 Mg Po Once Daily			С						Not Reported
		Cyanocobalamin 1,000 Mcg Po Once Daily			С						Not Reported
		Enoxaparin 40 Mg Sq Q12hr Enoxaparin 100 Mg Sq Q12hr Famotidine 10 Mg Po Once			C C C						Not Reported Not Reported Not Reported
		Daily Famotidine 20 Mg Po Once Daily			С						Not Reported
		Meropenem 500 Mg Iv Renally Dosed			С						Not Reported
		Thiamine 100 Mg Po Once Daily Zinc Sulfate 220 Mg Po Daily			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2020	180866	78 DIRECT	Υ	ŀ	HO, RI				6 DAY	Female	e USA

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Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Electrocardiogram Qt	R	emdesivir Iv 0.4 Mg/Ml	Υ		S	Intravenous (not otherwise specified	i)				Gilead
Prolonged	D	exmedetomidine			С	•	,				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	17942222	2 EXPEDITED (15-DAY)		[DE, OT	US-GILEAD-2 0474770	2020-		78 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	Duration		<u>Mfr</u>
Blood Pressure Systoli Decreased; Condition	c R	emdesivir			S	Intravenous (not otherwise specified	100 M	g, Qd			Gilead
Aggravated; Death; Disseminated	А	torvastatin			С		Unk				Not Reported
Intravascular Coagulat	ion; A	spirin (E.C.) [Aspirin]			С		Unk				Not Reported
Hypothermia	С	efepime			С		Unk				Not Reported
	Е	noxaparin			С		Unk				Not Reported
	D	uoneb			С		Unk				Not Reported
	Р	antoprazole			С		Unk				Not Reported
	V	alacyclovir Hcl			С		Unk				Not Reported
	А	cetaminophen			С		Unk				Not Reported
	Р	ropofol			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18055651	EXPEDITED (15-DAY)		[DE, OT	US-GILEAD-2 0484380	2020-		97 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	R	emdesivir			S	Intravenous drip	200 M	g, Once			Gilead
Increased; Death	С	arboxymethylcellulose Sodium			С		Unk				Not Reported
	С	eftaroline			С		Unk				Not Reported
	Р	remarin			С	Vaginal	Unk				Not Reported
	Е	noxaparin			С	-	Unk				Not Reported



	Dex	amethasone			С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18082333	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486234	20-	70 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO	Role	Route	Dosage Text	Duration		Mfr
Covid-19 Pneumonia; General Physical Heal		ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Deterioration	Rer	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18082535	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486581	20-	74 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Death	Rer	ndesivir			S	Intravenous (not otherwise specified)	200 Mg, Once (Bolus Dose)			Gilead
	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd (Maintenance Dose)	е		Gilead
	Bup	ropion			С		Unk			Not Reported
	Chle	orhexidine			С		Unk			Not Reported
	Cita	llopram			С		Unk			Not Reported
	Dex	amethasone			С		Unk			Not Reported
	Dipl	henhydramine			С		Unk			Not Reported
	End	xaparin			С		Unk			Not Reported
	Fur	osemide			С		Unk			Not Reported
	Insu	ılin, Regular			С		Unk			Not Reported
	Mel	atonin			С		Unk			Not Reported
	Mur	pirocin			С		Unk			Not Reported
	Nife	edipine			С		Unk			Not Reported
	Que	etiapine			С		Unk			Not Reported

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					201404 . 10	P			
Та	msulosin			С		Unk			Not Reported
Zo	lpidem			С					Not Reported
Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
8085583	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486599	20-	67 YR	Male	USA
<u>Pr</u>	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
; Re	mdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Re	mdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
En	oxaparin			С		Unk			Not Reported
De	xamethasone			С		Unk			Not Reported
Pro	ppofol			С		Unk			Not Reported
Fe	ntanyl			С		Unk			Not Reported
Dil	tiazem			С		Unk			Not Reported
Ну	dralazine			С		Unk			Not Reported
La	betalol			С		Unk			Not Reported
Me	etoprolol			С		Unk			Not Reported
Pla	asma			С		Unk			Not Reported
Ox	ygen			С					Not Reported
Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
8085960	DIRECT	Υ		ОТ			80 YR	Male	USA
<u>Pr</u>	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
re	mdesivir	Υ		S	Intravenous drip	Other Frequency:200mg X 1,100mg Qd;			Gilead
n; Atr T De En	opine xamethasone oxaparin			0000					Not Reported Not Reported Not Reported Not Reported Not Reported
	Zo Zase # 8085583 Pr Re Re En De Pro Fe Dil Hy Lai Me Pla Ox Zase # 8085960 Pr Re d Atr De En Chi	Product Remdesivir Remdesivir Enoxaparin Dexamethasone Propofol Fentanyl Diltiazem Hydralazine Labetalol Metoprolol Plasma Oxygen Case # Case Type 8085960 DIRECT Product Remdesivir Remdesivir re d Atracurium n; Atroning	Zolpidem Case # Case Type Health 8085583 EXPEDITED (15-DAY) Product Comp. Remdesivir Remdesivir Enoxaparin Dexamethasone Propofol Fentanyl Diltiazem Hydralazine Labetalol Metoprolol Plasma Oxygen Case # Case Type Health 8085960 DIRECT Y Product Comp. Remdesivir Remdesivir Y Remdesivir Y Product Comp. Remdesivir Y	Zolpidem Case # Case Type Health Prof 8085583 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Remdesivir Enoxaparin Dexamethasone Propofol Fentanyl Diltiazem Hydralazine Labetalol Metoprolol Plasma Oxygen Case # Case Type Health Prof 8085960 DIRECT Y Product Comp. OTC Remdesivir Remdesivir Y re d Atracurium n; Atropine Dexamethasone Enoxaparin	Zolpidem Case Type Health Prof DE, OT	Tamsulosin C Zolpidem C Case # Case Type Health Prof Det, OT US-GILEAD-20 0486599 Product Comp. OTC Role Route Remdesivir S Intravenous (not otherwise specified) Remdesivir S Intravenous (not otherwise specified) Enoxaparin C Dexamethasone C Propofol C Fentanyl C Diltiazem C Hydralazine C Labetalol C Metoprolol C Plasma C Oxygen C Case # Case Type Health Prof Outcomes Mfr Control # 8085960 DIRECT Y OT Product Comp. OTC Role Route Remdesivir Y S Intravenous drip Remdesivir C Role Route Mfr Control # 10	Tamsulosin	Zolpidem	Tamsulosin Zolpidem C C Unk Zolpidem C C C Zase #

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						•			
Hydro	cortisone Sod Succ			С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
	,			С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
				С					Not Reported
									Not Reported
				C					Not Reported
				C					Not Reported
Vasor	oressin			С					Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18085980	DIRECT	Υ	0	Γ			27 YR	Female	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Remo	lesivir			S			5 DAY		Not Reported
							3 D/(1		•
Acten	lia .			C					Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18087217	DIRECT						79 YR	Female	USA
Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Remo	desivir			S			5 DAY		Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18087222	DIRECT	Υ	DE	≣			69 YR	Male	USA
Prod	uct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
	Insulin Insulin Insulin Insulin Insulin Insulin Insulin Melat Piper: Sodiu Vance Dopa Hydro Insulin Isopro Midaz Norep Propo Vasop Vasop Prod Remo Acten Case # 18087217 Prod Remo Case # 18087222	18085980 DIRECT Product Remdesivir Actemra Case # Case Type 18087217 DIRECT Product Remdesivir Case # Case Type 18087222 DIRECT	Insulin Glargine Insulin Lispro Insulin Nph Melatonin Piperacillin-Tazobactam Sodium Bicarbonate Vancomycin Dopamine Hydromorphone Insulin Regular Isoproterenol Midazolam Norepinephrine Propofol Vasopressin Case # Case Type Health 18085980 DIRECT Y Product Comp. Remdesivir Actemra Case # Case Type Health 18087217 DIRECT Product Comp. Remdesivir Actemra Case # Case Type Health 18087217 DIRECT Product Comp. Remdesivir Actemra Case # Case Type Health 18087217 DIRECT	Insulin Glargine Insulin Lispro Insulin Nph Melatonin Piperacillin-Tazobactam Sodium Bicarbonate Vancomycin Dopamine Hydromorphone Insulin Regular Isoproterenol Midazolam Norepinephrine Propofol Vasopressin Case # Case Type Health Prof Or Product Comp. OTC Remdesivir Actemra Case # Case Type Health Prof Or Remdesivir Actemra Case # Case Type Health Prof Or Remdesivir Actemra Case # Case Type Health Prof Or Remdesivir Product Comp. OTC Remdesivir Actemra Case # Case Type Health Prof Or Remdesivir Product Comp. OTC Remdesivir	Insulin Glargine C Insulin Lispro C Insulin Nph C C Melatonin C C Piperacillin-Tazobactam C C C Sodium Bicarbonate C C C C C C C C C	Insulin Glargine	Insulin Glargine	Insulin Clargine	Insulin Glargine C C C C C C C C C

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18087224	DIRECT		(TC			28 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Alanine Aminotransfer Increased	ase Remo	desivir			S				J	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18087255	DIRECT	Υ	(ОТ			76 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Hypotension; Renal Impairment	Furos Nore	desivir semide binephrine ylprednisolone			S C C C				<u> </u> 	Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18087258	DIRECT	Υ	(ТС			41 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Diarrhoea; Vomiting	Remo	desivir			S	Intravenous bolus		5 DAY		Gilead
	Dexa Enox Insuli Insuli Zinc S	rbic Acid methasone aparin n Aspart n Detemir Sulfate ine-Guaifenesin			000000				 	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18087261	DIRECT	Υ	I	DE			75 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>

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S Clostridium Difficile Colitis; Remdesivir Gilead Intravenous (not Hypotension; Pneumonia; otherwise specified) Respiratory Failure FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age **Sex** Country Υ USA 29-Jul-2020 18087267 DIRECT DE 41 YR Female **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text** Duration Mfr S Alanine Aminotransferase Hydroxychloroquine Not Reported Oral 5 DAY Increased: Aspartate Ns Fluid С Not Reported Aminotransferase С Albumin 25% Not Reported Increased: Blood Alkaline С Azithromycin Not Reported Phosphatase Increased С Not Reported Ceftriaxone С Potassium Chloride Ivpb Not Reported С Propofol Not Reported S Remdesivir Not Reported С Sodium Bicarbonate Large Not Reported Volume С Acetaminophen 500mg Tablet Not Reported С Ascorbic Acid Tablet Not Reported С Cholecalciferol 5000 Unit Tablet Not Reported С Dexamethasone 6mg Po Daily Not Reported С Docusate Not Reported С Enoxaparin 40mg Sq Q24h Not Reported Ċ Enoxaparin 60mg Sq Q12h Not Reported С Etomidate Iv Not Reported С Not Reported Furosemide 20mg lvp C Furosemide 40mg lvp Not Reported Insulin Aspart Not Reported С Ivermectin 12 Po X 1 Not Reported С Ondansetron Ivp Not Reported S Remdesivir Not Reported FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # **503B Facility** <u>Age</u> Sex Country US-GILEAD-2020-USA 29-Jul-2020 18087333 **EXPEDITED (15-DAY)** OT 47 YR Male 0486207 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr S **Blood Creatinine** Remdesivir Gilead Intravenous (not 200 Mg, Once

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Increased					otherwise specified)				<u>.</u>
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Rocephin [Ceftriaxone Sodium]			С		Unk			Not Reported
	Azithromycin			С		Unk			Not Reported
	Dexamethasone			С		Unk			Not Reported
	Sodium Phosphate			С		Unk			Not Reported
	Fentanyl Citrate			С		Unk			Not Reported
	Magnesium Sulfate			С		Unk			Not Reported
	Norepinephrine Bitartrate			С		Unk			Not Reported
	Pantoprazole			С		Unk			Not Reported
	Potassium Chloride			С		Unk			Not Reported
FDA Received Date Case	# Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020 1808	7532 EXPEDITED (15-DAY)		Н)	US-GILEAD-20 0486136	20-	52 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Pressure Increased	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Atracurium Insulin Glargine Chlorhexidine Gluconate Sennosides Docusate Albuterol Hfa Rocuronium B Brau Dexamethasone Sodium Phosphate			00000000					Not Reported
	Piperacillin Fentanyl			C C					Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Fa	acility Age	<u>Sex</u>	Country
29-Jul-2020	18087678	EXPEDITED (15-DAY)			CA, DE, OT	US-GILEAD-20 0486660	20-		Unkno	wn USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duratio</u>	<u>n</u>	<u>Mfr</u>
Congenital Anomaly;		desivir			S	Transplacental	Unk			Gilead
Foetal Exposure Durin Pregnancy	g Levo	phed			С	Transplacental	Unk			Not Reported
riognanoy	Нера	arin			С	Transplacental	Drip			Not Reported
	Fent	anyl			С	Transplacental	Unk			Not Reported
	Love	nox [Levofloxacin]			С	Transplacental	Unk			Not Reported
	Ceftr	iaxone			С	Transplacental	Unk			Not Reported
	Nimb	ex [Nimesulide]			С	Transplacental	Unk			Not Reported
	Dexa	amethasone			С	Transplacental	Unk			Not Reported
	Prec	edex			С	Transplacental	Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Fa	acility Age	<u>Sex</u>	Country
29-Jul-2020	18088069	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486162	20-	81 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duratio</u>	<u>n</u>	Mfr
Death; Dysphagia; General Physical Heal		desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Deterioration	Rem	desivir			S	Unknown	200 Mg, Once			Gilead
	Dexa	amethasone			С	Intravenous (not otherwise specified)	5 Mg, Qd			Not Reported
	Carv	edilol			С	Oral	3.125 Mg, Bid			Not Reported
	Valp	roate Sodium			С		500 Mg			Not Reported
	Tica	grelor			С	Oral	90 Mg Q12h			Not Reported
	Spiro	onolactone			С	Oral	25 Mg, Qd			Not Reported
	Entre	esto			С	Oral	24/26			Not Reported
	Pant	oprazole			С	Oral	40 Mg, Qd			Not Reported

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Furd				С	Oral	400 Mg, Bid			Not Reported
	osemide			С	Intravenous (not otherwise specified	40 Mg, Qd			Not Reported
Fluc	conazole			С	Oral	100 Mg, Qd			Not Reported
Eze	timibe			С	Oral	10 Mg, Qd			Not Reported
End	xaparin			С	Subcutaneous	80 Mg Q12hr			Not Reported
Ato	rvastatin			С	Oral	80 Mg			Not Reported
Asa				С	Oral	81 Mg, Once			Not Reported
Albu	uterol [Salbutamol]			С	Respiratory (inhalation)	Unk, Bid			Not Reported
Clin	imix E			С		Unk			Not Reported
Nos	;Carbohydrates			С		Unk			Not Reported
				С	Oral	Unk Unk, Qd			Not Reported
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18088776	EXPEDITED (15-DAY)		С	T	US-GILEAD-20 0486244	020-	57 YR	Female	USA
Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Ren	ndesivir			S	Unknown	200 Mg, Once			Gilead
Ren	ndesivir			S	Unknown	100 Unk			Gilead
Ren	ndesivir			S	Unknown	100 Unk			Gilead
Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18089307	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0486950	020-	60 YR	Female	USA
Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Ami Azit	odarone hromycin			S C C	Intravenous bolus	200 Mg, Once			Gilead Not Reported Not Reported Not Reported
1	Eze Enc Ator Asa Albu Clin Tpn Nos Nos Thia Case # 18088776 Pro Ren Ren Ren Ren Case # 18089307 Pro Se Ren Ami Azit	Ezetimibe Enoxaparin Atorvastatin Asa Albuterol [Salbutamol] Clinimix E Tpn [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos] Thiamine Case # Case Type 18088776 EXPEDITED (15-DAY) Product Remdesivir Remdesivir Remdesivir Remdesivir Case # Case Type 18089307 EXPEDITED (15-DAY)	Ezetimibe Enoxaparin Atorvastatin Asa Albuterol [Salbutamol] Clinimix E Tpn [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos] Thiamine Case # Case Type Health 18088776 EXPEDITED (15-DAY) Product Comp. Remdesivir Amiodarone Azithromycin	Ezetimibe Enoxaparin Atorvastatin Asa Albuterol [Salbutamol] Clinimix E Tpn [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos] Thiamine Case # Case Type Health Prof O Product Comp. OTC Remdesivir Amiodarone Azithromycin	Ezetimibe C Enoxaparin C Atorvastatin C Asa C Albuterol [Salbutamol] C Clinimix E Tpn [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos] Thiamine C C Case # Case Type Health Prof Outcomes 18088776 EXPEDITED (15-DAY) OTC Remdesivir S Case # Case Type Health Prof Outcomes 18089307 EXPEDITED (15-DAY) DE, OT Product Remdesivir S Remdesivir S Remdesivir	Ezetimibe Enoxaparin Atorvastatin C C Coral Asa C Coral Albuterol [Salbutamol] Clinimix E Ciny [Amino Acids Nos;Carbohydrates Nos;Minerals Nos;Vitamins Nos] Thiamine C Case # Case Type Health Prof Comp. Ezetimibe	Ezetimibe	Ezetimibe	

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Covid-19; Glomerular Filtration Rate Decreased

Filtration Rate Decreas											
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2020	18089362	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0486238	20-		64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage '	<u>Text</u>	Duration		<u>Mfr</u>
Respiratory Failure; Sa Cov-2 Test Positive	ars- Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
		desivir romycin			S C		Unk				Gilead Not Reported
	Roce	phin			С		Unk				Not Reported
	Dexa	methasone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18089399	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0486606	20-		61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage '	<u>Text</u>	Duration		<u>Mfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified)	Unk				Gilead
	Meto Fuma	orolol [Metoprolol orate]			С						Not Reported
	Hepa Doxa Dexa	rin zosin zosin methasone			C C						Not Reported Not Reported Not Reported
	Clopi Aspir	dogrel in 81			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18089522	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0486614	20-		20 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase Remo	desivir			S	Intravenous bolus	100 Mg	, Qd			Gilead



						Dotanoa No	POIL				
Aminotransferase	Trazo				С		Unk				Not Reported
ncreased	Dexar	methasone			С		Unk				Not Reported
	Acetai	minophen			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18089790	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0486578)20-		91 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Dexar	methasone			С		Unk				Not Reported
	Loven	ox			С		Unk				Not Reported
	Glime	piride			С		Unk				Not Reported
	Irbesa	ırtan			С		Unk				Not Reported
	lverme	ectin			С		Unk				Not Reported
	Azithro	omycin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090945	DIRECT	Υ						27 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Diarrhoea; Nausea;	Remd	esivir			S	Intravenous drip	Other F	Frequency:Once;			Not Reported
Tachycardia; Vomiting	Acetal Acetal Aspirir Azithre Ceftria Enoxa Risaqe Methy Monte Zofrar	al Saline Infusion minophen 1000mg Tab minophen 650mg Tab n 81mg Chewable Tab omycin 500mg Tab axone 1g In 100ml Ns aparin 40mg Syringe uad Capsule diprednisolone 40mg Iv elukast 10mg Tab n 4mg Inj sium Chloride Cr 40meg			000000000000						Not Reported

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	Zir	nc Sulfate			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090946	DIRECT	Υ	[DΕ			58 YR	Male	USA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Re	mdesivir			S		Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
29-Jul-2020	18090948	DIRECT	Υ	[DΕ			65 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest	Re	mdesivir			S	Intravenous drip				Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
29-Jul-2020	18090949	DIRECT	Υ	ŀ	Ю			73 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Nephropath Toxic		emdesivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090950	DIRECT	Υ	H	HO, OT			63 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Condit Aggravated; Renal Inju	ıry;	mdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Transaminases Increa	Ce De Dip	etaminophen fepime xamethasone phenhydramine etronidazole			0000	,				Not Reported Not Reported Not Reported Not Reported Not Reported

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						Detailed Re	sport			
	Olanza Tocilizu Vancor Sennos	umab nycin			C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date C	ase #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020 18	8090951	DIRECT	Υ					22 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase	e Remde	esivir			S	Intravenous drip				Not Reported
Increased; Aspartate Aminotransferase	Nc	mycin 500mg In 250mg			С	•				Not Reported
Increased; Liver Function Test Increased	iodixari	nol 320mg/Ml 100ml			С					Not Reported
Tool moroadea		ninophen 650mg Tab			C C					Not Reported
		81mg Tab natate Capsule 100mg			C					Not Reported Not Reported
	Tums 5				C C C					Not Reported
	Ceftria	xone 2g In Ns 100ml			С					Not Reported
		ex Dm 30/600mg			C					Not Reported
		cline 100mg In 100ml Ns			С					Not Reported
		parin 40mg Syrnge nesin-Codeine 100- 5ml			C C					Not Reported Not Reported
	Maravi	roc 300mg			С					Not Reported
		prednisolone 125mg			С					Not Reported
		sone 40mg Tab			С					Not Reported
		l Saline 500ml n C 500mg			C C					Not Reported Not Reported
		alciferol 25mcg			Č					Not Reported
		ulfate Cap 220mg			С					Not Reported
FDA Received Date C	ase #	Case Type	Health	Prof Ou	itcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020 18	8090952	DIRECT	Υ	LT				77 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Unevaluable Event	Remde	esivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Remde	esivir			S	Intravenous drip	23. 1. 10quo			Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090953	DIRECT	Υ						80 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased	rase Remo	lesivir			S	Intravenous (not otherwise specified))				Gilead
		lesivir 200 Mg Iesivir 100 Mg			C C						Not Reported Not Reported
	Albute	0			С						Not Reported
	Apixa	ban			С						Not Reported
		bic Acid			С						Not Reported
		astatin			С						Not Reported
		sonide			С						Not Reported
		calciferol			С						Not Reported
		methasone			С						Not Reported
		loxacin			С						Not Reported
		hyroxine			С						Not Reported
	Mema				С						Not Reported
	Metop				C C						Not Reported Not Reported
	Zinc	prazole			C						Not Reported
											•
FDA Received Date	Case #	Case Type	<u>Health</u>		utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090954	DIRECT	Υ	H	O, LT, OT				42 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		Mfr
Hepatic Enzyme	Remo	lesivir			S	Intravenous bolus					Not Reported
Increased	Remo	lesivir			S	Intravenous (not otherwise specified))				Not Reported
	Rocu	ronium			С						Not Reported
	Propo	ofol			С						Not Reported
	Potas	sium Phosphate			С						Not Reported
	Mirala	ax			С						Not Reported
		pinephrine			С						Not Reported
	Morpl	nine			C C						Not Reported
		etanide									Not Reported



	Doxy Enox	methasone cycline aparin utidine			C C C				N N	lot Reported lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090955	DIRECT	Υ					61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Infusion Site Extravasa	ation Remo	desivir			S				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090956	DIRECT	Υ	0	Т			68 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified))		G	ilead
	Dexa	methasone			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18090957	DIRECT	Υ	DI	E			91 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified))		G	Bilead
	Dexa	methasone			С				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2020	18093125	DIRECT	Υ	DI	E			80 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
General Physical Heal Deterioration; Therapy Interrupted; Vascular		desivir 100mg	Υ		S	Intravenous (not otherwise specified))		G	ilead

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Access Complication		Remdesivir 100mg	Y		S	Intravenous (not otherwise specified)				Gilead
FDA Received Date	Case #	Case Type	<u>Healt</u>	h Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	179591	15 EXPEDITED (15-D	AY)		HO, OT	US-GILEAD-20 0474419	20-	28 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Diarrhoea; Leukocytos		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Transaminases Increa	ised	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Tocilizumab			С	Intravenous (not otherwise specified)	400 Mg			Not Reported
		Plasma			С		291 MI			Not Reported
		Acetaminofen			С	Oral	975 Mg			Not Reported
		Acetaminofen			С	Oral	650 Unk			Not Reported
		Acetaminofen			С	Intravenous (not otherwise specified)	1000 Unk			Not Reported
		Simethicone			С	Oral	15 MI			Not Reported
		Albuterol [Salbutamol]			С	Respiratory (inhalation)	180 Mcg			Not Reported
		Albuterol [Salbutamol]			С		2.5 Mg			Not Reported
		Azithromycin			С	Intravenous (not otherwise specified)	500 Mg			Not Reported
		Budesonide			С		0.25 Mg			Not Reported
		Budesonide Captopril			C C	Oral	6.25 Mg			Not Reported Not Reported
		Captopril			С	Oral	12.5 Unk			Not Reported
		Ceftriaxone			С	Intravenous (not otherwise specified)	1 G			Not Reported
		Enoxaparin			С	Subcutaneous	40 Mg			Not Reported
		Fentanyl			С	Intravenous (not	Unk			Not Reported

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·											
						otherwise specified)					
	Furd	osemide			С	Intravenous (not otherwise specified)	40 Mg				Not Reported
	Furd	osemide			С	Intravenous (not otherwise specified)	20 Unk				Not Reported
	Furd	osemide			С	Intravenous (not otherwise specified)	40 Unk				Not Reported
	Mela	atonin			С	Oral	6 Mg				Not Reported
	Mor	phine			С	Intravenous (not otherwise specified)	2 Mg				Not Reported
	Ond	lasetron [Ondansetron]			С	Intravenous (not otherwise specified)	Unk				Not Reported
		lasetron [Ondansetron] umococcal Vaccine			C C	Intramuscular	0.5 MI				Not Reported Not Reported
	Pota	assium Chloride			С	Oral	40 Meg				Not Reported
	Pota	assium Chloride			С	Oral	20 Unk				Not Reported
	Pota	assium Chloride			С	Oral	40 Unk				Not Reported
	Sod	ium Chloride			С	Intravenous (not otherwise specified)	3 MI				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u># 50</u>	03B Facility	Age	<u>Sex</u>	Country
30-Jul-2020	17970934	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0477763)20-		85 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO	Role	<u>Route</u>	Dosage Te	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, 0	Qd			Gilead
	Azit	hromycin			С	. ,					Not Reported
		riaxone			C C						Not Reported
		amethasone			С						Not Reported
		notidine arin Axicur			C C						Not Reported Not Reported
	nep Insu				C						Not Reported
		epime			Č						Not Reported
		medetomidine			С						Not Reported
	Doc	usate			С						Not Reported

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						Dotalloa IX	opo. .				
	Methylp Midazo Norepir	norphone orednisolone lam nephrine side [Sennoside A+B] ate nycin			0000000					N N N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	17979287	EXPEDITED (15-DAY)		0	т	US-GILEAD-2 0478145	020-		34 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration	<u>Mf</u>	<u>r</u>
Alanine Aminotransfer Increased; Product Preparation Error	ase Remde	sivir			S	Intravenous drip	200 M	g/M2, Qd		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18021692	EXPEDITED (15-DAY)		0	т	US-GILEAD-2 0482369	020-		35 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	Duration	<u>Mf</u>	<u>r</u>
Hepatic Enzyme Increased; Transamina	Remde ases	sivir			S	Intravenous (not otherwise specified	Unk			G	ilead
Increased	Ceftriax Azithro Lisinop Gabapo Enoxap Dexam Doxepi	mycin ril entin parin ethasone			0000000					N N N N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18091971	DIRECT	Υ	0	Т				71 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	<u>Role</u>	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>

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Dizziness	Remd	esivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Not Reported
	Metop				C C C C	,				Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020 1	8092382	DIRECT	Υ					38 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Adverse Drug Reaction; Alanine Aminotransferas Increased; Aspartate Aminotransferase Increased; Transaminaso Increased		esivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020 1	8092386	DIRECT	Υ	Н)			62 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Aspartate	Remde	a civir			S	latas es a ses data				Gilead
Aminotransferase	rtoma	281711				Intravenous drip				
ncreased; Blood Bilirubi ncreased	Acetar N Apixak Cistatr Dexan Fentar Gabap Midazo	minophen pan acurium nethasone nyl pentin plam inephrine			000000000	intravenous drip				Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18092389	DIRECT	Υ		DE			69 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Cardiac Arrest; Hypoxi	ia Remo	esivir			S	Intravenous (not otherwise specified)			1	Not Reported
	Metop Aceta Dexar Ketoro Loraz Morph Enoxa Docus Famo Omep Senna	emide prolol minophen methasone plac epma nine aparin sate tidine prazole a methasone			00000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18093860	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486676	20-	73 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Covid-19 Pneumonia;	Remo	esivir			S	Unknown	100 Mg, Qd		(Gilead
Respiratory Distress	Docus	sate			С	Oral	100 Mg, Bid		ı	Not Reported
	Lover	ox [Enoxaparin Sodium]			С	Intravenous (not otherwise specified)	70 Mg, Bid		1	Not Reported
	Insulir	١			С		Sliding Scale		1	Not Reported
	Insulir	n Aspart			С	Subcutaneous	7 lu, Tid With Meals		ı	Not Reported
	Lantu	S			С	Subcutaneous	17 lu, Qhs		ı	Not Reported
	Ativar				С	Intravenous (not	1 Mg			Not Reported

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					otherwise specified)				
Los	sartan			С	Oral	25 Mg, Qd			Not Reported
Мо	rphine			С	Intravenous (not otherwise specified)	1 Mg			Not Reported
Мо	rphine			С	Intravenous (not otherwise specified)	4 Mg			Not Reported
Мо	rphine			С	Intravenous (not otherwise specified)	Pca			Not Reported
				С	Intravenous (not otherwise specified)	20 Mg, Qd			Not Reported
Sei	nna Acutifolia			С	Oral	1 Tablet, Qhs			Not Reported
Thi	amine			С	Intravenous (not otherwise specified)	100 Mg, Qd			Not Reported
Pre	ecedex			С		Titrated			Not Reported
Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18094971	EXPEDITED (15-DAY)			ОТ	US-GILEAD-202 0477762	20-	58 YR	Female	USA
Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Re	mdesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
Re	mdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Ato De End Lisi Ace	orvastatin xamethasone oxaparin inopril etaminophen			C C C					Not Reported
	Mo Mo Mo Mo Mo Pro See See Thi Pre 18094971 Pro Re Re Re Asp Ato De: End Lisi Ace	Product Remdesivir Remdesivir Aspirin [Acetylsalicylic Acid] Atorvastatin Dexamethasone Enoxaparin Lisinopril Acetaminophen	Morphine Morphine Morphine Protonix [Pantoprazole Sodium Sesquihydrate] Senna Acutifolia Thiamine Precedex Case # Case Type Health 18094971 EXPEDITED (15-DAY) Product Comp. Remdesivir Remdesivir Aspirin [Acetylsalicylic Acid] Atorvastatin Dexamethasone Enoxaparin Lisinopril	Morphine Morphine Morphine Morphine Protonix [Pantoprazole Sodium Sesquihydrate] Senna Acutifolia Thiamine Precedex Case # Case Type Health Prof 18094971 EXPEDITED (15-DAY) Product Comp. OTC Remdesivir Remdesivir Aspirin [Acetylsalicylic Acid] Atorvastatin Dexamethasone Enoxaparin Lisinopril Acetaminophen	Morphine C Morphine C Morphine C Morphine C Protonix [Pantoprazole Sodium Sesquihydrate] C Senna Acutifolia C Thiamine C Precedex C Case # Case Type Health Prof Outcomes 18094971 EXPEDITED (15-DAY) OT Product Comp. OT Role Remdesivir S Remdesivir S Aspirin [Acetylsalicylic Acid] C Atorvastatin C Dexamethasone C Enoxaparin C Lisinopril C CC	Losartan C Oral Morphine C Intravenous (not otherwise specified) Protonix [Pantoprazole Sodium Sesquihydrate] C Intravenous (not otherwise specified) Senna Acutifolia C Oral Thiamine C Intravenous (not otherwise specified) Precedex C C Case # Case Type Health Prof Outcomes Mfr Control # 18094971 EXPEDITED (15-DAY) OT US-GILEAD-20: 0477762 Product Comp. OTC Role Route Remdesivir S Intravenous (not otherwise specified) Remdesivir S Intravenous (not otherwise specified) Aspirin [Acetylsalicylic Acid] C Atorvastatin C C Dexamethasone C E Enoxaparin C C C C C	Losartan	Losartan	Losartan



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18095728	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486976	020-		63 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Remde	esivir			S	Intravenous (not otherwise specified	100 Mg)	g, Qd		C	Bilead
	Ascort Aspirir Atorva Azithro Cefepi Choleo Clopid	nethasone pic Acid n (E.C.) statin pmycin me calciferol ogrel cobalamin parin idine enem			00000000000000						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096015	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0487389	020-		80 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	Duration	<u>M</u>	<u>fr</u>
Death	Remde	esivir			S	Intravenous (not otherwise specified		g, Once		C	Gilead
	Remde	esivir			S	Intravenous (not otherwise specified	100 Mg)	g, Qd		C	Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096598	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486979	020-		89 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	Text	Duration	<u>M</u>	fr

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Death; Hypoxia; Pneumonia Pseudomo	onal;	Remdesivir			S	Intravenous (not otherwise specified)	Unk			Gilead
Renal Impairment		Plasma			С	,				Not Reported
		Dexamethasone			č					Not Reported
		Amiodarone			Č					Not Reported
		Amlodipine			C C					Not Reported
		Aspirin (E.C.)			C					Not Reported
		Atorvastatin			С					Not Reported
		Cefepime			C C					Not Reported
		Ceftolozane			С					Not Reported
		Tazobactam			С					Not Reported
		Clopidogrel			C C					Not Reported
		Enoxaparin			С					Not Reported
		Ezetimibe			С					Not Reported
		Famotidine			C					Not Reported
		Meropenem			C					Not Reported
		Metoprolol			C					Not Reported
		Pravastatin			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	180968	71 DIRECT	Υ		DE, DS, HC OT), LT,		38 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Brain Herniation; Brain	1	Remdesivir			S	Intravenous bolus				Not Reported
Injury; Brain Oedema; Cardiac Arrest		Remdesivir			S	Intravenous bolus				Not Reported
		Convalescent Plasma			C					Not Reported
		Tocilizumab Decadron			C C					Not Reported Not Reported
FDA Received Date	Case #		Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
										 _
30-Jul-2020	180968	80 DIRECT	Υ		DE			63 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Hypoxi Respiratory Acidosis	ia;	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
		Convalescent Plasma Dexamethasone 6 Mg Iv Once			C C	. ,				Not Reported Not Reported



						Dotanoa No	Port			
	Daily Asco	rbic Acid 1000 Mg Po Once			С				N	ot Reported
	Daily				С					ot Reported
		romycin 500 Mg Iv Once			С					ot Reported
	Enox	aparin 70 Mg Sq Q12hrs otidine 20 Mg Iv Q12hr			C C					ot Reported ot Reported
	Insuli	n Glargine 10 Units Sq At			C					ot Reported
		n Glargine 15 Units Sq Bid			С					ot Reported
		Tmp Iv Q6hr Sulfate 220 Mg Po Once			C C					ot Reported ot Reported
	Daily									
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096891	DIRECT	Υ		ОТ			71 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Nausea	Remo	desivir			S	Intravenous (not otherwise specified)			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096906	DIRECT	Υ		DE			63 YR	Female	USA
Preferred Term	Prod	l <u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Covid-19; Disease Complication	Remo	desivir			S	Intravenous bolus			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096915	DIRECT	Y		DE			96 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Condition Aggravated	Remo	desivir			S	Intravenous (not otherwise specified)			G	ilead
	Ceftr	iaxone			С	-1			N	ot Reported

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	Flagy Albute Lover	erol			C C C				N	lot Reported lot Reported lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096967	DIRECT	Υ					81 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Dyspnoea; Flushing; Oxygen Saturation	Veklu	ry (Remdesivir)	Υ		S	Intravenous (not otherwise specified)	1	5 DAY	C	Silead
Decreased	Albute	erol/lpratropium			С	,			N	lot Reported
	Resta				С					lot Reported
	Ibupro	ofen			С					lot Reported
		prazole			С					lot Reported
	Aspiri				С					lot Reported
		asone Propionate			C C C					lot Reported
	Mirala				C					lot Reported
		astatin			C					lot Reported
		methasone			С					lot Reported
	Labet	aparin			C C C					lot Reported lot Reported
		aloi Ilazine			C					lot Reported
		onatate			C					lot Reported
		enesin			Č					lot Reported
		minophen			Č					lot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18096997	DIRECT	Υ					59 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Inappropriate Schedul Product Administration		lesivir			S	Intravenous (not otherwise specified))		C	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country

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Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Blood Creatinine Increased; Creatinine	Remo	esivir			S	Intravenous (not otherwise specified	Other Frequency:Once;		Gi	lead
Renal Clearance Abnormal	Remo	esivir			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18097016	DIRECT	Υ					61 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	ŗ
Duplicate Therapy Erro Product Dispensing Er		esivir			S	Intravenous (not otherwise specified)		Gi	lead
Product Prescribing Er	Zinc S Azithr	methasone Sulfate omycin bic Acid aparin			C C C C		,		No No No	ot Reported ot Reported ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18097027	DIRECT	Υ	(ОТ			39 YR	Female	USA
<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	ŗ
Alanine Aminotransfera	ase Remo	esivir			S	Intravenous (not otherwise specified)		Gi	lead
		tidine rin emide penem			C C C C C				No No No	ot Reported of Reported of Reported of Reported of Reported of Reported of Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18097038	DIRECT	Υ	(ОТ			63 YR	Female	USA
<u>Preferred Term</u>	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	ŗ

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Alanine Aminotransferas Increased	e Remde	esivir			S	Intravenous (not otherwise specified)				Gilead
	Zinc St Ascorb Aspirin Rosuva Rocurc	ic Acid astatin nium nephrine			00000000					Not Reported
FDA Received Date C	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020 1	8097047	DIRECT	Υ		ОТ			34 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferas Increased	e Remde	esivir			S	Intravenous (not otherwise specified)				Gilead
FDA Received Date C	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020 1	8097065	DIRECT	Υ		ОТ			50 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia; Liver	Remde	esivir			S	Intravenous drip				Not Reported
Function Test Increased	Ceftan Ceftria: Dexam Enoxap Guaifei	ethasone parin nasin odone-Acetaminophen			0000000	·				Not Reported
FDA Received Date C	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020 1	8097076	DIRECT	Υ		ОТ			67 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



Bradycardia	Remo	lesivir			S	Intravenous drip		10 DAY	١	Not Reported
	Propo	ofol			С				١	Not Reported
	Fenta				С					Not Reported
	Panto	prazole			С					Not Reported
	Levot	hyroxine			С					Not Reported
		aparin			С					Not Reported
		methasone			С					Not Reported
		omycin			С					Not Reported
		axone			C					Not Reported
		ızimab			C					Not Reported
		acillin/Tazobactam			C					Not Reported
	Ipratro	opium			С				<u> </u>	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18097088	DIRECT	Y		ОТ			27 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Dystonia	Remo	lesivir			S				N	Not Reported
Dystoriia		pazine			C					Not Reported
	•							_		·
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18097098	DIRECT	Y					65 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Intercepted Product Preparation Error; Prod Preparation Issue	Remo duct	lesivir	Y		S	Intravenous drip			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18097531	DIRECT	Υ		HO, RI, OT			80 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
	_	lesivir 100mg Vial	Υ		S	Intravenous (not			(Gilead
Acute Kidney Injury; Therapy Interrupted	Remo	lesivii 100mg viai	·			otherwise specified)				

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						otherwise specified)				
		Ceftriaxone Dexamethasone			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	180978	22 EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486167	20-	67 YR	Female	e USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
		Amiodarone			С	Oral	200 Mg			Not Reported
		Dexamethasone			С	Intravenous (not otherwise specified)	6 Mg, Qd			Not Reported
		Enoxaparin			С	Subcutaneous	100 Mg			Not Reported
		Famotidine			С	Intravenous (not otherwise specified)	20 Mg, Bid			Not Reported
		Lantus			С	Subcutaneous	Up To 20 lu			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	180978	39 EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0486577	20-	82 YR	Female	e USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Bradycardia; Death; D Ineffective; Oxygen	_	Remdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Saturation Decreased		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg Q24h			Gilead
		Acetaminophen			С	Oral	1000 Mg, Q6h Prn			Not Reported
		Albuterol [Salbutamol]			С	Respiratory (inhalation)	2 Puffs, Q8h			Not Reported
		Alprazolam			С		0.25 Mg, Q6h Prn			Not Reported
		Amlodipine			С	Oral	5-10 Mg			Not Reported
		Ascorbic Acid			С	Oral	1000 Mg, Tid			Not Reported

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			•	
Atorvastatin	С	Oral	40 Mg, Qhs	Not Reported
Chlorhexidine	С	Oral	15 MI, Bid	Not Reported
Cholecalciferol	С	Oral	20000 Units	Not Reported
Clonidine	С	Oral	0.1-0.2 Mg	Not Reported
Dexamethasone	С	Intravenous (not otherwise specified)	6 Mg Q12-24hr	Not Reported
Diphenhydramine	С	Intravenous (not otherwise specified)	25 Mg Q6h Prn	Not Reported
Enoxaparin	С	Subcutaneous	30-90 Mg Q24h	Not Reported
Famotidine	С	Oral	20 Mg, Qd	Not Reported
Gabapentin	С	Oral	100 Mg, Tid	Not Reported
Hydralazine	С	Intravenous (not otherwise specified)	10 Mg Q 6 Hr Prn	Not Reported
Levofloxacin	С	Intravenous (not otherwise specified)	500 Mg Q 28 Hr	Not Reported
Lorazepam	С	Intravenous (not otherwise specified)	0.5 Mg Q4hr Prn	Not Reported
Mupirocin	С	Nasal	Unk, Bid	Not Reported
Ondansetron	С	Intravenous (not otherwise specified)	4 Mg Q 8 Hr Prn	Not Reported
Patiromer Sorbitex Calcium	С	Ophthalmic	8.4 G, Once	Not Reported
Sodium Bicarbonate	С	Oral	650-1300 Bid-Tid	Not Reported
Sodium Bicarbonate In Dextrose 5%	С	Intravenous (not otherwise specified)	Continuous	Not Reported
Sodium Bicarbonate In Dextrose 5%	С	Intravenous (not otherwise specified)	Unk Continuous	Not Reported
Sodium Polystyrene Sulfonate	С	Oral	15 G, Qd	Not Reported
Sucralfate	С	Oral	1 G, Q6h	Not Reported
Timolol Maleate 0.5%	С		1 Drop Both Eyes, Bid	Not Reported
Zinc Sulfate	С	Oral	220 Mg, Bid	Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2020	18098576	DIRECT	Υ		RI, OT				65 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	ото	Role	Rout	<u>e</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Platelet Count Decreas Therapy Cessation	sed; Re	emdesivir 100mg Injection	Υ		S		enous (not vise specified)				Gilead
	Re	emdesivir 100mg Injection	Υ		S	Intrave	enous (not wise specified)				Gilead
		ithromycin examethasone			C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	17818827	EXPEDITED (15-DAY)			DE, HO, LT		US-GILEAD-20 0468514	20-	52 YR	Female	uSA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role	Rout	<u>e</u>	Dosage Text	Duration		Mfr
Death; Respiratory	Re	emdesivir			S	Unkno	own	100 Mg			Gilead
Distress	Су	clobenzaprine			С			Unk			Not Reported
	As	pirin Ec			С			Unk			Not Reported
	Do	oxycycline			С			Unk			Not Reported
	Ру	ridostigmine			С			Unk			Not Reported
	Ato	orvastatin			С			Unk			Not Reported
	Ca	llcium Carbonate			С			Unk			Not Reported
	Zir	nc			С			Unk			Not Reported
	Or	ndansetron			С			Unk			Not Reported
	Dip	ohenhydramine			С			Unk			Not Reported
	An	niodarone			С			Unk			Not Reported
	Fa	motidine			С			Unk			Not Reported
		eftriaxone			С			Unk			Not Reported
		etaminophen			С			Unk			Not Reported
	Alb	outerol [Salbutamol]			С			Unk			Not Reported



							1			
		emide			С					Not Reported
		n Detemir			C					Not Reported
	Loraz				000000					Not Reported
	Metop				C					Not Reported
		sium Chloride			C					Not Reported
	Apixa				C					Not Reported
	Cefep				C					Not Reported
		hexidine			C					Not Reported
		edetomidine			C C C					Not Reported
	Fenta				C					Not Reported
	Hepai				C					Not Reported
		n Aspart			С					Not Reported
	Ketan				С					Not Reported
	Metro	nidazole			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	17856483	EXPEDITED (15-DAY)		DI	E, OT	US-GILEAD-20 0469863	20-	67 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Unk			Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	17881226	EXPEDITED (15-DAY)		0	Т	US-GILEAD-20 0470048	20-	69 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Melate	onin			С					Not Reported
	Levot	hyroxine			C C					Not Reported
	D	ofol.			С					Not Reported
	Propo	7101								
		pinephrine			C C					Not Reported



	Hydror Merop Prisma Linezo Famot Hepari Lisinop Diclofe Insulin	isol lid Idine n oril			000000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	17950432	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0475638	20-	78 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Death	Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg, Unk			Gilead
	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Unk			Gilead
	Dopan Fentar Hepari Insulin Metopi Norepi Vecuro	nyl n rolol nephrine			000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	17952475	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0475664	20-	42 YR	Female	e USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Foetal Heart Rate Increased; Maternal	Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
Exposure During Pregnancy	Remde	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18013909	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0481352	20-		Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg			Gilead
	Propo	ofol			S	Unknown				Not Reported
	Fenta Mida: Atrop	zolam			C C C					Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18021543	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0482491	20-	82 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Covid-19	Remo	desivir			S	Intravenous (not otherwise specified)	200/100mg, Qd			Gilead
	Dexa	methasone			С	Intravenous (not otherwise specified)	6 Mg			Not Reported
	Furos	semide			С	Intravenous (not otherwise specified)	20 Mg			Not Reported
	Panto	oprazole			С	Oral	40 Mg			Not Reported
	Valsa	artan			С	Oral	320 Mg			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18034091	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0483269	20-	21 YR	Femal	e USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Maternal	rase Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead

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Exposure During Pregnancy		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg	, Once			Gilead
		Acetaminophen			С	. ,	Unk				Not Reported
		Dexamethasone			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	180380	72 EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0470345	20-		85 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Decreased Appetite; Haemoglobin Decreas		Remdesivir			S	Intravenous (not otherwise specified)	200 Mg	ı, Qd			Gilead
Hypernatraemia; Mela Mental Status Change Ulcer Haemorrhage		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
ereer riaememage		Acetaminophen			С	Oral					Not Reported
		Amlodipine			С	Oral					Not Reported
		Diclofenac			С	Oral					Not Reported
		Finasteride			С	Oral					Not Reported
		Lisinopril			С	Oral					Not Reported
		Pantoprazole			С	Intravenous (not otherwise specified)					Not Reported
		Simvastatin			С	Oral					Not Reported
		Tamsulosin			С	Oral					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	180695	78 EXPEDITED (15-DAY)			DE, LT, OT	US-GILEAD-20 0485585	20-		50 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Acute Kidney Injury; A Respiratory Distress		Remdesivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
Syndrome; Death; Mu Organ Dysfunction Syndrome; Shock	ıltiple	Dexamethasone Vitamin C Asc Acid Zinc			C C C						Not Reported Not Reported Not Reported



						Dotanoa itt				
	Azithr	omycin			С					Not Reported
	Ceftria	axone			C C					Not Reported
		acurium			С					Not Reported
	Dexm	edetomidine			C C					Not Reported
		aparin			С					Not Reported
	Fenta				С					Not Reported
		pentin			C C					Not Reported
	Ketan	nine			С					Not Reported
		pinephrine			С					Not Reported
		prazole			С					Not Reported
	Propo				C C					Not Reported
		vastatin			С					Not Reported
		ecalciferol			С					Not Reported
	Aspiri	n [Acetylsalicylic Acid]			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18097139	DIRECT	Υ					67 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Remo	desivir			S	Intravenous (not				Gilead
						otherwise specified)			
	Mstt1	041a			С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18099278	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20	020-	63 YR	Male	USA
						0487565				
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	0487565 <u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
_	<u>Produ</u> Remd		Comp.	<u>OTC</u>	Role S		100 Mg, Qd			Mfr Gilead
_	Remo	desivir	Comp.	OTC	S	Route Intravenous (not	100 Mg, Qd			Gilead
_	Remo	desivir	Comp.	OTC	s C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported
_	Remo Plasm Dexar	desivir	Comp.	OTC	s C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported Not Reported
	Remo Plasm Dexar Ascor	desivir na methasone bic Acid	Comp.	OTC	S C C C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported Not Reported Not Reported
_	Remo Plasm Dexar Ascor Ceftria	desivir na methasone bic Acid axone	Comp.	OTC	S C C C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported Not Reported Not Reported Not Reported
_	Remo Plasm Dexar Ascor Ceftric Azithr	desivir na methasone bic Acid axone romycin	Comp.	OTC	S C C C C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
_	Remo Plasm Dexar Ascor Ceftria Azithr Enoxa	desivir na methasone bic Acid axone romycin aparin	Comp.	OTC	S C C C C C C C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported
Preferred Term Cardiac Arrest	Remo Plasm Dexar Ascor Ceftria Azithr Enoxa Famo	desivir na methasone bic Acid axone romycin aparin	Comp.	OTC	S C C C C	Route Intravenous (not	100 Mg, Qd			Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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		c Sulfate arbonate			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18099507	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0487050	020-	23 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>N</u>	<u>Mfr</u>
Liver Function Test	Rei	mdesivir			S	Intravenous bolus	200 Mg, Once		(Gilead
Increased	Azi	thromycin			С		250 Mg		ļ	Not Reported
	Far	notidine			С		20 Mg, Bid		ļ	Not Reported
	Cef	ftriaxone			С		1 G Q24h		1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18099542	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0487536	020-	63 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>N</u>	<u>//fr</u>
Alanine Aminotransfera	ase Rei	mdesivir			S	Intravenous (not otherwise specified	200 Mg, Once)		(Gilead
	Rei	mdesivir			S	Intravenous (not otherwise specified	100 Mg, Qd)		(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18099549	EXPEDITED (15-DAY)			ОТ	US-GILEAD-2 0487413	020-	61 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>N</u>	<u>//fr</u>
Acute Kidney Injury; B	lood Rei	mdesivir			S	Intravenous bolus	200 Mg, Once		(Gilead
Creatinine Increased; Glomerular Filtration R	eate Fer	ntyl			С		Unk		1	Not Reported
Decreased		repinephrine			С		Unk		I	Not Reported
	Pro	pofol			С		Unk		I	Not Reported
	Ro	curonium			С		Unk		[Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100023	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0487474)20-	63 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate	ase Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Aminotransferase Increased; Blood Creatinine Increased;	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Covid-19; Glomerular		n Glargine			С		35 lu, Bid			Not Reported
Filtration Rate Decreas	sed Panto	prazole			С		40 Mg, Qd			Not Reported
	Gaba	pentin			С		300 Mg, Tid			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100350	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0487983)20-	78 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Death	Remo	lesivir			S	Unknown	200 Mg, Qd			Gilead
	Remo	lesivir			S	Unknown	100 Mg, Qd			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100399	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0487417	020-	66 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test	Remo	lesivir			S	Intravenous bolus	200 Mg, Once			Gilead
Increased	Apixa	ban			С		5 Mg, Bid			Not Reported
	Bupro	ppion			С		50 Mg, Tid			Not Reported
	Dulox	etine			С		30 Mg, Qd			Not Reported
	Aripip	razole +Pharma			С		5 Mg, Bid			Not Reported
	Insuli	n Glargine			С		15 Units Hs			Not Reported
	Levot	hyroxine			С		100 Mcg Qd			Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100690	EXPEDITED (15-DAY)		H	HO, OT	US-GILEA 0487549	ND-2020-		89 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Lip Erythema; Lip Swe	elling Rem	desivir			S	Intravenous (no otherwise spec		Mg, Qd		C	Gilead
	Enox	kaparin			С	Subcutaneous	30 M	g		١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100843	EXPEDITED (15-DAY)		ŀ	Ю	US-GILE <i>l</i> 0487466	AD-2020-		73 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	Duration	<u>M</u>	<u>fr</u>
Blood Creatinine Increased	Rem	desivir			S	Intravenous (no otherwise spec		Mg, Once		C	Gilead
	Rem	desivir			S	Intravenous (no otherwise spec		Mg, Qd		C	Silead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100879	EXPEDITED (15-DAY)		[DE, OT	US-GILE <i>l</i> 0487538	AD-2020-		12 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Circulatory Collapse;		desivir			S	Unknown	200 N	Mg, Once		C	Silead
Death; Renal Impairme	ent Rem	desivir			S	Unknown	100 N	Иg, Qd			Silead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18100913	EXPEDITED (15-DAY)		[DE, OT	US-GILEA 0487393	ND-2020-		41 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death; Liver Function	Test Rem	desivir			S	Unknown	Unk			C	Gilead
Increased	Hydr	oxychloroquine			S	Oral	400 N	Иg, Bid		N	Not Reported

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	Albun	nin			С					Not Reported
		omycin			Č					Not Reported
	Ceftri				C C					Not Reported
		sium Chloride			С					Not Reported
	Propo				С					Not Reported
		m Bicarbonate			C C C					Not Reported
		minophen			С					Not Reported
		bic Acid								Not Reported
		calciferol			C C C					Not Reported
		methasone			C					Not Reported
	Docus									Not Reported
	Enoxa				C					Not Reported
	Etomi				C C C					Not Reported
		emide -			C					Not Reported
	Insulii Iverm				C					Not Reported Not Reported
		ectin nsetron			C					Not Reported
FDA Received Date		Case Type	Hoalth	Prof C	outcomes	Mfr Control #	503B Facility	Age	Sex	Country
						WIII COILLIOI #	SUSB Facility			_
31-Jul-2020	18102972	DIRECT	Υ	С	PΤ			55 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfe ncreased	rase Remo	lesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once Loading;			Gilead
					С					Not Reported
		zumab omvcin			C					
FDA Received Date	Azithr	zumab omycin <u>Case Type</u>	Health	Prof O	Outcomes	Mfr Control #	503B Facility	Age	Sex	Not Reported
	Azithr	omycin <u>Case Type</u>			C Outcomes	Mfr Control #	503B Facility	Age		Not Reported Country
	Azithr	omycin	<u>Health</u> Y		С	Mfr Control #	503B Facility	Age 68 YR	<u>Sex</u> Female	Not Reported Country
FDA Received Date 31-Jul-2020 Preferred Term	Azithr	Case Type DIRECT			C Outcomes	Mfr Control #	503B Facility Dosage Text		Female	Not Reported Country
31-Jul-2020	Azithr Case # 18102974 Prode	Case Type DIRECT uct	Y	C	C Outcomes OT		-	68 YR	Female	Not Reported Country USA
31-Jul-2020 Preferred Term White Blood Cell Cou	Azithr Case # 18102974 Produ Remo Ceflria	Case Type DIRECT uct	Y Comp.	<u>отс</u>	C Outcomes OT Role S		Dosage Text	68 YR	Female	Country USA Mfr Not Reported



Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test	Remo	lesivir	Υ		S	Intravenous bolus				Gilead
Increased	Dexar	methasone			С					Not Reported
	Bume	tanide			Č					Not Reported
	Hepai				Ċ					Not Reported
		enesin			Č					Not Reported
		zumab			Ċ					Not Reported
	Insulir				С					Not Reported
		acurium			С					Not Reported
	Dexm	edetomidine			Ċ					Not Reported
	Fenta	nyl			Ċ					Not Reported
	Propo				С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103017	DIRECT	Υ		DE			56 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Respiratory Failure	Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
	Aceta	minophen			С	other wide openined)				Not Reported
	Album				Č					Not Reported
		acurium			C					Not Reported
	Epopr	rostenol			C					Not Reported
	Fenta				Ċ					Not Reported
	Insulir				Ċ					Not Reported
		bacillus			C					Not Reported
	Midaz				C					Not Reported
		pinephrine			Č					Not Reported
		prazole			C C					Not Reported
		/lephrine			Ċ					Not Reported
		acillin/Tazobactam			C					Not Reported
	Propo				Ċ					Not Reported
		m Polystyrene Sulfonate			Ċ					Not Reported
		zumab			Ċ					Not Reported
		essin			Ċ					Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103026	DIRECT	Υ					69 YR	Female	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Rem	desivir			S	Intravenous drip	Other Frequency:X1, The 100 Mg Qd;	n		Gilead
	Solu	-Medrol			С		3 . ,			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103031	DIRECT	Υ	0	T			36 YR	Male	USA
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased	rase Rem	desivir			S	Intravenous (not otherwise specified))			Not Reported
	Acet	aminophen			С	·	,			Not Reported
		curium			С					Not Reported
		ephrine			С					Not Reported
		pime			С					Not Reported
		otidine			С					Not Reported
	Fent	,			С					Not Reported
	Hepa				С					Not Reported
		ocodone ocortisone			С					Not Reported Not Reported
	nyui Labe				C C					Not Reported
		ulin R			C					Not Reported
	Duor				C					Not Reported
		izolam			Č					Not Reported
		phed			Ċ					Not Reported
		ansetron			Č					Not Reported
		nethazine			Č					Not Reported
		pressin			Č					Not Reported
		uronium			Č					Not Reported
	Prop				Ċ					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103049	DIRECT	Υ	D	E			75 YR	Male	USA

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Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration]	<u>Mfr</u>
Death		Remdesivir	Υ		S	Intravenous drip	Other Frequency:Once;			Gilead
		Remdesivir	Υ		S	Intravenous drip				Gilead
		Ascorbic Acid Aspirin Dexamethasone Docusate Doxycycline Enoxparin Famotidine Gabapentin Insulin Glargine Insulin Lispro Ipratropium Metoprolol Multivitamin Ondansetron			00000000000000	intravenous drip				Not Reported
		Piperacillin/Tazobactam Zinc Sulfate			C C					Not Reported Not Reported
FDA Received Date		Case Type	Health	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	Sex	Country
31-Jul-2020	181030	51 DIRECT	Υ	0	T			73 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>]	<u>Mfr</u>
Hypoglycaemia; Hypothermia; Oxyger Saturation Decreased	า	Remdesivir Insulin Isophane/Reg 70/30			S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	181030	66 DIRECT	Υ	0	T			38 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>]	<u>Mfr</u>
Acute Respiratory Dis Syndrome; Critical Illr		Remdesivir			S	Intravenous (not otherwise specifie	d)			Gilead
Liver Function Test Increased; Respirator Failure		Acetaminophen Azithromycin			C C		-,			Not Reported Not Reported

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							<u> </u>			
	Ceftria	xone			С					Not Reported
		ne-Guifenesin			С					Not Reported
	Dexan	nethasone			С					Not Reported
	Dexme	edetomidine			C					Not Reported
	Enoxa				С					Not Reported
	Famot				C					Not Reported
	Fentar				C C C					Not Reported
	Furose	emide			С					Not Reported
	Linezo	lid								Not Reported
	Midazo				C					Not Reported
	Multivi	tamin With Iron			С					Not Reported
	Norepi	inephrine			С					Not Reported
	Perflut	en Lipid Microspheres			С					Not Reported
	Polyet	hylene Glycol (Glycolax)			С					Not Reported
	Potass	sium Chloride			C C C					Not Reported
	Propof	fol								Not Reported
	Rocur	onium			С					Not Reported
	Senno	sides			С					Not Reported
	Vanco	mycin			С					Not Reported
FDA Received Date Ca	se #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020 18 ⁻	103069	DIRECT	Υ	0	Т			74 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Glomerular	Remde	esivir			S	Intravenous (not otherwise specified)				Gilead
Filtration Rate Decreased;		vline			С	. ,				Not Reported
Hypotension; Urine Output		cortisone			C					Not Reported
Decreased		cillin/Tazobactam			C C					Not Reported
	Quetia				Č					Not Reported
	Midazo				Č					Not Reported
EDA Basaland Data Co			Haalda	D(0		Mfr. O - u tu - l #	FOOD Families	A	0	·
FDA Received Date Ca	<u>se #</u>	Case Type	Health	Prot O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020 18	103071	DIRECT	Υ	D	E			49 YR	Male	USA
Preferred Term	Produ	ı <u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Cardiac Arrest; Product Storage	Remde	esivir			S	Intravenous (not otherwise specified)				Not Reported

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Note: If the field is blank, there is no data.

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Error	Dexamethasone			С					Not Reported
	Doxazosin			С					Not Reported
	Furosemide			С					Not Reported
	Isosorbide Dinitrate			С					Not Reported
	Losartan			С					Not Reported
	Metoprolol			C C					Not Reported
	Aspirin			С					Not Reported
	Gabapentin			С					Not Reported
	Morphine			С					Not Reported
	Oxycodone-Acetaminophen			С					Not Reported
	Ropinirole			С					Not Reported
	Vecuronium			C C C					Not Reported
	Enoxaparin			C C					Not Reported
	Ticagrelor			С					Not Reported
	Famotidine			С					Not Reported
	Atorvastatin			С					Not Reported
	Insulin			С					Not Reported
	Amitriptyline			С					Not Reported
	Duloxetine			С					Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020 18103	3075 DIRECT	N	ОТ				53 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Alkaline	Remdesivir	Y		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Phosphatase Increased	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Temazepam			С					Not Reported
	Senna			C C					Not Reported
	Ondansetron			С					Not Reported
	Nystatin			С					Not Reported
	Dexamethosone			С					Not Reported
	Enoxaparin			С					Not Reported
	Robitussin			C					Not Reported
	Insulin			С					Not Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103076	DIRECT	N		ОТ			37 YR	Female	e USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Alkaline Phosphatase Increase	ed;	ndesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Transaminases Increa	sed Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)				Gilead
	Dila Tyle Norv Albu Zofr	nol ⁄asc terol			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103088	DIRECT	Υ		ОТ			80 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Bradycardia	Rem	ndesivir			S	Intravenous drip		5 DAY		Not Reported
	Ator Cita Clop Dex Eno	aminophen vastatin lopram pidogrel amethasone xaparin ansetron			000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103093	DIRECT	Υ					52 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Confusional State; Hallucination, Auditory		ndesivir			S	Intravenous bolus	Other Frequency:Once;			Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103095	DIRECT	Υ					49 YR	Male	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Product Administration Error; Product Dose Omission	n Rem	desivir			S	Intravenous bolus			1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>/ Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103097	DIRECT	Υ	(ОТ			53 YR	Male	USA
Preferred Term	Prod	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Inappropriate Schedule Product Administration		desivir	Υ		S	Intravenous (not otherwise specified)	5 DAY	(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	18103366	DIRECT	Υ					69 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Transaminases Increa	sed Vekl	ury (Remdesivir)			S	Intravenous (not otherwise specified)		(Gilead
	Asco Aspi Benz Bude Doxy Enox Enox Hepa Insu	terol Inhaler orbic Acid Iv rin Enteric Coated zonatate esonide Respule ycycline Iv kaparin kaparin arin Subq lin Regular lin Glargine			00000000000				1 1 1 1 1 1 1	Not Reported
	Levo Prop	othyroxine profol uronium			000				1	Not Reported Not Reported Not Reported Not Reported

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							1 -			
	F A C D F	Ropinirole Rosuvastatin Albuterol/Ipratropium Cefepime Dexmethasone Fentanyl Pca Pantoprazole Iv			000000				N N N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	1810389	7 DIRECT	N	[ÞΕ			15 YR	Female	USA
Preferred Term	<u>F</u>	Product	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Respiratory Dist Syndrome; Blood Creatinine Increased; Blood Urea Increased; Cardiac Arrest; Diseas Progression; Hyperca Oxygen Saturation Decreased; Pulseless Electrical Activity; Pyre Respiratory Failure; U Output Decreased	; se pnia; exia;	Remdesivir 100mg	Y		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			G	illead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2020	1810411	3 DIRECT	Υ	[ÞΕ			16 YR	Female	UMI
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Respiratory Dist Syndrome; Blood	tress F	Remdesivir 100mg	Υ		S	Intravenous (not otherwise specified)			N	lot Reported
Creatinine Increased; Blood Urea Increased; Cardiac Arrest; Condit Aggravated; Disease Progression; Drug Ineffective; Hypercaph Oxygen Saturation Decreased; Pulseless	; tion nia;	Silead Sclences			С	Intravenous (not otherwise specified)			٨	lot Reported



Electrical Activity; Pyrexia; Renal Impairment; Respiratory Failure; Urine Output Decreased

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18101474	EXPEDITED (15-DAY)			DE, OT	US-SUN PHARMACEUT INDUSTRIES L 2020R1-25517	TD-	70 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role Role	Route	Dosage Text	Duration		<u>Mfr</u>
Condition Aggravated;		omycin			S	Unknown	Unk			Sun
Death; Drug Ineffective; Heparin-Induced	; Hydro	xychloroquine			S	Unknown	Unk			Ipca
Thrombocytopenia;	Ceftria	axone			S	Unknown	Unk			Not Reported
Hypotension; Platelet Count Decreased:	Bivalir	udin			S	Unknown	0.15 Mg/Kg/H			Not Reported
Pulmonary Embolism;	Unfra	ctionated Heparin			S	Unknown	5000 Unit, Bid			Not Reported
Tachycardia	Unfra	ctionated Heparin			S		18 Units/Kg/H			Not Reported
	Tociliz	zumab			S	Unknown	Unk			Not Reported
	Cisatr	acurium			S	Unknown	Unk			Not Reported
	Remd	esivir			S	Unknown	Unk			Not Reported
	Vasop	pressin			S	Unknown	Unk			Not Reported
	Norep	inephrine			S	Unknown	Unk			Not Reported
	Nitric	Oxide			S		Unk			Not Reported
	Tened	teplase			S	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103103	DIRECT			DE			53 YR	Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Death	Remd	esivir			S					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103107	DIRECT		D	ÞΕ			76 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Rem	ndesivir			S				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103111	DIRECT	Υ	C	T			66 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Atrial Fibrillation	Rem	ndesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		١	Not Reported
	Toci	lizumab			S				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103116	DIRECT	Υ	C	T			25 YR	Male	USA
<u>Preferred Term</u>	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransfer Increased	ase Rem	ndesivir			S	Intravenous (not otherwise specified)			(Gilead
	Asca Azitl Dex Zinc Eno	tylcysteine orbic Acid Iv nromycin 500 Mg Iv amethasone 6 Mg Iv Sulfate 200 Mg Po Bid xaparin 1 Mg/Kg Subq Bid usate 100 Mg Po Bid			000000	,			1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2020	18103144	DIRECT	Υ					57 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Aspartate	Rem	ndesivir			S	Intravenous drip		5 DAY	(Silead

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					Dotalioa i	vopo. c				
Aminotransferase	Acetaminophen 650mg Tab			С						Not Reported
Increased; Disease	Albuterol-Ipratropium 2.5-			С						Not Reported
Complication	0.5mg/3ml Nebulizer Soln									•
·	Aspirin 81mg Chew Tab			С						Not Reported
	Azithromycin 500mg In Ns			С						Not Reported
	250ml									•
	Dexamethasone 10mg In 50ml			С						Not Reported
	Ns									•
	Dexmedotomidine 500mcg In			С						Not Reported
	100ml Ns									•
	Lovenox 100mg Syringe			С						Not Reported
	Lovenox 40mg Syringe			С						Not Reported
	Epoprostenol 1.5mg in 60ml Ns			С						Not Reported
	Inh Solution									•
	Famotidine 20mg Inj			С						Not Reported
	Furosemide 20mg Inj			С						Not Reported
	Ketamine 1000mg In 100ml Ns			С						Not Reported
	Oxycodone Ir 5mg Tab			C						Not Reported
	Lorazepam 2mg Tab			C						Not Reported
	Melatonin 3mg Tab			С						Not Reported
	Solu-Medrol 40mg			С						Not Reported
	Miconazole 2% With Zinc Oxide			С						Not Reported
	Cream									•
	Midazolam 2mg Inj			С						Not Reported
	Midodrine 10mg Tab			С						Not Reported
	Levophed In D5w			С						Not Reported
	Rocuronium 100mg			С						Not Reported
FDA Received Date Case	e # Case Type	Hoalth	Prof C	utcomes	Mfr Contro	N#	503B Facility	Age	Sex	Country
TDA Received Date Cast		Health	<u> </u>	<u>utcomes</u>	WIII COILLI	<u> </u>	JUJD I acility	<u>Age</u>	<u>Jex</u>	-
01-Aug-2020 1810	DIRECT	Υ						56 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury;	Remdesivir			S	Intravenous drip					Gilead
Alanine Aminotransferase					mavenous unp					
Increased; Aspartate	Acetaminophen 160mg/5ml Soln			С						Not Reported
Aminotransferase	Atropine 0.5mg Inj			C C						Not Reported
Increased; Blood	Azithromycin			C						Not Reported
Creatinine Increased;	Bumetanide 10mg In 100ml D5!									Not Reported
Liver Function Test	Ceftriaxone 1gram In 100ml Ns			С						Not Reported
Increased	Clonazepam 2mg Tab			С						Not Reported
	Desmopressin 1mcg Inj			С						Not Reported



	En En Ve So Fa Un Hy Ke So Me Mir	motidine 20mg Inj rosemide 40mg Inj ifractionated Heparin idromorphone Inj itamine 1000mg/100ml Ns ilumedrol etolazone 10mg Tab dodrine 20mg Tab vophed 8mg/100ml enylephrine 100mg/250ml In			0000 000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103159	DIRECT	Υ					63 YR	Male	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Hepatic Function Abnormal	Ac Pro Ce Az 25 Lo Fu Ga 10 La Hu So	emdesivir etaminophen 1000mg Tab oventil Hfa eftriaxone 1g In 100ml Ns ithromycin 500mg In Ns 0ml venox 70mg Syr rosemide 40mg Inj auifenesin-Dextromethorphan 0mg/10mg/5ml ntus imalog imulin R olumedrol iriva 18mcg Cap			% 0000 000 00000	Intravenous drip	Other Frequency:Once;			Gilead Not Reported
FDA Received Date	Case #	Case Type	Health		<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103165	DIRECT	Υ		НО			31 YR	Female	e USA

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Preferred Term	<u>Produ</u>	<u></u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u></u>
Hepatitis Viral; Transaminases Increa		esivir Iv			S	Intravenous (not otherwise specifi			No	ot Reported
	Enoxa	parin 40mg Sq			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103169	DIRECT		DE	Ē			87 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Death	Remd	esivir			S				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2020	18103174	DIRECT		DE	Ē			90 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Death	Remd	esivir			S				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103179	DIRECT	Υ	0	Γ			27 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Alanine Aminotransfer Increased; Aspartate	ase Remd	esivir			S	Intravenous (not otherwise specifi			Gi	lead
Aminotransferase Increased; Therapy		minophen			С		•			ot Reported
Cessation		n-Acetaminophen-Caffeine			С					ot Reported
		lorperazine omycin			C C					ot Reported ot Reported
	Ceftria				C					ot Reported
	Bupro				Č					ot Reported
	Ketoro				С					ot Reported
	Loraze				С					ot Reported
		tin Swish And Swallow			C					ot Reported
		natate			С					ot Reported of Reported
	(C) = = = 1	nsetron			С				NI/	- 1 1 1

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103184	DIRECT		C	T				Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Therapy Interrupted	Re	mdesivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103189	DIRECT	Υ	D	ÞΕ			79 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Refusal Of Treatment Patient	By Re	mdesivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103201	DIRECT	Υ					61 YR	Male	USA
<u>Preferred Term</u>	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Infusion Site Swelling	Re	mdesivir			S	Intravenous drip			G	ilead
	Be Lov Ga Lar Hu On Mir Se Tra	pirin 81mg Chew Tab nzonatate Cap 100mg venox 40mg Syr bapentin 100mg Cap ntus malog dansetron 4mg Inj ralax nna 8.6mg Tab nzodone 50mg Tab amin C 500mg Tab			00000000000				N N N N N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103206	DIRECT	Υ					46 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>

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Alanine Aminotransfer	ase Rem	desivir			S	Intravenous drip	Other Frequency:X1;		(Gilead
Increased; Aspartate Aminotransferase Increased; Condition Aggravated; Dizziness Hypoaesthesia; Thera Interrupted	Province Pro	aminophen 1000mg Tab entil Hfa izine 10mg Tab kaparin 40mg Syr kaparin 60mg Syr otidine 20mg Tab semide Inj zepam 0.25mg Tab tonin 3mg Tab ansetron 4mg Inj Con 50mg Cr Tab te Nasal Spray			000000000000	·				lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103213	DIRECT	Υ					73 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Glomerular Filtration R Decreased	Rate Rem	desivir			S				N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103220	DIRECT		[DE			81 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Rem	desivir			S				N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2020	18103226	DIRECT	Υ	(ТС			82 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Liver Function Test Increased; Therapy Cessation	Rem	desivir			S				١	lot Reported



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	17950546	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0475646	20-	66 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Unk			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Unk			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	17950557	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0475632	20-	79 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Covid-19	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Unk			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Unk			Gilead
		ycline I			000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	17951557	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0473011	20-	60 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test Increased	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Amiod	larone			С		Unk			Not Reported

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	Apix	raban			С	Oral	5mg Q12h			Not Reported
	Diltia	azem			С		Unk			Not Reported
	Met	oprolol			С	Oral	12.5 Mg Q12h			Not Reported
	Pan	toprazole			С	Oral	40 Mg, Qd			Not Reported
	Toci	ilizumab			С		400 Mg, Once			Not Reported
	Нер	arin			С	Intravenous (not otherwise specified)	1150-1300 Units/Hr			Not Reported
	Ade	nosine			С	Intravenous (not otherwise specified)	6 Mg			Not Reported
	Tyle				С					Not Reported
	Albu	uterol Hfa			С	Respiratory (inhalation)	180 Mcg Q6h			Not Reported
	Ipra	tropium			С	Respiratory (inhalation)	34 Mcg			Not Reported
	Ond	lansetron			С		4 Mg, Once			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18021106	EXPEDITED (15-DAY)		[DE, OT	US-GILEAD-202 0482495	20-	40 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Death	Ren	ndesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Cisa	atracurium			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Fen	tanyl			С	Intravenous (not otherwise specified)	Unk			Not Reported
	Insu				C C					Not Reported
		amine azolam			C					Not Reported Not Reported
	Wilde	azolam			C	Intravenous (not otherwise specified)	Unk			Not Reported
		esonide			С	. ,				Not Reported
	Carl	ooxymethylcellulose			С	Ophthalmic	Unk			Not Reported
		tropium Bromide And uterol Sulfate			С					Not Reported

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						Botanoa ito	POIL				
	Norep Propo	inephrine fol			C C	Intravenous (not otherwise specified)	Unk				Not Reported Not Reported
	Gaba	pentin			С	Oral	Unk				Not Reported
	Aztred	onam			С	Intravenous (not otherwise specified)	Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18044852	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0484004	20-		20 YR	Female	e USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased; Maternal	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
Exposure During Pregnancy	Remd Oxyge				S C						Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	!	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18045042	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0484008	20-		80 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg	, Qd			Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Dexar	methasone			С		Unk				Not Reported
		en inephrine oressin			0000						Not Reported Not Reported Not Reported Not Reported Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18052169	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0482484)20-		69 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Death; Pyrexia	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
	Rem	ndesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Cisa	tracurium			С		Unk				Not Reported
		medetomidine xaparin			C C	Subcutaneous	40 Mg				Not Reported Not Reported
	Fent	anyl			С		Unk				Not Reported
	Hydi	ralazine			С		Unk				Not Reported
	Insu	lin			С		Unk				Not Reported
	Prop	pofol			С	Intravenous (not otherwise specified)	Titrate				Not Reported
	Carb	ooxymethylcellulose			С	Ophthalmic	Unk				Not Reported
	Nore	epinephrine			С		Unk				Not Reported
	Insu	lin Aspart			С	Subcutaneous	Sliding				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18103451	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0487735)20-		63 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Acute Kidney Injury; Cardiac Arrest;		ndesivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
Transaminases Increa	Cefe Dexa Diph Metr	lizumab epime amethasone ienhydramine ronidazole izapine			000000						Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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		Vancomycin Sennoside A		C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health F	Prof Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	181037	42 EXPEDITED (15-DAY)		HO, OT	US-GILEAD-20 0487467)20-	60 YR	Female	USA
Preferred Term		Product	Comp.	OTC Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; A Kidney Injury; Blood	cute	Remdesivir		S	Intravenous (not otherwise specified)	100 Mg, Qd		(Gilead
Creatinine Increased; Shock		Acetaminophen		С	Unknown	Unk		1	Not Reported
		Amiodarone		С	Unknown	Unk		1	Not Reported
		Amlodipine		С	Unknown	Unk		1	Not Reported
		Asa		С	Unknown	Unk		1	Not Reported
		Atorvastatin		С	Unknown	Unk		1	Not Reported
		Azithromycin		С	Unknown	Unk		1	Not Reported
		Carvedilol		С	Unknown	Unk		1	Not Reported
		Ceftriaxone		С	Unknown	Unk		1	Not Reported
		Dexamethasone		С	Unknown	Unk		1	Not Reported
		Fentanyl		С	Intravenous (not otherwise specified)	Unk		1	Not Reported
		Furosemide		С	Unknown	Unk		1	Not Reported
		Heparin		С	Unknown	Unk		1	Not Reported
		Insulin		С	Unknown	Unk		1	Not Reported
		Lansoprazole		С	Unknown	Unk		1	Not Reported
		Vasopressin		С	Unknown	Unk		1	Not Reported
		Potassium Chloride		С	Unknown	Unk		1	Not Reported
		Epinephrine		С		Unk		1	Not Reported
		Propofol		С		Unk		١	Not Reported
FDA Received Date	Case #	Case Type	Health F	Prof Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	181037	55 EXPEDITED (15-DAY)		ОТ	US-GILEAD-20 0487454)20-		Male	USA

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Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Drug Ineffective; Produ Preparation Issue	uct Remo	lesivir			S	Unknown	Unk			(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	<u>rol #</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104148	DIRECT	Υ	D	E				77 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Death	Remo	lesivir			S	Intravenous bol	us			(Gilead
	Dexa	methasone			С					1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	<u>rol #</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104149	DIRECT	Υ	D	E				72 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Death	Remo Remo	lesivir lesivir			S C						Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	<u>rol #</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104150	DIRECT	Υ	Ľ	Т				79 YR	Unknown	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Platelet Count Decreas	sed Remo	lesivir			S	Intravenous drip)			(Gilead
	Azithr Lover	methasone omycin 500 Mg Daily nox 40 Mg Daily entin 300 Mg Tid			C C C					1 1	Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	<u>rol #</u> <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104151	DIRECT	Υ	D	E				71 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Death	Remo	lesivir			S						Gilead

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	Rem	desivir			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104152	DIRECT	Υ		НО			88 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain Upper Chest Pain; Hepatomegaly; Liver Function Test Increase	Azith Ceftr Doxy Asco Acetr Albut Bella Enox Mont Pipel Pred Dexa Diltia Thiai	donna/Opium Suppository caparin celukast racillin/Tazobactam nisone amethasone			s 000000000000000	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104153	DIRECT	Υ		ОТ			63 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Rem	desivir			S	Intravenous drip				Gilead
	Pant Thiai Vanc Fent Hepa Keta Mida Nore	arin			0000000000					Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104154	DIRECT	Υ					32 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test	Remo	lesivir	Υ		S	Intravenous bolus				Gilead
Increased	Lantu Fish (Fenof Huma Prima Vanco Merop Doxyo Benzo Trama Dexai	prazole s Dil ibrate ilog xin omycin penem cycline onatate adol methasone Iv			000000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104155	DIRECT	Υ	[DE			60 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo Remo				S C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104156	DIRECT	Υ	(TC			76 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Remo	lesivir Injection			S	Intravenous (not otherwise specified)				Not Reported
	Dexa	methasone			С	carried opcomod)				Not Reported

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	Cefep Vanco				C C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104162	DIRECT	Υ	I	НО				75 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Urea Abnormal; Glomerular Filtration Rate Abnorm	ı				S C						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104269	EXPEDITED (15-DAY)		I	DE, OT	US-GILEAD-20 0488298	020-		56 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Death	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
		minophen			С						Not Reported
	Album	ın acurium			C C						Not Reported Not Reported
		ostenol			C						Not Reported
	Fentai	nyl			С						Not Reported
		Nph [Insulin Isophane			С						Not Reported
	Bovine Lactor	ej pacillus			С						Not Reported
	Midaz				Č						Not Reported
		inephrine			Č						Not Reported
	Panto	orazole			С						Not Reported
		lephrine			C C						Not Reported
		cillin / Tazobactam			С						Not Reported
		IOI			C						Not Reported
	Propo				_						Mat Danasta !
		m Polystyrene Sulfonate			CCC						Not Reported Not Reported

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EDA Bessived Data	Coop #	Coop Tymp	Lloolth	Duet	Outcomes	Mfr Control	# 503B Facility	Λ σ σ	Cov	Country
	Case #	Case Type			Outcomes	<u>wir Control</u>	# OUSD FACILITY	Age	<u>Sex</u>	Country
03-Aug-2020	18104356	DIRECT	Υ		НО			38 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Alanine Aminotransfera Increased	ase Remde	esivir			S	Intravenous drip			G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104603	DIRECT	Y		ОТ			79 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Alanine Aminotransfera Increased	ase Remde	esivir			S	Intravenous (not otherwise specified)		G	ilead
	Dexam Aspirin Hepari				C C C		,		N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18104604	DIRECT	Υ					70 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Aspartate Aminotransferase	Remde	esivir			S	Intravenous (not otherwise specified)		G	ilead
Increased	Clopide	ephrine ogrel ethasone dine			0 0 0 0 0				N N N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18106190	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-2 0486993	020-	50 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> f	<u>'r</u>

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	Albutor	rol [Salbutamol Sulfate]		С	Intravenous (not otherwise specified)	100 M				Not Reported
					Respiratory (inhalation)	Unk				·
	Aspirin	[Acetylsalicylic Acid]		С	Unknown	Unk				Not Reported
	Atorvas	statin		С	Unknown	Unk				Not Reported
	Budeso	onide		С	Respiratory (inhalation)	Unk				Not Reported
	Fluticas	sone		С	Nasal	Unk				Not Reported
	Furose	mide		С	Unknown	Unk				Not Reported
	Guaife	nesin		С	Unknown	Unk				Not Reported
	Hydrala	azine		С	Unknown	Unk				Not Reported
	Loraze	pam		С	Unknown	Unk				Not Reported
	Losarta	an		С	Unknown	Unk				Not Reported
	Melato	nin		С	Unknown	Unk				Not Reported
	Zinc Su	ulfate		С	Unknown	Unk				Not Reported
	Iverme	ctin		С	Unknown	Unk				Not Reported
	Thiami	ne		С	Unknown	Unk				Not Reported
	Vancor	mycin		С	Unknown	Unk				Not Reported
	Amlodi	pine		С	Unknown	Unk				Not Reported
	Ascorb	ic Acid		С	Intravenous (not otherwise specified)	Unk				Not Reported
	Azithro	mycin		С	Unknown	Unk				Not Reported
	Cefepir	me		С	Unknown	Unk				Not Reported
	Famoti	dine		С	Unknown	Unk				Not Reported
	Heparii	n		С	Unknown	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2020	18107384	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-202 0488611	20-		67 YR	Male	USA

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Haemorrhage	rred Term	<u>P</u> ı	<u>roduct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Doxycycline Zosyn		Remdesivir				S					Gilead
Viglob-Ex C Unk N N		Re	emdesivir			S					Gilead
Plasma											Not Reported Not Reported
Argatroban C		lvi	glob-Ex			С		Unk			Not Reported
Argatroban C Unk No FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex 03-Aug-2020 18107532 EXPEDITED (15-DAY) 0T US-GILEAD-2020- 79 YR Male Preferred Term Product Comp. OTC Role Route Dosage Text Duration Minoreased Alanine Aminotransferase Remdesivir S Intravenous (not otherwise specified) Albuterol Hfa Apixaban C C Ascorbic C C Atorvastatin Budesonide C Cholecalciferol C C C C C C C C C C C C C C C C C C C		PI	asma			С		Unk			Not Reported
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex		Ar	gatroban			С		Unk			Not Reported
O3-Aug-2020 18107532 EXPEDITED (15-DAY) OT US-GILEAD-2020-0487812 79 YR Male Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mincreased Alanine Aminotransferase Remdesivir S Intravenous (not otherwise specified) Albuterol Hfa C C Apixaban C C Apixaban C C C Ascorbic C C C N N N N Ascorbic C C N N N N Ascorbic C C N N N N N N N N N N N N N N N N N		Ar	gatroban			С		Unk			Not Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Minoreased Alanine Aminotransferase Remdesivir S Intravenous (not otherwise specified) Albuterol Hfa Apixaban C C Apixaban Ascorbic C C N N Atorvastatin C C N N Budesonide C C C N N N N Atorvastatin C C N N N N N N N N N N N N N N N N N	Received Date C	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Alanine Aminotransferase Remdesivir S Intravenous (not otherwise specified) Albuterol Hfa C NApixaban C NAScorbic C NAtorvastatin C NAScorbic C NATorvastatin C NAScorbic C NATorvastatin C NAScorbic	ug-2020 1	18107532	EXPEDITED (15-DAY)			ОТ		20-	79 YR	Male	USA
Albuterol Hfa C N Apixaban C N Ascorbic C N Atorvastatin C N Budesonide C N C N C N C N C N C N C N C N N C N C N N C N N C N N C N N C N N C N N C N N N C N N N C N	rred Term	<u>P</u> ı	roduct	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Apixaban C		se Re	emdesivir			S	`				Gilead
Ascorbic C						C					Not Reported
Atorvastatin C N Budesonide C N Cholecalciferol C N Cholecalciferol C N Dexamethasone C N Levofloxacin C N Levothyroxine C N Memantine C N Metoprolol Metoprol						С					Not Reported
Budesonide C N Cholecalciferol C Dexamethasone C Levofloxacin C Levothyroxine C Memantine C Metoprolol C Pantoprazole Zinc C FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex						C					Not Reported Not Reported
Cholecalciferol C N						Č					Not Reported
Levofloxacin C N						Ċ					Not Reported
Levothyroxine		De	examethasone			С					Not Reported
Memantine						Ç					Not Reported
Metoprolol C N Pantoprazole C N Pantoprazole C N Pantoprazole C N Pantoprazole C Pantoprazole C Pantoprazole C Pantoprazole C Pantoprazole C Pantoprazole Pantoprazol						С					Not Reported
Pantoprazole C N Zinc C N N S Sex Sex Sex Sex Sex Sex Sex Sex Sex S											Not Reported
Zinc C N FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex						C					Not Reported Not Reported
FDA Received Date											Not Reported
	Received Date C	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
03-Aug-2020 18107815 EXPEDITED (15-DAY) DE, OT US-SA-2020SA199688 Unknown	ug-2020 1	18107815	EXPEDITED (15-DAY)			DE, OT	US-SA-2020SA	199688		Unknov	wn USA

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Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Covid-19; Disseminated	Lovenox			S	Subcutaneous	40 Mg, Qd			Sanofi
Intravascular Coagulation; Intra-Abdominal Haemorrhage;	Remdesivir			S	Intravenous (not otherwise specified)	Unk			Not Reported
Retroperitoneal	Ascorbic Acid			С		Unk			Not Reported
Haemorrhage; Septic Shock; Shock	Fenofibrate			С		Unk			Not Reported
Haemorrhagic	Heparin			С		Unk			Not Reported
	Methylprednisolone			С		Unk			Not Reported
	Nph Insulin			С		Unk			Not Reported
	Insulin Human;Insulin Human Injection, Isophane			С		Unk			Not Reported
	Sodium Chloride			С		Unk			Not Reported
	Sitagliptin			С		Unk			Not Reported
	Midazolam			С		Unk			Not Reported
	Pantoprazole			С		Unk			Not Reported
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Aug-2020 1794	1111 EXPEDITED (15-DAY)		H	IO, OT	US-GILEAD-20: 0473733	20-	39 YR	Male	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test	Remdesivir			S	Unknown	100 Mg, Qd			Gilead
Increased; Respiratory Failure	Aspirin [Acetylsalicylic Acid]			С	Oral	81 Mg, Qd			Not Reported
	Ceftriaxone			С	Intravenous (not otherwise specified)	1 G, Qd			Not Reported
	Chlorhexidine			С	Oral	Unk			Not Reported
	Dexamethasone			С	Intravenous (not otherwise specified)	6 Mg, Qd			Not Reported
	Famotidine			С	Oral	20 Mg, Bid			Not Reported
	Furosemide			С	Intravenous (not otherwise specified)	20 Mg, Q8h			Not Reported
	Metoclopramide			С	Intravenous (not	5 Mg, Q8h			Not Reported

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						otherwise specified	d)				
	Mvi [Vit	amins Nos]			С		Unk			No	Reported
	Senna-S [Docusate				С	Oral	Unk,	Bid		No	Reported
	Vancon	;Sennoside A+B] nycin			С	Intravenous (not otherwise specified	Unk d)			No	Reported
	Artificia	l Tears [Hypromellose]			С	·	Unk			No	Reported
	Dexme	detomidine			С	Intravenous (not otherwise specified	d)			No	Reported
	Fentany	yl .			С	Intravenous (not otherwise specified)					Reported
	Heparir	1			С	Intravenous (not otherwise specified	d)			No	Reported
	Insulin				С	Intravenous (not otherwise specified	d)			No	Reported
	Midazo	lam			С	Intravenous (not otherwise specified	d)			No	Reported
	Oxygen Cotrimo				C C		7 Do:	ses			Reported Reported
	Tocilizu Plasma Ativan Preced				C C C					No No	Reported Reported Reported Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u> #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Aug-2020	17975539	EXPEDITED (15-DAY)		C	T	US-GILEAD-2 0477764	2020-		27 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Remde	sivir			S	Unknown	Unk			Gile	ead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u> #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Aug-2020	18026839	EXPEDITED (15-DAY)		C	E, OT	US-GILEAD-2 0482905	2020-		68 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>	<u>Mfr</u>	

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Acute Kidney Injury; Acute Respiratory Failure;	Remdesivir	S	Intravenous (not otherwise specified)	200 Mg, Qd	Gilead
Cardiac Arrest; Congestive Cardiomyopathy; Covid-	Remdesivir	S	Intravenous (not otherwise specified)	100 Mg, Qd	Gilead
19; Ischaemic Hepatitis;	Fentanyl	С			Not Reported
Metabolic Acidosis;	Norepinephrine	С			Not Reported
Multiple Organ	Propofol	С			Not Reported
Dysfunction Syndrome;	Vasopressin	С			Not Reported
Renal Failure; Sepsis;	Albuterol Hfa	С			Not Reported
Septic Shock	Ascorbic	С			Not Reported
·	Vitamin D3	С			Not Reported
	Doxycycline	С			Not Reported
	Enoxaparin	С			Not Reported
	Famotidine	С			Not Reported
	Novolog Mix	С			Not Reported
	Levemir	С			Not Reported
	Nitroglycerin Recip	С			Not Reported
	Zinc Sulfate	С			Not Reported
	Ceftriaxone	С			Not Reported
	Lovenox Hp	С			Not Reported
	Ivermectin	С			Not Reported
	Dexamethasone	С			Not Reported
	Vitamin C + Zinc	С			Not Reported
	Plasma	С		Unk	Not Reported