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

Selection Criteria:

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

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

^{*. &}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.



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	e <u>He</u>	alth Prof	Out	comes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2020	1773169	NON-EXP	EDITED		ОТ		US-SA-2020SA	110743			Male	USA
Preferred Term	1	<u>Product</u>	Con	<u>пр. ОТ</u>	<u>C</u>	Role	Route	Dosage	Text	<u>Duration</u>		<u>Mfr</u>
Anaemia; Aspartate	ļ	Lovenox				S	Subcutaneous	100 Mg	g, Bid			Sanofi
Aminotransferase Increased; Blood Calcium Decreased; Blood Potassium Decreased;	ium ^I	Remdesivir				S	Intravenous (not otherwise specified)	Unk				Not Reported
	;	Eliquis				С	Unknown	Unk				Not Reported
Gastrointestinal Haemorrhage	,	Acetaminophen				С	Unknown	Unk				Not Reported
riacinomiage	,	Ascorbic Acid				С	Unknown	Unk				Not Reported
	,	Atorvastatin				С	Unknown	Unk				Not Reported
	I	Dexmedetomidine				С	Unknown	Unk				Not Reported
	,	Apixaban				С	Unknown	Unk				Not Reported
	,	Aspirin [Acetylsalicy	lic Acid]			С	Unknown	Unk				Not Reported
	,	Azithromycin				С	Unknown	Unk				Not Reported
	ı	Docusate Sodium				С	Unknown	Unk				Not Reported
	ı	Fluticasone Furoate	;Vilanterol			С	Unknown	Unk				Not Reported
	(Gabapentin				С	Unknown	Unk				Not Reported
	ı	Hydrocodone				С	Unknown	Unk				Not Reported
	I	Insulin Aspart				С	Unknown	Unk				Not Reported
	I	Lantus				С	Unknown	Unk				Not Reported
	I	Loratadine				С	Unknown	Unk				Not Reported
	I	Polyethylene Glycol				С	Unknown	Unk				Not Reported
	I	Prednisone				С	Unknown	Unk				Not Reported
	;	Sertraline				С	Unknown	Unk				Not Reported
		Inula Helenium Roo Alexandrina Leaf	t;Senna			С		Unk				Not Reported
	(Quetiapine				С		Unk				Not Reported
		Propofol				С		Unk				Not Reported



	Panto	prazole			С		Unk				Not Reported	
	Multiv	vitaminum			С	Unk				Not Reported		
	Hydro	omorphone		C 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 prolol Succinate arin			C C C						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-May-2020	17774804	DIRECT	Υ	Н	0				61 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage '	Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Therapy Interrupted	Rem	desivir	Υ		S	Intravenous (not otherwise specified))				Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774838	DIRECT	Υ	D	E				74 YR	Male	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Cardio-Respiratory Arr Dialysis; Pneumonia		desivir	Υ		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
12-May-2020	17774848	DIRECT	Υ	Н	0				69 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Bl	lood Rem	desivir			S	Intravenous drip					Gilead
Creatinine Increased;	Vano	comycin			С	·					Not Reported
Oliguria		ssium Chloride			С						Not Reported
		iidate inylcholine			C C						Not Reported Not Reported
	Fent				C						Not Reported
	Nalo	•			С						Not Reported
		racillin/Tazobactam			C						Not Reported
	Nore	pinephrine			С						Not Reported
Inhaled Epoprostenol Famotidine			C C						Not Reported Not Reported		
	⊢am/										



	Bisacodyl Suppository Gabapentin Insulin Lispro Propofol Senna Iv Furosemide 40 Mg X 1 Hydroxychloroquine Or Placebo Enoxaparin Heparin Metolazone 10 Mg				0000000000			Not Reported		
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774850	DIRECT	Υ		ОТ			61 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	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; Ce Va Dia Do Fei Fui He Ins No Pa	mdesivir fepime ncomycin izepam cusate ntanyl rosemide parin 7,500 Units Sq ulin Lispro repinephrine ntoprazole etiapine			» 000000000000	Intravenous drip				Gilead Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2020	17774851	DIRECT	Υ		НО			54 YR	Female	e USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Renal Impairment	Re	mdesivir	Υ		S	Intravenous drip		2 DAY		Gilead



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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
13-May-2020	17775263	DIRECT	Υ						Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
ncorrect Dose Remdesivir Administered; Product				S	Intravenous (not otherwise specified)			G	ilead	
Label Confusion	Remo	desivir			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
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>Mf</u>	<u>r</u>
Clinical Trial Participal Thrombocytopenia	Aspiri Amloo Chole Torse Enox Levot	dipine ecalciferol			80000000				N N N N 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
13-May-2020	17781018	DIRECT	Υ	D	E			69 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>
Cardio-Respiratory Ar Clinical Trial Participal Product Use In Unapproved Indication	nt;	desivir			S	Intravenous bolus	Other Frequency:Once;		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	<u>outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-May-2020	17781025	DIRECT	Υ					41 YR	Male	USA



Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Blood Creatinine Increased; Chest X-Ray Abnormal; Clinical Trial Participant; Oxygen Consumption Increased; Product Use In Unapproved Indication; White Blood Cell Count Increased	Remdesivir Fentanyl Hydralazine Piperacillin-Tazobactam Pantoprazole Enoxaparin Propofol			s c c c c c c c					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 Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020 1778	4372 DIRECT	Υ	OT	Г			70 YR	Male	USA
Preferred Term	<u>Product</u>	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			» 00000000000000	Intravenous drip	Other Frequency:Once;			Gilead Not Reported
FDA Received Date Case	<u>Case Type</u>	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020 1779	0333 DIRECT	Υ					71 YR	Femal	e USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
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	Health	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2020	17790340	DIRECT	Υ	C	DΤ			66 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Clinical Tria Participant; Product Us Unapproved Indication Therapy Interrupted	il se In	lesivir			S	Intravenous (not otherwise specified)				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
14-May-2020	17790341	DIRECT	Υ	C	DΤ			63 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remd	lesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
Increased; Product Lab Confusion; Product	oel Furos	emide			S	Intravenous bolus				Not Reported
Preparation Error	Calciu Docus Epopr Etomi Fenta Gabay Loraz Marav Methy Midaz Norep Propo	rostenol Inhalation date nyl pentin epam viroc vlprednisolone colam pinephrine			00000000000000					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>
Cardio-Respiratory Arr Clinical Trial Participar				S	Intravenous (not otherwise specified)	1			Gilead	
Product Use In Unapproved Indication	1	Ascorbic Acid 500mg Atorvastatin 20mg Tab Azithromycin 500mg Iv Ceftriaxone 1gm Iv Daily Cholecalciferol 4,000 Units Da 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 P Fentanyl 50mcg Q2h 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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		<u>-</u>	
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



	Dexd	or			С		I I-I-		<u> </u>	Not Reported
	Sinte				С		Unk			Not Reported
	Sinte	-			С		Unk			Not Reported
	Dorm	•			С		Unk			Not Reported
	Dorm				С		Unk			Not Reported
	Dorm				С		Unk			Not Reported
		drenaline			С		Unk			Not Reported
		drenaline			С		Unk			Not Reported
		drenaline					Unk			· ·
					С		Unk			Not Reported
	Propo				С		Unk			Not Reported
	Propo				С		Unk			Not Reported
	Propo				С		Unk			Not Reported
	Propo				С		Unk			Not Reported
		ronium			С		Unk			Not Reported
	Tracr Tracr				C C					Not Reported Not Reported
	Traci						Unk			·
	Traci	lum			С		Unk		·	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17792126	DIRECT	Υ	D	E			57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Death	Remo	desivir			S	Intravenous bolus			(Gilead
		alescent Plasma			С	intraverious bolus				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	Sex	Country
15-May-2020	17792128	DIRECT	Υ	0	Т			59 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Chills; Hypotension; Infusion Related Reac		desivir			S	Intravenous drip	Other Frequency:X1		(Gilead



							(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>	<u>Country</u>
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



							-			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2020	17793631	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0466952	020-	65 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mf</u>	<u>r</u>
Cardiac Arrest; Pulsele Electrical Activity	ess Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Qd		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
15-May-2020	17794224	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0467265)20-	74 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mf</u>	<u>r</u>
Acute Respiratory Distr Syndrome; Cardio- Respiratory Arrest; Cov 19 Pneumonia		esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		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
15-May-2020	17797263	DIRECT	Y	0	T			66 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Poor Quality Product Administered; Product Storage Error	Remd	esivir	Υ		S	Intravenous (not otherwise specified))	6 DAY	G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
15-May-2020	17797264	DIRECT	Y					57 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Acidosis; Blood Creatin		esivir			S	Intravenous drip			G	ilead
Increased; Fluid Overlo	Lactol Aspirii	oacillus			C C C	·			Ne Ne	ot Reported ot Reported ot Reported ot Reported

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						Dotalloa IX	JPO. 1			
	Propo Hepa Famo Methy Huma Humu Venel	rin Subcutaneous tidine /lpredinosolone Ilog Ilin Nph ex n Mist			000000000				No No No No No No 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-May-2020	17797623	DIRECT	Υ	0	Γ			66 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Hypotensic	Remo	lesivir			S	Intravenous drip			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-May-2020	17797878	DIRECT	Υ	0	Γ			71 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Hypotension	Remo	lesivir			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
17-May-2020	17797266	DIRECT	Υ	0	Γ			46 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Seizure	Remo	lesivir			S	Intravenous bolus			Gil	ead
		bic Acid			С					t Reported
	Atorva Enoxa	astatin aparin			C C					t Reported t Reported
	Famo	tidine			С				No	t Reported
	Insulii Melat				C C					t Reported t Reported
		/lprednislone			č					t Reported

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							Detailed Ne	port			
	Zinc Fentanyl Norepinephrine					C C C	Not Reported Not Reported Not Reported				
FDA Received Date	Case #	Case Type	He	alth F	Prof	Outcomes Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	177972	67 DIRECT	Υ			ОТ			41 YR	Female	USA
Preferred Term		Product	Con	<u>np.</u>	ОТС	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase	ase	Remdesivir Convalescent Plasma For Co 19	vid-			S C				_	illead ot Reported
Increased		Tocilizumab Or Placebo/Cova Study	icta			С				N	ot Reported
FDA Received Date	Case #	Case Type	He	alth F	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	177972	68 DIRECT	Υ			ОТ			72 YR	Female	USA
Preferred Term		Product	Con	<u>np.</u>	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Blood Creatinine Increased; Coronary Artery Stenosis;		Remdesivir Remdesivir				S S	Intravenous bolus Intravenous (not	Other Frequency:Once;			ilead ilead
Depressed Level Of Consciousness; Hemiparesis; Mental Status Changes; Rena Ischaemia	ıl	Convalescent Plasma For Co 19	vid-			С	otherwise specified)			N	ot Reported
FDA Received Date	Case #	Case Type	<u>He</u>	alth F	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	177972	69 DIRECT	Υ			ОТ			57 YR	Female	USA
Preferred Term		Product	Con	<u>np.</u>	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Renal Function Test		Remdesivir				S	Intravenous drip			G	ilead
Abnormal		Cefepime Vancomycin				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
17-May-2020	17797270	DIRECT	Υ					46 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Alanine Aminotransfer Increased; Liver Funct Test Increased; Thera Interrupted	ion Benzo py Ceftria Clona Doxyo Enoxa Furos Methy Omep Ropin Topira	onatate axone zepam cycline aparin emide r/prednisolone orazole irole			%00000000000				N N N N N N N	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
17-May-2020	17797271	DIRECT	Υ					70 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Alanine Aminotransfer ncreased	ase Remo	lesivir			S	Intravenous (not otherwise specified	Other Frequency:Once;		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
17-May-2020	17797281	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>ir</u>
Liver Function Test Increased; Therapy Interrupted	Remo	lesivir	Y		S	Intravenous drip	Other Frequency:Once;		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020	17797285	DIRECT	Υ					52 YR	Female	USA

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Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Pressure Systolic	Remo	esivir			S	Intravenous drip	Other Frequency:Once;			Gilead
ncreased; Hypertension; Therapy Change Digoxin Enoxaparin Furosemide Hydralazine Losartan Methylprednisolone Nebivolol Hydroxychloroquine FDA Received Date Case # Case Type		C C C C C C C C C C C C C C C C C C C			·			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
17-May-2020 1	7797292	DIRECT	Υ	(TC			70 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Protein Total	Remo	esivir			S	Intravenous drip	Other Frequency:Once, Then 100mg;			Gilead
ncreased; Renal Tubula Necrosis; Sepsis	пераі	in/Enoxaparin Itaneous			С		<u>.</u>			Not Reported
		n 81 Mg			С					Not Reported
		n Lispro minophen			C C					Not Reported Not Reported
		nsetron			Č					Not Reported
		nyroxine 150 Mcg			Č					Not Reported
	Tociliz	rumab 400 Mg			С					Not Reported
		rynic Acid			С					Not Reported
	Metop				С					Not Reported
	Tradip				C C					Not Reported
	Injecti	thobenzamide 200 Mg on			C					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
17-May-2020 1	7798027	DIRECT	Υ	ı	રા			70 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>



Alanine Aminotransferase Increased	Remd	esivir (Gs-5734)	Υ		S	Intravenous (not otherwise specified)			C	Gilead
	Remd	esivir (Gs-5734)	Y		S	Intravenous (not otherwise specified)			C	Bilead
FDA Received Date Ca	ase#	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020 17	798044	DIRECT	Υ	H	0			60 DAY	Female	USA
<u>Preferred Term</u>	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Cardiac Failure; Coagulopathy; Organ	Remd	esivir			S	Intravenous (not otherwise specified)			C	Gilead
Failure; Transaminases Increased	Remd	esivir	Y		S	Intravenous (not otherwise specified)			C	Bilead
FDA Received Date Ca	ase#	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2020 17	801712	DIRECT	Υ	0	Т			32 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Transaminase Increased		esivir			S				١	lot 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
18-May-2020 17	798196	DIRECT	Υ	0	Т			23 YR	Male	USA
<u>Preferred Term</u>	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Drug Ineffective; Liver Function Test Increased;	Remd	esivir 200 Mg			S	Intravenous (not otherwise specified)			C	Gilead
Therapy Cessation	Dextro	minophen omethorphan natate parin			C C C	. ,			N	lot Reported lot Reported lot Reported lot Reported

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	Aspirin Ibupro Vitamin Zinc S Hydro Predni Albute	fen n C ulfate xychloroquine sone			0000000						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
18-May-2020	17798574	DIRECT	Υ		ОТ				23 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		Mfr
Drug Ineffective; Liver Function Test Increase		esivir 200 Mg			S	Intravenous (not otherwise specified)					Gilead
Therapy Cessation	Dextro Benzo Enoxa Aspirin Ibupro Vitami Zinc S	parin I fen n C ulfate kychloroquine sone			0000000000						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
18-May-2020	17800831	EXPEDITED (15-DAY)			DE	US-GILEAD-20 0467444	20-		69 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration		<u>Mfr</u>
Dyspnoea; Hypoxia	Remde	esivir			S	Intravenous (not otherwise specified)	200 Mg	g, Once			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801700	DIRECT	Υ		ОТ				53 YR	Male	USA

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Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Liver Function Test Abnormal	Remo	lesivir			S	Intravenous (not otherwise specified	d)			Gilead
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	17801703	DIRECT	Υ					60 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Incorrect Dose Administered	Remo	lesivir			S					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	17801706	DIRECT	Υ	D	E, LT			77 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; General Physical Heal		lesivir	Υ		S	Intravenous (not otherwise specified	d)	3 DAY		Gilead
Deterioration; Oxygen Saturation Decreased		ime 2g Iv Q12h			С					Not Reported
		bic Acid 1500mg Iv Q6h nine 200mg Iv Q12h			C C					Not Reported Not Reported
		cycline 100mg Po Bid			Č					Not Reported
		Iprednisolone 60mg lv			C					Not Reported
		prazole 20mg Po Q24h			С					Not Reported
		lline 100mg Po Q24h			С					Not Reported
	Methy Q24h	Iprednisolone 60mg lv			С					Not Reported
		ulosin 0.4mg Po Q24h			С					Not Reported
		Capsule 50mg Po Q24h			С					Not Reported
		opium Inh 2 Puffs Po Q6h			C					Not Reported
	Enoxa	aparin 30mg Sc Q12h			С					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
		DIRECT		0						



						Dotalloa IX	oport			
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Coronavirus Test Posit	tive; Remo	lesivir			S	Intravenous drip				Not Reported
Vomiting	Insulii Onda Oxyco Proch Ceftri	n Aspart n Glargine nsetron odone loroperazine			0 0 0 0 0 0 0	·				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>	<u>Sex</u>	Country
18-May-2020	17801711	DIRECT	Υ	(ОТ			70 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase Remo	lesivir			S	Intravenous (not otherwise specified	Other Frequency:Once;			Gilead
Aminotransferase Increased; Therapy Cessation	Atorva Propo	astatin fol			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
18-May-2020	17801746	DIRECT	Υ	(ОТ			84 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; Blo Creatinine Increased; Hypotension; Respirato Failure; Tachypnoea; Urine Output Decrease White Blood Cell Disord	Vanco ory Furos ed;	lesivir omycin emide			S C C					Gilead 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>	<u>Country</u>
18-May-2020	17801755	DIRECT	Υ		ОТ			77 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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Clinical Trial Participant; Liver Function Test Increased; Product Use In Unapproved Indication; Remdesivir S Intravenous drip

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-May-2020	178017	60 DIRECT	Υ						53 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participar Differential White Bloo		Remdesivir			S	Intravenous (not otherwise specified)					Gilead
Cell Count Abnormal; Leukopenia; Lymphocy Percentage Increased; Neutrophil Percentage Decreased; Product Us In Unapproved Indicati	se	Ascorbic Acid 1500mg Po Bid Cholecalciferol 50mcg Po Q24 Zinc Capsule 50mg Po Q24h Magnesium Oxide 420mg Po E Insulin Glargine 12 Units Sc QI Insulin Aspart Sliding Scale Tic Ac	Bid ns		C C C C C C	,					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
		Senna 17.2mg Po Daily Enoxaparin 30mg Sc Q12h			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
18-May-2020	178017	96 DIRECT	Υ		ОТ				70 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participar	nt;	Remdesivir			S	Intravenous (not otherwise specified)					Gilead
Product Use In Unapproved Indication		Hydroxychloroquine Or Matchi	ng		С	curerings openings,					Not Reported
Renal Impairment	,	Placebo Convalescent Plasma			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
		01 DIRECT	Υ		ОТ				55 YR		USA

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<u>Preferred Term</u>	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Acute Kidney Injury; Hypovolaemia; Renal	Remd Under	esivir Injection (For Use			S	Intravenous drip				Gilead
Tubular Necrosis		esivir Injection (For Use			S	Intravenous drip				Gilead
	Vanco Vanco	mycin 2g Iv Q12 mycin 1g Iv Q12 mycin 1g Iv X 1 parin idine			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>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801805	DIRECT	Υ	(ТС			80 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Renal Impairment	Remd	esivir			S	Intravenous bolus	Other Frequency:200mg > 1 100mg X4;	<		Gilead
	Azithro Hydro: Furose Carve Docus Folic A Neuro Clopid	Iprednisolone omycin xychloroquine emide dilol ate Acid ntin ogrel orazole			000000000000					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
18-May-2020	17801809	DIRECT	Υ	I	НО			72 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>]	<u>Mfr</u>
Acute Kidney Injury	Remd	esivir			S	Intravenous bolus				Gilead

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	Enox Hydr Hydr Insul Insul Pipel Polye	in romycin aparin ocortisone oxychloroquine in Glargine in Lispro racillin-Tazobactam ethylene Glycol 3350 omycin			000000000				No No No No No No No No	at 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	Y	0	Т			67 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Swelling; Throat Irritation	Amlo Albut Lisino Nysta Perca Pante Sitag Zinc Vitan Vitan Aspir Metfo Meth Dipric	atin Oral Susp ocet oprazole liptin nin D nin C in ormin ylprednisolone damole agliflozin in Lispro	Y		%00000000000000000				No No No No No No No No No No No No No N	at Reported but 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	Y	H	0			75 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	



Abdominal Pain;	Remd	esivir			S	Intravenous drip	Other Frequency:Once;	20 MIN	C	Gilead
Discomfort; Infusion Related Reaction; Nausea; Vomiting	Atorva Enoxa Hydro Lisino Panto Tiotro Norco Tussio Onda	sparin xychloroquine pril prazole pium 5			00000000000				P P P P P	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	17801824	DIRECT	Υ	С	Т			46 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Seizure	Remd	esivir			S	Intravenous drip			C	Gilead
	Melate Leveti Atorva	apine Iprednisolone onin racetam			00000000				\ \ \ \ \	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	17801829	DIRECT	Υ	Н	10			55 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Glomerular Filtration F	Rate Remd	esivir			S	Intravenous bolus			C	Gilead
Decreased; Hypoxia	Ceftria Doxyo Enoxa Methy	ycline			C C C				N	lot Reported lot Reported lot Reported lot Reported



							70.0			
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	178018	B5 DIRECT	Υ	0	Т			34 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Anxiety; Blood Pressul Increased; Body Temperature Increase Heart Rate Increased; Hyperhidrosis; Nausea Oxygen Saturation Decreased; Respirator Rate Increased	d; a;	Remdesivir			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
18-May-2020	178018	92 DIRECT	Υ	0	Т			38 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased		Remdesivir Ceftriaxone Famotidine Heparin Insulin Midazolam Norepinephrine Azithromycin Tocilizumab Vancomycin	Y		s 000000000	Intravenous drip				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
18-May-2020	178018	99 DIRECT	Υ					52 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Product Administration	1	Remdesivir			S	Intravenous bolus				Gilead
Error; Product Dose Omission		Tocilizumab 760mg Convalescent Serum			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 #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2020	17801905	DIRECT	Y		НО			15 YR	Female	USA
Preferred Term	<u>Pro</u>	duct	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypotension	Ren	ndesivir	Υ		S	Intravenous bolus	Other Frequency:Once;			Gilead
	Ren	ndesivir	Υ		S	Intravenous bolus				Gilead
	Cefe Mela Hyd Suc Mer	yntropin epime atonin rocortisone Sodium cinate captopurine hromycin			0000 00					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
18-May-2020	17801912	DIRECT	Y		LT			73 YR	Female	USA
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury;		ndesivir	Υ		S	Intravenous bolus				Gilead
Azotaemia; Continuou Haemodiafiltration; Glomerular Filtration R Decreased	Fam	xaparin notidine			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
18-May-2020	17802626	DIRECT	Υ		DE			76 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Covid-19; Dyspnoea; General	Con	valescent Plasma			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Not Reported
Physical Health Deterioration;		ndesivir			S					Not Reported
Hypotension; Liver	l inc	sone zolid			C C					Not Reported Not Reported
Function Test Abnorm Multiple Organ	^{al;} Van	comycin			С					Not Reported
apio oigaii	Pipe	eracillin/Tazobactam			С					Not Reported

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

Test Positive											
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	17802614	DIRECT	Υ	L	Γ				55 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mf	<u>'r</u>
Alanine Aminotransfer Increased	ase Rem	desivir	Y		S	Intravenous drip			5 DAY	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
19-May-2020	17802618	DIRECT	Υ	0	Т				75 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mf	<u>r</u>
Continuous Haemodiafiltration; Inadequate Haemodialysis; Renal Impairment	Rem	desivir			S	Intravenous drip			2 DAY	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
19-May-2020	17802638	DIRECT	Υ	D	E				60 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mf	<u>r</u>
Bacteraemia; Cardiac		desivir			S	Intravenous bolus				G	ilead
Arrest; Covid-19; Disest Complication; Pneumo	nnia AIIIIC	odarone			C C						ot Reported ot Reported
Pseudomonal; Respira Failure		odipine edilol			С					N	ot Reported
ranule	Docu				C C						ot Reported ot Reported
		aparin semide			C						ot Reported ot Reported

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						Botanea No	port			
	Ins	ulin Glargine			С					Not Reported
		ulin Lispro			C C					Not Reported
	Lac	ctobacillus Acidophilus			С					Not Reported
	Lar	nsoprazole			C C					Not Reported
		azepam			С					Not Reported
		ropenem			С					Not Reported
		toclopramide			C C					Not Reported
		Itivitamin			C					Not Reported
		ycodone			С					Not Reported
	Pol	yethylene Glycol 3350			С					Not Reported
		assium Chloride			C C					Not Reported
		utra-Phos			C					Not Reported
										Not Reported
					С					Not Reported
	Нус	aromorphone			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
19-May-2020	17802944	DIRECT	Υ		DE			70 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	ОТО	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Oxygen Saturation Decreased; Renal Fail		mdesivir			S	Intravenous (not otherwise specified)				Gilead
	Pla	droxychloroquine Or Matching cebo (Orchid Trial)			С	, ,				Not Reported
	Col	nvalescent 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	17802952	DIRECT	Υ		DE			53 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	ото	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Pulseless Electrical Activity	Rei	mdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Lev	viteracetam			С	. ,				Not Reported
					Č					Not Reported
	Oxi	carbazenine								
		carbazepine lodipine			Ċ					
	Am	lodipine			C					Not Reported
	Am End				C C C					

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FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17805154	EXPEDITED (15-DAY)		(OT	US-GILEAD-20 0466529	020-	71 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Chills; Hypotension; Nausea	Remde	esivir			S	Intravenous (not otherwise specified	200 Mg, Once)		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
19-May-2020	17805179	EXPEDITED (15-DAY)		ŀ	HO, OT	US-GILEAD-20 0467261	020-	61 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; B Creatinine Increased	lood Remde	esivir			S	Intravenous (not otherwise specified	200 Mg, Qd)		Gil	ead
	Remde	esivir			S	Intravenous (not otherwise specified	100 Mg, Qd)		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
19-May-2020	17805184	EXPEDITED (15-DAY)		(OT	US-GILEAD-20 0466961	020-	48 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mfr</u>	
Blood Creatinine Increased; Hepatic Function Abnormal	Remde	esivir			S	Intravenous (not otherwise specified	200 Mg, Qd)		Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806590	DIRECT	Υ	(OT			59 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased	Remde Amoloc Atracui Carved	dipine rium	Υ		S C C C	Intravenous drip			No No	ead t Reported t Reported t Reported

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		Famotidine Heparin Lidocaine Patch Midazolam Multivitamin Acetaminophen Atracurium Fentanyl Midazolam Norepinephrine			000000000					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
19-May-2020	178066	DIRECT	Υ	LT				60 YR	Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
General Physical Heal Deterioration; Haemodynamic Instab Pneumothorax; Pulmo Embolism; Sepsis; Sh	oility; onary	Remdesivir			S					Not Reported
FDA Received Date	Case #	<u>Case Type</u>	<u>Health</u>	Prof Ou	tcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	178066	DIRECT	Υ	ОТ				45 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer	ase	Remdesivir	Υ		S	Intravenous bolus				Gilead
Increased		Bisacodyl Suppository Bumetanide 1mg Inj Ceftriaxone 2g Inj Chlorhexidine 0.12% Swish Enoxaparin 100mg Fentanyl 100mcg/Hr Ipratropium-Albuterol Neb Lactated Ringer Infusion Potassium Phosphate 15mmol Bolus Propfol Infusion 40mcg/Kg/Min Rocuronium 10m/MI Infusion			000000000000000000000000000000000000000					Not Reported

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	Vanc	omycin			С					N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806653	DIRECT	Υ	LT	•				29 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Caesarean Section; For Heart Rate Abnormal; Haemodynamic Instab Respiratory Failure		desivir			S					N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806658	DIRECT	Υ	0	Γ				55 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blood Creatinine Increased; Condition Aggravated; Haemodialysis	Amlo Asco Ceftri Doxy	desivir Eua dipine 5mg rbic Acid 1000mg iaxone 1g cycline 100mg emide 40mg ırin			\$ C C C C C					N N N	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2020	17806695	DIRECT	Υ	0	Γ				75 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>
Atrial Fibrillation; Blood	d Remo	desivir			S	Intravenous drip				C	Gilead
Creatinine Increased; Body Temperature Increased; Infusion Related Reaction					C C C	·				N	lot Reported lot Reported lot Reported lot Reported
	Hydra Loraz Comb	alazine zepam bivent Respimat rbic Acid			0000					N N	Not Reported Not Reported Not Reported Not Reported Not Reported

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						Detailed Ne	port			
	Lev	olecalciferol vothyroxine c Sulfate			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
19-May-2020	17806699	DIRECT	Υ	0	Γ			72 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u> Mfr</u>
Acute Kidney Injury; Ac Respiratory Distress	cute Re	mdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
Syndrome; Septic Sho	Cis Fer Pro	repinephrine atracurium ntanyl opofol dazolam			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
19-May-2020	17806709	DIRECT	Υ	RI				54 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Wfr</u>
Bradycardia	Re	mdesivir			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
19-May-2020	17806721	DIRECT	Υ	DI	E, LT, OT			72 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Acute Kidney Injury; FI	luid Re	mdesivir			S	Intravenous bolus				Gilead
Overload; Hypoxia; Respiratory Disorder; Shock	Be Ce Ch Cis	etaminophen nsonatate fepime lorhexidine atracurium xmedetomidine			C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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	Fer He Hyd Iop Lac Lor Ma Me Me Me	nephrine ntanyl parin droxychloroquine amidol ctated Ringers azepam gnesium Sulfate latonin taclopramide toprolol Tartrate rphine			0000000000000		P • • • • • • • • • • • • • • • • • • •			Not Reported
FDA Received Date		Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	Age	Sex	Country
		DIRECT	Y		E, OT	<u> 331113111</u>	<u>5052 i domity</u>	72 YR		USA
19-May-2020	17806725	DIRECT	Ť	Di	Ξ, Ο1			72 TK	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney Injury; Cardiac Arrest; Hypernatraemia; Metabolic Acidosis; Paralysis; Respiratory Acidosis; Respiratory Failure	De Enn Ins Me Q1 Lor Me Q1 Do Epi Pho Epo Soo At Val Pip He Am	azepam 2 Mg Iv Q4h Prn ophed Infusion thylprednisolone 40 Mg Iv			% 0000 000 00000 00000	Intravenous (not otherwise specified)				Not Reported



	Rocu	hine Infusion ronium Infusion zumab 800 Mg Iv X1 Dose			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
19-May-2020	17806729	DIRECT	Υ		DE			92 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Remo	desivir			S	Intravenous bolus	Other Frequency:Once;			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
19-May-2020	17806734	DIRECT	Υ		DE			96 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Electrocardiogram Abnormal; Renal Failu		desivir Eua			S	Intravenous (not otherwise specified)				Gilead
Respiratory Failure		rbic Acid 500 Mg			С					Not Reported
		oime 1 Gram calciferol 50,000 Units			C C					Not Reported Not Reported
		omorphone 0.2 Mg Iv			Č					Not Reported
		ylprednisolone 40 Mg			С					Not Reported
	Inject Panto	oprazole 40 Mg Tablet			С					Not Reported
		a 17.2 Mg			C					Not Reported
		ım Chloride 0.9% Neb			С					Not Reported
		Sulfate 220 Mg zapine 7.5 Mg			C C					Not Reported Not Reported
		hine 4 Mg/MI Injection			C					Not Reported
		emide 20 Mg			Č					Not Reported
		oinephrine 8 Mg / 250 Ml			Č					Not Reported
		omycin			С					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	17806736	DIRECT	Υ		DE			54 YR	Male	USA

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Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mf</u>	<u>r</u>
Arrhythmia; Clinical Trial	Remdesi	vir Eua	Υ		S				N	ot Reported
Participant; Product Use In	Amikacin	1			С				N	ot Reported
Unapproved Indication;	Ascorbic	Acid			С				N	ot Reported
Pulseless Electrical	Aspirin				С				N	ot Reported
Activity; Tachycardia	Vasopres				С					ot Reported
	Cefepime				С					ot Reported
	Cholecal				С					ot Reported
	Diphenhy				С					ot Reported
	Docusate				С					ot Reported
	Doxycycl				С					ot Reported
	Enoxapa				С					ot Reported
	Fentanyl				С					ot Reported
	Robituss				С					ot Reported
	Insulin Li				C					ot Reported
	Tocilizum				C					ot Reported
	Melatonii				С					ot Reported
		ednisolone			С					ot Reported
	Midazola				С					ot Reported
	Monteluk				С					ot Reported
	Pantopra				С					ot Reported
	Vancomy				С					ot Reported
	Norepine	phrine			С				N	ot 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
19-May-2020 1780	06739	DIRECT	Y	(TC			46 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Cholelithiasis; Clinical Trial Participant; Product Use In Unapproved Indication; Sepsis; Shock;	Remdesi	vir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		G	ilead
Transaminases Increased										
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
19-May-2020 1780	06745	DIRECT	Υ	(TC			40 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>

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S Alanine Aminotransferase Remdesivir Gilead Intravenous (not Increased; Aspartate otherwise specified) Aminotransferase Increased **Case Type Health Prof** Outcomes Mfr Control # FDA Received Date Case # 503B Facility Sex Country <u>Age</u> 19-May-2020 17806790 DIRECT Υ OT 49 YR Female USA **Preferred Term Product** Comp. **OTC** Role **Route Dosage Text Duration** Mfr **Blood Alkaline** Remdesivir S Gilead Intravenous (not Other Frequency:Once; Phosphatase Increased: otherwise specified) **Blood Pressure** С Atorvastatin Not Reported Decreased; Body С Ceftriaxone Not Reported Temperature Increased С Desvenlafaxine Not Reported С **Epoetin Alfa** Not Reported Ċ Famotidine Not Reported С Heparin Not Reported С Hydrocortisone Sodium Not Reported Succinate С Insulin Glargine Not Reported С Not Reported Insulin Lispro С Not Reported Methadone С Metoprolol Not Reported С Potassium Chloride Not Reported Ċ Pregabalin Not Reported С Azithromycin Not Reported С Hydroxychloroguine Not Reported FDA Received Date Case # Case Type **Health Prof Outcomes** Mfr Control # 503B Facility Age Sex Country 17807091 DIRECT Υ DE 70 YR Male USA 19-May-2020 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text** Duration Mfr Remdesivir (Euc) (Remdesivir S Not Reported Death (Eau)) FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Age Sex Country RΙ 19-May-2020 17807562 DIRECT Υ 79 YR USA Female

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Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text		<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation; Blood Creatinine Increased;	(Eua D	esivir 100 Mg/20 Ml Iv Prug)			S	Intravenous (not otherwise specified))				Gilead
Blood Pressure Systolic	Cefepi	me			С						Not Reported
Increased; Glomerular	Δnan				Č						Not Reported
Filtration Rate Decrease	ca/Vit	D			C						Not Reported
Increased Bronchial		sium Sulfate			Č						Not Reported
Secretion; Oxygen	Quetia				С						Not Reported
Saturation Decreased;	Morph				С						Not Reported
Po2 Decreased	Pravas				С						Not Reported
	Ezetim	ibe			Ċ						Not Reported
	Fluoxe	tine			С						Not Reported
	Memai	ntine			С						Not Reported
	Rivaro				C						Not Reported
	Docus	ate			С						Not Reported
	Famot	dine			С						Not Reported
	Calcito	nin			С						Not Reported
	Kcl				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
19-May-2020 1	17807632	DIRECT	Υ	DI	E				77 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text		<u>Duration</u>		<u>Mfr</u>
Death	Remde (Eua))	esivir (Euc) (Remdesivir			S						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
20-May-2020 1	17807338	DIRECT	Υ						8 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text		<u>Duration</u>		<u>Mfr</u>
Incorrect Product Formulation Administere Product Use Issue	Remde ed;	esivir			S						Not Reported
FDA Received Date C	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B	Facility	<u>Age</u>	<u>Sex</u>	Country

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<u>Preferred Term</u>	<u>P</u>	roduct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Hypoxia; Pneumomediastinum	Ro	emdesivir			S				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
20-May-2020	17807341	DIRECT	Υ	0	Т			54 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased	ase Ro	emdesivir	Y		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
20-May-2020	17807897	DIRECT	Υ	0	Т			59 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Aspartate Aminotransferase		emdesivir 200mg	Υ		S	Intravenous (not otherwise specified)			G	ilead
Increased; Transamina Increased	ases Ro	emdesivir 100mg	Υ		S	Intravenous (not otherwise specified)			G	ilead
		emdesivir 100mg	Υ		S					ilead
		emdesivir 100mg	Υ		S					ilead
		ydromorphone			С					ot Reported
		cetaminophen			С					ot Reported
		ofran td3			С					ot Reported
		tralac			C C					ot Reported ot Reported
		eroquel			C					ot Reported
		alcium Gluconate			C					ot Reported
		asix			C					ot Reported
		ovenox			Č					ot Reported
		iralax			Č					ot Reported
		enadryl			Č					ot Reported
		evophed			Č					ot Reported
		agnesium Sulfate			C					ot Reported
		otassium Chloride			С					ot Reported

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		Clozaril			С					Not Reported
		Propofol			C					Not Reported
		Amidate			00000000000000					Not Reported
		Quellcin			Č					Not Reported
		Fantanyl			С					Not Reported
		Versed			С					Not Reported
		Humulin			С					Not Reported
		Humalog			С					Not Reported
		Ancef			С					Not Reported
		Protonix			C					Not Reported
		Flagyl			C					Not Reported
		Rocephin			C					Not Reported
		Vancomycin			C					Not Reported
		Zenpep Prilosec			C					Not Reported Not Reported
		Potassium Bicarbonate			C					Not Reported
		Zemuron			C					Not Reported
		Convalescent Plasm			Č					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	178100	DS6 EXPEDITED (15-DAY)		Н	O, OT	US-GILEAD-20 0467380	020-	69 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; BI	lood									
Creatinine Increased;	1000	Remdesivir			S	Intravenous (not otherwise specified)	100 Mg, 5 Mg/Ml Qd		(Gilead
	1000	Remdesivir Potassium Chloride			s C					Gilead Not Reported
Creatinine Increased;	ioou)		١	
Creatinine Increased;	iood	Potassium Chloride			С) Unk		N	Not Reported
Creatinine Increased;	lood	Potassium Chloride Etomidate			C C) Unk Unk		1	Not Reported
Creatinine Increased;	lood	Potassium Chloride Etomidate Succinylcholine Bromide			C C C		Unk Unk Unk Unk		7 7 7	Not Reported Not Reported Not Reported
Creatinine Increased;	iood	Potassium Chloride Etomidate Succinylcholine Bromide Fentanyl			C C C		Unk Unk Unk Unk Unk		n n n	Not Reported Not Reported Not Reported Not Reported
Creatinine Increased;	ioou	Potassium Chloride Etomidate Succinylcholine Bromide Fentanyl Naloxone			C C C C		Unk Unk Unk Unk Unk Unk		1 1 1 1	Not Reported Not Reported Not Reported Not Reported Not Reported
Creatinine Increased;	iood	Potassium Chloride Etomidate Succinylcholine Bromide Fentanyl Naloxone Piperacillin/Tazobactam			C C C C C		Unk Unk Unk Unk Unk Unk Unk Unk			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Creatinine Increased;	ioou	Potassium Chloride Etomidate Succinylcholine Bromide Fentanyl Naloxone Piperacillin/Tazobactam Norepinephrine			C C C C C		Unk Unk Unk Unk Unk Unk Unk Unk Unk		7 7 7 7 7	Not Reported



							Dotalica No	POIL					
		Bisacody	l Sandoz			С		Unk				Not R	eported
		Gabaper	ntin			С		Unk				Not R	eported
		Insulin Li Propofol	spro			C C		Unk					eported eported
	;	Senna A	cutifolia			С		Unk				Not R	eported
		Furosem Sodium]	ide [Furosemide			С	Intravenous (not otherwise specified)	40 Mg, Onc	ce			Not R	eported
		Hydroxyd	chloroquine			С	,	Unk				Not R	eported
		Enoxapa	rin			С		Unk				Not R	eported
		Heparin				С		Unk				Not R	eported
		Metolazo	ne			С		10 Mg				Not R	eported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	<u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>		Country
20-May-2020	178109	51	DIRECT	Υ						58 YR	Female)	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Tex	<u>t</u>	<u>Duration</u>		<u>Mfr</u>	
Vomiting		Remdesi	vir	Υ		S	Intravenous drip			5 DAY		Gilea	d
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	<u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>		<u>Country</u>
20-May-2020	1781095	57	DIRECT	Υ	(ОТ				74 YR	Female)	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Tex	<u>t</u>	<u>Duration</u>		<u>Mfr</u>	
Burning Sensation		Remdesi	vir			S	Intravenous bolus					Gilea	d
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control #	<u>503</u>	BB Facility	<u>Age</u>	<u>Sex</u>		<u>Country</u>
20-May-2020	1781096	62	DIRECT	Υ	(ОТ				69 YR	Male		USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Tex	<u>t</u>	<u>Duration</u>		<u>Mfr</u>	
Acute Kidney Injury; B	lood	Remdesi	vir Iv	Υ		S	Intravenous drip					Gilea	d
Creatinine Increased; Blood Urea Increased			spart Sliding Scale ol Injection			C C	ar enede drip						eported eported

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							•				
	Cisat	racurium Injection			С						Not Reported
		pinephrine Injection			С						Not Reported
		ofol Injection			С						Not Reported
		anyl Injection			С						Not Reported
		pressin Injection			С						Not Reported
		omycin Injection			С						Not Reported
		oime Injection			С						Not Reported
		aparin Injection			С						Not Reported
	Panto	oprazole Injection			С						Not Reported
		zumab Injection			C C						Not Reported
	Digo	kin Injection									Not Reported
		tonin Tablet			С						Not Reported
	Aspir	in 325mg Tablet			С						Not Reported
	Furos	semide Injection			000						Not Reported
		lazone Tablet									Not Reported
	Insuli	n Glargine			С						Not Reported
	Atorv	astatin Tablet			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
20-May-2020	17810969	DIRECT	Υ	0	Т				57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Blood Biliru Increased		desivir			S						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
20-May-2020	17810975	DIRECT	Υ	H	O, OT				73 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</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>Dutcomes</u>	Mfr Control:	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17810977	DIRECT	Υ	(DT			21 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Haemofiltration	Remo	lesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Stat 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
20-May-2020	17810978	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>
Blood Creatine Increas	sed; Remo	lesivir			S	Intravenous drip				Gilead
Haemofiltration		zumab			С	·				Not Reported
	Linez				С					Not Reported
		aparin			С					Not Reported
	Vitam Thian				C C					Not Reported Not Reported
	Pepci				Č					Not Reported
	Zinc	u .			č					Not Reported
	Prece	dex			Č					Not Reported
	Fenta	nyl			С					Not Reported
	Propo				С					Not Reported
		onium			C					Not Reported
	Cisati	acurium			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
20-May-2020	17810988	DIRECT	Υ					60 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; Rer njury	nal Remo	lesivir			S					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
	17810994	DIRECT	Υ		DT			55 YR	Male	USA

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<u>Preferred Term</u>	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Hypotension; Infusion Related Reaction	Remd	esivir	Υ		S	Intravenous (not otherwise specified)				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-May-2020	17811012	DIRECT	Υ	(TC			35 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Renal	Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
Impairment; Respirator	y Amlod	lipine 10 Mg Daily			С	. ,				Not Reported
Failure		oic Acid 500 Mg Po Bid			С					Not Reported
	Aspirir	n 81 Mg Po Daily			С					Not Reported
		exone 1g Iv Daily			С					Not Reported
		se 5% Iv, 100 MI/Hr			С					Not Reported
		nhydramine 25 Mg Iv X 1			C					Not Reported
		ycline 100 Mg Po Bid			С					Not Reported
	Po Bio				С					Not Reported
		parin 40 Mg Sq Bid			С					Not Reported
		tidine 20 Mg Bid			С					Not Reported
		nyl Iv Infusion			С					Not Reported
	40 Mg				С					Not Reported
		lazine 10 Mg Iv Q4h Prn			С					Not Reported
		ar Insulin Infusion			С					Not Reported
		Glargine			C					Not Reported
		Lispro			С					Not Reported
		nine Infusion			С					Not Reported
		Iprednisolone Iv			С					Not Reported
		lukast			С					Not Reported
		nsetron zumab Iv			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
20-May-2020	17811020	DIRECT	Υ		DE			72 YR	Male	USA



Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous bolus				Gilead
	Aspir	in			С					Not Reported
		romycin			С					Not Reported
	Cefaz				Ċ					Not Reported
		ricurium			Č					Not Reported
	Hepa				Č					Not Reported
		ocortisone			Č					Not Reported
		oxychloroquine			Č					Not Reported
		n Glargine			Č					Not Reported
		n Lispro			Č					Not Reported
		oprazole			Č					Not Reported
	Propo				Č					Not Reported
		ronium			C					Not Reported
		ım Bicarbonate			C					Not Reported
										Not Reported
		omycin			C C					
		ronium			C					Not Reported
		otensin li			С					Not Reported
		omorphone			С					Not Reported
	Fenta				С					Not Reported
	Midaz				С					Not Reported
		oinephrine ·			С					Not Reported
		pressin			С					Not Reported
FDA Received Date Ca	ase #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020 17	7811029	DIRECT	Y		ОТ			72 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	e Remo	desivir Injection			S	Intravenous (not otherwise specified)			Gilead
Aminotransferase	Aceta	minophen			С		,			Not Reported
ncreased		romycin			Ċ					Not Reported
		onatate			Ċ					Not Reported
		aparin			Č					Not Reported
		enesin			Č					Not Reported
		sium Chloride			Č					Not Reported
	Melat				Ċ					Not Reported

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	Valsa Vand	artan comycin			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
20-May-2020	17811036	DIRECT	Υ					66 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Respiratory Fail Blood Creatinine Increased	ure; Rem	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
20-May-2020	17811043	DIRECT	Υ	0	т			56 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Glomerular Filtration R Decreased; Therapy Interrupted	Amlo Cefe Enox Insul Insul Duo- Linez Morp Panto Aceta Fenta	aparin in Aspart in Detemir Neb colid hine oprazole aminophen			s	Intravenous bolus			1 1 1 1 1 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
20-May-2020	17811050	DIRECT	Υ	D	E			76 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
General Physical Heal Deterioration; Respirat Failure; Septic Shock;	tory	desivir	Υ		S	Intravenous bolus			(Gilead

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Therapy Cessation										
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	17811056	DIRECT	Υ	0	Т			71 YR	Male	AFG
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Platelet Count Decreas	sed Rer	mdesivir	Υ		S	Intravenous drip				Gilead
	Vita Zini Allc Azii Ber Cef Dip Enc Insi Insi Zes Mei	max amin C 1000mg c 220 appurinol 300mg thromycin nzonatate ftriazone 1gm yridamole axaparin ulin Glargine ulin Lispro storectic ropenem thylprednisolone dnisone			00000000000000					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
20-May-2020	17811063	DIRECT	Υ					49 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera	ase Rer	mdesivir	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
20-May-2020	17811080	DIRECT	Υ	D	E			70 YR	Female	e USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Ventricular Fibrillation	Rer	mdesivir	Υ		S	Intravenous bolus				Gilead
	Alb	umin 5% 25g			С					Not Reported

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								P			
		Bumetanide 1n	ng Q12h g With Vit D 5mcg			C					Not Reported Not Reported
		2 Daily Ceftriaxone 2g	Iv Daily			С					Not Reported
		Enoxaparin 80				С					Not Reported
		Furosemide 20				С					Not Reported
		Norepinephrine Infusion	· ·			С					Not Reported
		Oxycodone 5m				С					Not Reported
		Pantoprazole 4				C					Not Reported
			on 25mcg/Kg/Min			C					Not Reported
		Psyllium 58.6%				С					Not Reported
		Ribavirin 600m				С					Not Reported
		Sertraline 150r	ng Daily			С					Not Reported
		Vitamin D 2000) Units Daily			С					Not Reported
FDA Received Date	Case #	Case	<u>Type</u>	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	178110	088 DIRE	СТ	Υ		ОТ			27 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase	Remdesivir Via	Emergency Use			S	Intravenous drip				Not Reported
Aminotransferase			alescent Plasma			С					Not Reported
Increased; Blood Alkal	ine		0 Mg Iv In 100 MI			Ċ					Not Reported
Phosphatase Increase		Nacl	· ·								
Haemofiltration; Liver			0 Mg Iv In 100 MI			С					Not Reported
Function Test Increase Renal Impairment; Rig Ventricular Dysfunction	ht	Nacl									
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	178110	92 DIRE	СТ	Υ		HO, LT, OT			34 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blister; Erythema; Ras Macular	h	Remdesivir Acetaminopher Morphine Vancomycin	า			s C C					Gilead Not Reported Not Reported Not Reported



						Detailed Re	port			
		ine arin one			0000000					Not Reported
FDA Received Date Cas	se #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020 178	311136	DIRECT	Y	D	S, HO, LT,	ОТ		42 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Eye Movement Disorder; Hypoxia; Lung Infiltration; Miosis; Pyrexia; Respiratory Distress; Tachycardia; Unresponsive To Stimuli; Unresponsive To Stimuli	Prn Azithron Enoxapa Famotid	nophen 650mg Po Q4h nycin 500mg Po Daily arin 40mg Subq Daily ine 20mg Po Daily etron 4mg Iv Q6h Prn			s c c c c c	Intravenous drip				Gilead Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date Cas		Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
20-May-2020 178	311139	DIRECT	Υ	Н	IO, LT			53 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Oxygen Saturation Decreased; Respiratory Distress	Aspirin E Doxycyc Atorvast Pyridost Calcium Ceftriaxo Acetami Zinc Ondanso	Il nzaprine Ec Sline atin igmine Carbonate one nophen etron ydramine			%0000000000000					Gilead Not Reported



	Famo	tidine			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-May-2020	17811147	DIRECT	Υ		DS, HO, LT			60 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Carotid Artery Occlusion	on; Remd	esivir			S	Intravenous (not otherwise specified)				Gilead
	Aspiri Azithr Ceftria Furos Hydro Magn	omycin axone emide xychloroquine Or Placebo esium Sulfate sium Bicarbonate			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>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2020	17811158	DIRECT	Υ		DE			60 YR	Male	ALB
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Oxygen Saturation Decreased	Remd	esivir			S		Other Frequency:Loadin Dose;	g		Gilead
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
20-May-2020	17812033	DIRECT	Υ					63 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Hypotension; Rash;	Remd (Eua)	esivir (Eua) (Remdesivir			S	Intravenous (not otherwise specified)				Not Reported
Tachycardia					_		500D F			
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>

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<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mf</u>	<u>r</u>
Hepatic Failure; Hypertension; Hypotension; Multiple Organ Dysfunction Syndrome; Oxygen Saturation Decreased		desivir			S	Intravenous (not otherwise specified)		1 DAY	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
21-May-2020	17812224	DIRECT	Υ	DI	≣			41 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Condition Aggravated Lung Disorder; Pulmo Embolism; Sudden De	nary _{Pemo}	lesivir Iesivir			S C	Intravenous bolus				ilead 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	DI	≣			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Death	Remo	desivir	Υ		S	Intravenous (not otherwise specified)			Gi	ilead
	Sarilu				С	,				ot Reported
	Apixa				С					ot Reported
		emide			C					ot Reported
		theylene Glycol osides			C C					ot Reported ot Reported
	Bisac				C					ot Reported
		Sulfate			Č					ot Reported
		bic Acid			Č					ot Reported
		alazine			С					ot Reported
	Ferro	us Sulfate			С					ot Reported
	Docus				С					ot Reported
	Metop				С					ot Reported
	Ropin				C					ot Reported
		ulosin			C					ot Reported
	Carbi	dopa/Levodopa			С				No	ot Reported



	Finas	rtan ketine kteride oprazole			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
21-May-2020	17812244	DIRECT	Υ	D	E			79 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Death	Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
	Levet Enox Cyan Folic Finas Teraz Panto Aspir	teride zosin oprazole			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
21-May-2020	17812245	DIRECT	Υ	0	Т			50 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Chills; Hypotension	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
21-May-2020	17812248	DIRECT	Υ					67 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Poor Quality Product Administered; Product Storage Error		desivir			S					Not 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
21-May-2020	17812559	DIRECT	Υ	O	Γ			64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hyperhidrosis;		lesivir			S	Intravenous bolus				Gilead
Hypotension; Vomiting	Aspiri Prece Diltia: Docu Dulox Enox: Ferro Furos Halop Hydra Lantu Insuli Lacto Loraz Magn	edex zem sate setine aparin us Sulfate semide seridol alazine s n Lispro bacillus epam esium Oxide y/prednisolone sium Chloride a quel			000000000000000000000000000000000000000					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
21-May-2020	17812562	DIRECT	Υ	OT	Г			70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Infusion Site Extravasa	ation Remo	lesivir			S	Intravenous drip				Gilead
	Remo	lesivir			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
21-May-2020	17812592	DIRECT	Υ					69 YR	Male	USA

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Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u> Fext</u>	Duration	<u>M</u>	<u>fr</u>
Liver Function Test Increased	Remd	esivir	Υ		S	Intravenous (not otherwise specified)			G	Gilead
	Actem	n ohed net did olprednisolone			00000000		,			N N N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812596	DIRECT	Υ	C	T				74 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage -	<u> Fext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Supraventricular Tachycardia	Remd	lesivir			S					G	Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17812599	DIRECT	Y						39 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage ⁻	<u> Fext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Dysphagia; Throat Irritation	Remd	esivir			S					٨	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	<u>#</u>	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	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u> Fext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Malfunction; Medication Error	Remd	lesivir			S	Intravenous (not otherwise specified	Unk)			G	Silead

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020	17815405	DIRECT	Υ	0	Γ			53 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Remo	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
21-May-2020	17815427	DIRECT	Υ					69 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Body Temperature Increased; Condition	Remo	desivir			S	Intravenous (not otherwise specified)	Other Frequency:X1 Then100mg Q24h;	5 DAY		Not Reported
Aggravated	Aceta	aminophen			С	. ,				Not Reported
	Amlo	dipine			С					Not Reported
	Apixa				С					Not Reported
	Aspır Daily	in (Enteric Coated) 81 Mg			С					Not Reported
		astatin			С					Not Reported
		tropine			C C					Not Reported
	Carve				С					Not Reported
		proex			С					Not Reported
		otidine			С					Not Reported
		fenesin + Codeine Prn			C C					Not Reported
		sulosin			C					Not Reported
		in Glargine			C					Not Reported Not Reported
		in, Regular (Sliding Scale) opium And Albuterol			C					Not Reported
	Inhali				C					Not Reported
		adine			С					Not Reported
		ylprednisolone Sodium			Č					Not Reported
	Succ									
		elukast			С					Not Reported
	Morp	hine, Intravenous (Prn)			С					Not Reported
	Ibruti	nib			С					Not Reported
		oprazole			С					Not Reported
	Queti	iapine (And I Ran Out Of			С					Not Reported

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	Room	: Zosyn)									
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2020 1	7815613	DIRECT	Υ	R	I				61 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Dialysis	Remd Remd	~~			S C						Gilead Not Reported
FDA Received Date C	ase #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020 1	7763474	EXPEDITED (15-DAY)		Н	0	US-ROCHE	-2594510		47 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate	e Actem	nra			S	Intravenous (not otherwise specific	ed)				Not Reported
Aminotransferase Increased; Deep Vein	Remd	esivir			S	Unknown	•				Not Reported
Thrombosis; Intentional	Hydro	xychloroquine			S	Unknown					Not Reported
Product Use Issue; Off Label Use	Hydro	xychloroquine			S	Unknown					Not Reported
Label Ose	Loven Zosyn Tylenc Vancc Zithroi Calciu Potass Chole Melate	en amide ox [Enoxaparin Sodium] ol omycin max im Gluconate sium Chloride calciferol			000000000000						Not Reported Not Reported
FDA Received Date C	ase #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020 1	7815622	DIRECT	Υ	D	E				67 YR	Female	USA



Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Acute Respiratory Dis Syndrome; Cardiac Ai		Remdesivir Injection			S	Intravenous (not otherwise specified)				Gilead
Pulseless Electrical		Cefepime			С					Not Reported
Activity; Respiratory		Azithromycin			Č					Not Reported
-ailure		Diltiazem			Č					Not Reported
		Enoxaparin			Č					Not Reported
		Lorazepam			Č					Not Reported
		Magnesium Sulfate			Č					Not Reported
		Metoprolol Tartrate			C					Not Reported
		Potassium Chloride			Č					Not Reported
		Sodium Chloride 0.9% Iv			C					Not Reported
		Solution			C					Not Nepolied
		Hydralazine			С					Not Reported
		Morphine			C					Not Reported
		Vecuronium			C					Not Reported
		Epinephrine Drip			C					Not Reported
		Phenylephrine Drip			C					Not Reported
		Propofol Drip			C					Not Reported
		Sodium Bicarbonate Drip			C					Not Reported
										•
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	1781562	29 DIRECT	Υ		ОТ			77 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; B Creatinine Increased;	Blood	Remdesivir Injection			S	Intravenous (not otherwise specified)				Gilead
Dialysis		Cefepime			С					Not Reported
		Enoxaparin			C					Not Reported
		Duoneb			Ċ					Not Reported
		Pantoprazole			C					Not Reported
		Sodium Chloride 0.9% Iv			Ċ					Not Reported
		Solution			-					, .
		Propofol			С					Not Reported
			Hoolth	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
FDA Received Date	Case #	Case Type	пеанн	1 101	<u>Outcomics</u>					
FDA Received Date 22-May-2020	<u>Case #</u> 1781563		<u>rieaitii</u> Y		OT			78 YR	Female	

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Preferred Term	<u>Product</u>	Comp.	OTC R	ole Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Disseminated Intravascular Coagulation;	Remdesivir Injection		S	Intravenous (not otherwise specifie	ed)		Gilead
General Physical Health Deterioration; Hypotension; Hypothermia; Infusion Related Reaction	Aspirin Atorvastatin Cefepime Enoxaparin Duoneb Pantoprazole Valacyclovir Acetaminophen Propofol		0 0 0 0 0 0 0				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 Outcor	nes Mfr Contro	503B Facility	<u>Age</u>	Sex Country
22-May-2020 17815	5658 DIRECT	Υ	DE			59 YR	Female USA
Preferred Term	Product	Comp.	OTC R	ole Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
acidosis; Acute Kidney njury; Blood Lactic Acid ncreased; Cardio- Respiratory Arrest; laemoglobin Decreased; lypotension; White Blood Cell Count Increased	Remdesivir		S	Intravenous bolus			Gilead
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Outcor	nes Mfr Contro	503B Facility	<u>Age</u>	Sex Country
22-May-2020 17815	5906 DIRECT		DE, HC			69 YR	Female USA
referred Term	Product	Comp.	OTC R	ole Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Acidosis; Disseminated Intravascular Coagulation; Hypoxia; Paralysis; Renal Failure; Shock	Remdesivir Naloxone Norepinephrine Inhaled Epoprostenol Famotidine Aspirin Chewable Gabapentin Insulin Lispro		8 C C C C C C C C				Not Reported

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						Dotaliou ito	port			
	Pro Las Enc Hep Mei Eto	ntanyl pofol ix oxaparin oarin tolazone midate ccinylcholine			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
22-May-2020	17816199	DIRECT	Υ					44 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Incorrect Dose Administered; Product Dispensing Error	Alb Car Cef Fur Hep Hyo Nor	ndesivir uterol Nebulizer vedilol epime osemide parin drocortisone epinephrine ncomycin	Y		s C C C C C C C C C	Intravenous (not otherwise specified)				Gilead 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
22-May-2020	17816200	DIRECT	Υ	[DE			66 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alka Phosphatase Increase Blood Prolactin Increa Cardiac Failure Congestive; Lung Disorder; Oxygen	Use line ed; sed;	mdesivir Under Emergency e Authorization (Eua			S	Intravenous (not otherwise specified)		4 DAY		Gilead

Saturation Decreased



							, p = 1.			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816201	DIRECT	Υ	D	E			80 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Dialysis; Metabolic Acidosis; Pneumonia Viral		desivir Under Emergency Authorization (Eua)			S	Intravenous (not otherwise specified)	Other Frequency:Once;	1 DAY		Gilead
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
22-May-2020	17816202	DIRECT	Υ	0	Т			67 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)	1			Gilead
		oime cycline aparin 40 Mg Bid			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
22-May-2020	17816203	DIRECT	Υ	0	Т			68 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Bilirubin Increas		desivir Eua cycline n			S 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
22-May-2020	17816204	DIRECT	Υ	H	0			82 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Covid-19 Pneumonia;	Remo	desivir			S					Not Reported

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Disease Progression										
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	17816205	DIRECT	Υ		ОТ			56 YR	Female	USA
Preferred Term	Pro	duct	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Blood Creatinine Increased; Renal Impairment	Acei Acei Albu Apix Dex Baci Ceft Dox Mida Ferr Fluc Folic Furc Hep Mere Toci Van	openem lizumab comycin epinephrine	Y		» 000000000000000000000000000000000000	Intravenous bolus			N N N N N N N N N N N N N N N N N N N	ilead of 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	17816206	DIRECT	Υ		LT, OT			66 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Atrial Fibrillation	Rem	ndesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once Once Load;	5 DAY	G	ilead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816207	DIRECT	Υ		DE				75 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; Covid-19	Remo	desivir			S	Intravenous (not otherwise specified	d)				Gilead
	Chole Zinc S Ascor Aceta Rispe Mirta: Trazo Rispe Rosu Rivar Folic	erol 2 Mg/5ml Syrup ecalciferol Sulfate rbic Acid aminophen eridone zipine odone eridone vastatin oxaban			00000000000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816208	DIRECT			НО				62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Hypotension	Remo	desivir			S						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816211	DIRECT	Υ						78 YR	Fema	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Agitation; Anxiety; Hallucination, Visual; Intensive Care Unit Delirium	Loraz Gaba	desivir zepam Iv 0.25 Mg ipentin 100 Mg ip 1 Mg			S C C C	Intravenous drip	Other	Frequency:Once;			Gilead Not Reported 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
22-May-2020	17816477	DIRECT	Y	0	Т			75 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Transaminases Increa	sed Remo	desivir Injection			S	Intravenous (not otherwise specified)	Other F		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
22-May-2020	17816490	DIRECT	Υ	0	Т			59 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increa	sed Remo	desivir Injection			S	Intravenous (not otherwise specified)	Other Frequency:Dosing) Event Desc;		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
22-May-2020	17816502	DIRECT	Υ	0	Т			87 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>	
Liver Function Test Increased; Sars-Cov-2 Test Positive		desivir	Υ		S	Intravenous drip	Other Frequency:Once;		Gil	ead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17816556	DIRECT	Υ	Н	O, OT			84 YR	Female	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; Covid-19	Remo	desivir	Υ		S	Intravenous (not otherwise specified))		Gil	ead
	Diltiaz Enoxa	aparin semide			C C C C				No No No	nt Reported nt Reported nt Reported nt Reported nt Reported

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	Par Lor	toprolol ntoprazole azepam ntanyl			C C C				N	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
22-May-2020	17816562	DIRECT	Υ	0	Γ			53 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Transaminases Increa	sed Rei	mdesivir	Υ		S	Intravenous (not otherwise specified))		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	17816575	DIRECT	Υ	Н)			43 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Aspartate	Rei	mdesivir	Υ		S	Intravenous drip				Silead
Aminotransferase Increased; Blood Creatinine Increased; Renal Impairment; Sep Shock	No	rosemide 40 Mg Iv repinephrine			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
22-May-2020	17816997	DIRECT	Υ	Н)			65 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury; Bl Creatinine Increased;		mdesivir Solution For ection			S	Intravenous (not otherwise specified))		C	Gilead
Haemodialysis	De: Ace	oxaparin xmedetomidine etaminophen otine Patch			C C C		•		N	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-May-2020	17817002	DIRECT	Υ		ОТ			69 YR	Male	USA
Preferred Term	<u>Pı</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participan		emdesivir Under Emergency se Authorization (Eua).			S	Intravenous (not otherwise specified)				Gilead
Product Use In Unapproved Indication; Replacement	i In:	ntanyl Infusion sulin Regular (Humulin R) ding Scale			C					Not Reported Not Reported
Therapy; Respiratory Failure; Shock	Pr Er Fu In: No	opofol Infusion loxaparin (Lovenox) losemide sulin Glargine lorepinephrine (Levophed) lsopressin			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
22-May-2020	17817004	DIRECT	Υ		ОТ			39 YR	Femal	e USA
Preferred Term	<u>Pı</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participan Hepatic Enzyme Increased; Product Use Unapproved Indication		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
22-May-2020	17818496	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0468321	20-	72 YR	Male	USA
Preferred Term	<u>Pı</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney Injury; Acute Respirato	ry	emdesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Distress Syndrome; Co 19 Pneumonia; Hypernatraemia; Renal	IX.	emdesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
Impairment	· Er	oxaparin [Enoxaparin Sodium	1		С	. ,	100 Mg			Not Reported

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	Insulir	1			С		Unk				Not Reported
	Methy	Iprednisolone			С		Unk				Not Reported
	Loraz	epam A			С		Unk				Not Reported
	Levop	hed			С		Unk				Not Reported
	Dopar	mine			С		Unk				Not Reported
	Epine	phrine Hydrochloride			С		Unk				Not Reported
	Pheny	/lephrine			С		Unk				Not Reported
	Epopr	rostenol			С		Unk				Not Reported
	Vanco	omycin			С		Unk				Not Reported
	Pipera	acillin/Tazobactam			С		Unk				Not Reported
	Hepar	rin			С		Unk				Not Reported
	Amioo	darone			С		Unk				Not Reported
		nine [Ketamine			С		Unk				Not Reported
	Hydro Morph	chloride] nine			С		Unk				Not Reported
	Rocur	onium			С		Unk				Not Reported
	Tociliz	zumab			С	Intravenous (not otherwise specified)	800 Mg				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	17818529	EXPEDITED (15-DAY)			DE, LT, OT	US-GILEAD-20 0468184	20-		77 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	<u>Route</u>	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		Mfr
Death	Remd	esivir			S	Intravenous (not otherwise specified)	Unk				Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Cefep				C						Not Reported
		bic Acid			С						Not Reported
	Thiam	nine cycline			C C C						Not Reported Not Reported
		rycline Iprednisolone			C						Not Reported Not Reported
		prazole			C						Not Reported



						Detailed IX	cport				
	Tams Zinc Ipratro	aline A ulosin opium aparin			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported	
FDA Received Date	Case #	Case Type	Health Prof Outcom			Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17818539	EXPEDITED (15-DAY)		DI	E, OT	US-GILEAD-2 0468282	2020-		53 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Pulseless Electrical Activity	s Remo	desivir			S	Intravenous (not otherwise specified		g, Once			Gilead
	Oxcai	rbazepine			С		Unk				Not Reported
	Amloo	dipine			С		Unk				Not Reported
	Enoxa	aparin			С		Unk				Not Reported
	Famo	tidine			С		Unk				Not Reported
	Insulii	n Lispro			С		Unk				Not Reported
	Levet	iracetam			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
22-May-2020	17818552	EXPEDITED (15-DAY)		DI	E, LT, OT	US-GILEAD-2 0468312	2020-		72 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Hypoxia; Respiratory	Remo	desivir			S	Intravenous (not otherwise specified	100 M d)	g, Qd			Gilead
Failure; Shock	Conva	alescent Plasma			С		Unk				Not Reported
		nsetron			С						Not Reported
		prazole			00000						Not Reported
		ylephrine sium Phosphate Dibasic			C						Not Reported Not Reported
		sium Chloride			Č						Not Reported
	Prism	asate Bk0/3.5			С						Not Reported
	Prism										Not Reported
	Propo	otol			С						Not Reported



	Scop	olamine Aminoxide			С						Not Reported
		ım Chloride			C C						Not Reported
		omycin					Unk				Not Reported
		pressin			С						Not Reported
		nin B12 Aaa			С						Not Reported
		Sulfate			С						Not Reported
	Cefer				C						Not Reported
		hexidine									Not Reported
		racurium nedetomidine			C						Not Reported Not Reported
	Norm				C						Not Reported
		aparin			C						Not Reported
		ephrine			C						Not Reported
	Fenta				00000000000						Not Reported
	Hepa				Č						Not Reported
		oxychloroquine			Č						Not Reported
	lopan				С						Not Reported
		ited Ringers			С						Not Reported
		zepam			С						Not Reported
		nesium Sulfate			С						Not Reported
	Melat				C						Not Reported
		prolol Tartrate			С						Not Reported
	Morp				С						Not Reported
	Nore	pinephrine			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17818827	EXPEDITED (15-DAY)		Н	O, LT, OT	US-GILEAD-20 0468514)20-		52 YR	Female	e USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Respiratory Distress	Remo	desivir			S	Intravenous (not otherwise specified)	100 M	g			Gilead
		alescent Plasma			С	. ,					Not Reported
	-	bbenzaprine			С		Unk				Not Reported
	Aspir				С		Unk				Not Reported
	-	cycline			С		Unk				Not Reported
	Pyrid	ostigmine			С		Unk				Not Reported
	Atorv	astatin			С		Unk				Not Reported



					20101110					
C	alcium Carbonate			С		Unk				Not Reported
Z	inc			С		Unk				Not Reported
C	ndansetron			С		Unk				Not Reported
	iphenhydramine			С		Unk				Not Reported
Д	miodarone			С		Unk				Not Reported
F	amotidine			С		Unk				Not Reported
C	eftriaxone			С		Unk				Not Reported
Д	cetaminophen			С		Unk				Not Reported
Д	lbuterol [Salbutamol]			С		Unk				Not Reported
Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
1781883	1 EXPEDITED (15-DAY)			DE				96 YR	Female	USA
<u> </u>	Product	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
F	emdesivir			S	Unknown	200 N	/lg, Once			Gilead
R	emdesivir			S	Unknown		_			Gilead
Case #	Case Type	Health	Prof	Outcomes	Mfr Co	entrol #	503B Facility	<u>Age</u>	Sex	Country
1781885	B EXPEDITED (15-DAY)			HO, LT, OT				34 YR	Male	USA
<u> </u>	Product	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
	emdesivir			S	Unknown	Unk I	Лg			Gilead
lar R	emdesivir			S	Unknown	Unk I	Лg			Gilead
Д	cetaminophen			С		Unk				Not Reported
				C						Not Reported
						llnk				
V	lorphine ancomycin otassium Chloride			c c		Unk Unk				Not Reported Not Reported
V F	ancomycin			С		Unk				Not Reported
V F T	ancomycin lotassium Chloride			C C						Not Reported Not Reported
	Z C C C C A A A A A A A A A A A A A A A	Product Remdesivir Remdesivir Case # Case Type 17818858 EXPEDITED (15-DAY) Product h Remdesivir Remdesivir Acetaminophen	Zinc Ondansetron Diphenhydramine Amiodarone Famotidine Ceftriaxone Acetaminophen Albuterol [Salbutamol] Case # Case Type Health 17818831 EXPEDITED (15-DAY) Product Comp. Remdesivir Remdesivir Remdesivir 17818858 EXPEDITED (15-DAY) Product Comp. Remdesivir Remdesivir Acetaminophen	Zinc Ondansetron Diphenhydramine Amiodarone Famotidine Ceftriaxone Acetaminophen Albuterol [Salbutamol] Case # Case Type Health Prof 17818831 EXPEDITED (15-DAY) Product Remdesivir Remdesivir Remdesivir 17818858 EXPEDITED (15-DAY) Product Case # Case Type 17818858 EXPEDITED (15-DAY) Product Acetaminophen Comp. OTO	Zinc	Zinc	Zinc	Zinc	Zinc	Zinc

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ADIVI		ATTO IX				DE	etalied Re	port				
	End	oxaparin			С			Unk				Not Reported
	Cet	ftriaxone			С			Unk				Not Reported
	Alb	uterol [Salbutamol]			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
22-May-2020	17818878	EXPEDITED (15-DAY)		D	S, HO, LT	, OT	US-GILEAD-20 0468569	20-		60 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Rou	<u>te</u>	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Cerebrovascular Accid	dent Rei	mdesivir			S		venous (not wise specified)	100 Mg	g, Qd			Gilead
		mdesivir etaminophen			S C			Unk				Gilead Not Reported
	Asp	oirin [Acetylsalicylic Acid]			С			Unk				Not Reported
	Azi	thromycin			С			Unk				Not Reported
	Cef	ftriaxone			С			Unk				Not Reported
	Fur	rosemide			С			Unk				Not Reported
	Нус	droxychloroquine			С			Unk				Not Reported
	Ма	gnesium Sulfate			С			Unk				Not Reported
	Pot	assium Bicarbonate			С			Unk				Not Reported
	End	oxaparin			С			Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	<u>outcomes</u>		Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2020	17819757	DIRECT	Υ	R	:I					56 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Rou	<u>te</u>	Dosage	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participal		mdesivir (Eua) 100mg Vial	Υ		S		venous (not wise specified)					Gilead
Product Use In Unapproved Indication Renal Replacement	n; Rei	mdesivir (Eua) 100 Mgvial	Υ		S		venous (not wise specified)	Every 2	24 Hr			Gilead
Therapy	Ace	repinephrine etaminophen umin			C C C		. ,					Not Reported Not Reported Not Reported

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	Azithr	omycin			С						Not Reported
		tanide			C C C						Not Reported
	Ceftria	axone			С						Not Reported
	Clona	zepam			С						Not Reported
	Desm	opressin			С						Not Reported
	Docus	sate			С						Not Reported
	Dopar	mine			С						Not Reported
	Enoxa	aparin			С						Not Reported
	Epopr	ostenol			С						Not Reported
	Famo	tidine			С						Not Reported
	Fenta	nyl			С						Not Reported
	Furos	emide			С						Not Reported
	Hepar				С						Not Reported
		morphone			С						Not Reported
	Ketan				000000000						Not Reported
	Insulir	า			С						Not Reported
	Midod	Irine			С						Not Reported
		/lephrine			С						Not Reported
	Propo				C C C						Not Reported
		onium			C						Not Reported
	Senno				C						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	17822985	DIRECT	Υ	ОТ	-				61 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation	Remd	lesivir			S	Intravenous drip					Gilead
	Noren	pinephrine			С	•					Not Reported
	Fenta				C						Not Reported
	Midaz				C C						Not Reported
	Aceta	minophen			C						Not Reported
	Enoxa				C						Not Reported
	Famo				C						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-May-2020	17822988	DIRECT	Υ						44 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>



Product Preparation E	rror F	Remdesivir Injection	Y		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
22-May-2020	1782299	0 DIRECT	Υ		ОТ			35 YR	Male	USA
Preferred Term	ļ	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Therapy Cessation	ase F	Remdesivir			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
22-May-2020	1782299	7 DIRECT	Υ		ОТ			74 YR	Male	USA
Preferred Term	ļ	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Continuous Haemodiafiltration;	F	Remdesivir			S	Intravenous bolus	Other Frequency:Once, Then;			Gilead
Respiratory Failure; Thrombosis In Device; Urine Output Decrease		Remdesivir			S	Intravenous (not otherwise specified)				Gilead
Office Output Decrease	(Convalescent Plasma Focilizumab Or Placebo Trial			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-May-2020	1782322	0 DIRECT	Υ		RI			60 YR	Male	USA
Preferred Term	1	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Kidney Injury	/ F	Remdesivir (Eua) 100 Mg Vial	Υ		S	Intravenous (not otherwise specified)				Gilead
	F	Remdesivir (Eua) 100 Mg Vial	Υ		S	Intravenous (not otherwise specified)				Gilead
	A	Albumin			С	. ,				Not Reported

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		outerol			С					Not Reported
		metanide			С					Not Reported
		ffeine Citrate			C C					Not Reported
		lorothiazide			C					Not Reported
		oxaparin			C					Not Reported
		motidine			C					Not Reported
		rosemide			C					Not Reported
		bapentin			С					Not Reported
		sulin Glargine			C					Not Reported
		sulin Lispro			C					Not Reported
		sulin Regular			C					Not Reported
		ctulose			C					Not Reported
		ignesium Sulfate			000000					Not Reported
		ethylprednisolone			C					Not Reported
		etolazone			C					Not Reported
		dazolam			С					Not Reported
		dodrine			C					Not Reported
		ycodone			C C C					Not Reported
		peracillin/Tazobactam			C					Not Reported
		tassium Chloride			C					Not Reported
		ietiapine			C C					Not Reported
		curonium			C					Not Reported
		ncomycin			С					Not Reported
		xmedetomidine			C C					Not Reported
		oprostenol			C					Not Reported
		parin			С					Not Reported
		dromorphone			С					Not Reported
		tamine			C C					Not Reported
		repinephrine			C					Not Reported
		opofol			C					Not Reported
		sopressin			С					Not Reported
		etaminophen			C C					Not Reported
	FE	ntanyl			<u> </u>					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
23-May-2020	17822998	DIRECT	Υ					50 YR	Female	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Cough; Hypoaesthesia	ı; Re	mdesivir Eua	Υ		S	Intravenous drip				Gilead
Pruritus	Ce	ftriaxone (Rocephin) 1,000			С					Not Reported



		0.9 % Sodium Chloride 50 MI Ad								
	Ènóxa	aparin (Lovenox) (Conc: 40 0.4 MI) Injection 40 Mg			С					Not Reported
	Benzo	onatate (Tessalon Perles)			С					Not Reported
	Dextr (Cond	ule 100 Mg omethorphan-Guaifenesin c: 10-100 Mg/5 Ml) tussin Dm) Sy			С					Not Reported
	Ònda	nsetron (Zofran) (Conc: 2			С					Not Reported
	Polye	ethylene Glycol 3350 lax) Packet 17 G			С					Not Reported
	Prom Mg In	ethazine (Phenergan) 6.25 0.9 % Sodium Chloride			С					Not Reported
	Senn (8.6-5	50 MI I osides-Docusate Sodium 50 Mg/Tab) (Senna Plus)			С					Not Reported
	Simva	et 2 Table astatin (Zocor) Tablet 40			С					Not Reported
	Mg Tram	adol (Ultram) Tablet 50 Mg			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
23-May-2020	17823000	DIRECT	Υ	С	T			85 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Erythema; Pain	Remo	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
23-May-2020	17823003	DIRECT	Υ	D	E			74 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Hospice Care	Remo	desivir			S	Intravenous (not otherwise specified)				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
23-May-2020	17823009	DIRECT	Υ	C	T			39 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Malaise; Renal Impair	ment Remo	desivir			S	Intravenous (not otherwise specified)			(Gilead
	Midaz	urium zolam semide			C C C				1	Not Reported Not Reported 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-May-2020	17823018	DIRECT	Υ	F	IO, OT			49 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 Creatinine	Remo	desivir Injection			S	Intravenous drip			(Gilead
Increased	Remo	desivir			С	·			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
23-May-2020	17823020	DIRECT	Υ	L	T			64 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatinine Increased; Hyperkalae		desivir	Υ		S	Intravenous drip			(Gilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2020	17823021	DIRECT	Υ	D	E, DS			68 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	desivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;		(Gilead
	Tocili	zumab			С				1	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
23-May-2020	17823024	DIRECT	Υ					64 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransfera Increased; Aspartate		desivir (5 Mg/MI Injection centrate)			S	Intravenous (not otherwise specified	Other Frequency:Once;		(Gilead
Aminotransferase Increased	Azith Benz Ceftr Enox Meth	rbic Acid 500 Mg Tab romycin 500 Mg Ivpb conatate 100 Mg Cap iaxone 1 Gm Ivpb caparin Inj ylprednisolone 40 Mg Iv Sulfate 220 Mg Cap			000000				1 1 1 1	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-May-2020	17823028	DIRECT	Υ		ОТ			42 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatine Increas Nephropathy Toxic	sed; Rem	desivir	Υ		S	Intravenous bolus	Other Frequency:X1;		(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
23-May-2020	17823098	DIRECT	Υ		LT			66 YR	Male	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blood Creatine Increas Dialysis; Gastrointestin		desivir			S	Intravenous (not otherwise specified)		(Gilead
Haemorrhage; Glomer Filtration Rate Decreas Hepatic Failure; Hyperkalaemia;	sed; Aspii Diltia Insul				C C C	·			1	Not Reported Not Reported Not Reported Not Reported
Hypovolaemic Shock; Metabolic Acidosis; Re Failure; Shock Haemorrhagic	Proto	onix ax			000				1	Not Reported Not Reported Not Reported

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	Fenta Verse Ketar	ed			C C C					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
23-May-2020	17823103	DIRECT	Υ	LT				66 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Blo Creatine Increased;	ood Remo	desivir			S	Intravenous (not otherwise specified)				Gilead
Dialysis; Gastrointestina Haemorrhage; Glomeru Filtration Rate Decrease Hepatic Failure; Hypovolaemic Shock; Liver Function Test Increased; Shock Haemorrhagic	ılar Diltia ed; Insuli	zem n Lispro ylprednisolone nix x nox n mine ed			000000000000	•				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-May-2020	17823031	DIRECT	Υ					62 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; Liver Function		desivir	Υ		S	Intravenous (not otherwise specified)				Gilead
Test Increased	Huma Levo	nox anyl alazine alog ohed orazole			0000000	. ,				Not Reported
	Humi				C					Not Reported Not Reported

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	Vecui Keppi Solun Tylen Melat	ed Im Bicarbonate ronium ra nedrol ol onin Jlycerin			000000000					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
24-May-2020	17823035	DIRECT	Υ					31 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Eua F	Remdesivir	Υ		S	Intravenous (not otherwise specified	l)			Not Reported
	Lover	nox			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-May-2020	17823037	DIRECT	Υ	0	Т			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>
Vomiting	Remo	desivir			S	Intravenous drip				Gilead
	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
24-May-2020	17823040	DIRECT	Υ	0	Т			79 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	Remo	desivir			S	Intravenous bolus				Gilead
	Aspiri Atorva Fenta Hepa	astatin ınyl			C C C					Not Reported Not Reported Not Reported Not Reported

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	Insuli Lactu Levot Norep Panto Propo Queti Senn	chyroxine binephrine oprazole ofol apine			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
24-May-2020	17823060	DIRECT	Υ	(ТС			81 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
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		0			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
24-May-2020	17823067	DIRECT	Υ	İ	DE			86 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<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	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2020	17823073	DIRECT	Υ	I	НО			68 YR	Female	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					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
24-May-2020	17823078	DIRECT	Υ	DI	Ε			68 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Haemodialysis	Remo	desivir			S	Intravenous (not otherwise specified)				Not Reported
	Fenta Methy Insuli Insuli Vanc Dapto Labe Duon Atorv Bupro Cefep Cisat	ylprednisolone in Glargine in Lispro in Regular comycin omycin talol ieb Nebulizer castatin opion			000000000000000					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	17823118	DIRECT	Υ	0	Т			54 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous bolus				Gilead
	Nore Vanc Piper Propo	zolam pinephrine omycin racillin/Tazobactam ofol			C C C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	Selin Senn				C C					Not Reported Not Reported

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		Trazodone Zinc			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
24-May-2020	178231	25 DIRECT	Υ		ОТ				71 YR	Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Blood Lactic Acid Decreased; Renal Injur	ry;	Remdesivir Injection			S	Intravenous (not otherwise specified)		equency:Once;			Gilead
Respiratory Rate Increased; Septic Shoo	·k·	Apixaban 5 Mg			С						Not Reported
Tachypnoea; Urinary	ν,	Aspirin 81 Mg			С						Not Reported
Casts		Insulin Lispro Sliding Scale			C C						Not Reported Not Reported
		Norepinephrine Infusion Vasopressin Infusion			C						Not Reported Not Reported
		Cisatracurium Infusion			Č						Not Reported
		Propofol Infusion			С						Not Reported
		Fentanyl Infusion			C						Not Reported
		Tocilizumab 400 Mg			С						Not Reported
		Unfractionated Intravenous Heparin			С						Not Reported
		Piperacillin/Tazobactam 4.5			С						Not Reported
		Grams Q6h			Ü						rtot rtoportou
		Vancomycin 1250 Mg Q12h			С						Not Reported
		Tradipitant/Placebo			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
25-May-2020	178209	23 EXPEDITED (15-DAY)			DE, OT	US-SA-2020SA	130868			Male	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Disseminated		Lovenox			S	Subcutaneous	40 Mg, C	Qd			Sanofi
Intravascular Coagulati Intra-Abdominal Haemorrhage;	ion;	Remdesivir			S	Intravenous (not otherwise specified)	Unk				Not Reported
Retroperitoneal		Ascorbic Acid			С	. ,	Unk				Not Reported
Haemorrhage; Septic		Fenofibrate			С		Unk				Not Reported
Shock; Shock		Heparin			С		Unk				Not Reported



						Dotalloa IX	5 6 6 1			
	Methy	ylprednisolone			С		Unk		ļ	Not Reported
	Nph I	nsulin			С		Unk			Not Reported
		n Human;Insulin Human ion, Isophane			С		Unk		I	Not Reported
		ım Chloride			С		Unk		I	Not Reported
	Sitag	liptin			С		Unk		!	Not Reported
	Midaz	zolam			С		Unk		!	Not Reported
	Panto	pprazole			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
25-May-2020	17823157	DIRECT	Υ	0	Т			32 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>
Hepatic Enzyme	Remo	desivir	Υ		S	Intravenous drip			(Gilead
Increased	Albut	erol Hfa 90mcg/Puff			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
25-May-2020	17823162	DIRECT	Υ	0	Т			56 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	Zosyr Doxy	desivir n cyline axone			S C C C				<u> </u> 	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
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>N</u>	<u>lfr</u>
Bradycardia	Remo	desivir			S	Intravenous drip				Gilead
	Propo	oxychloroquine ofol omorphone			C C C				1	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
25-May-2020	17823171	DIRECT	Υ					59 YR	Female	USA
Preferred Term		<u>roduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	
Infusion Site Extravasat	tion Re	emdesivir	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
25-May-2020	17823177	DIRECT	Υ	(TC			57 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Burning Sensation	Ro	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
25-May-2020	17823181	DIRECT	Υ	(TC			75 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Hypopnoea; Infusion Related Reaction; Rash Rash Pruritic; Respirato Distress; Wheezing	n; Al Pory Ca En Su Fa In In M Po Se Ta	emdesivir lopurinol 100 Mg Tablet arvedilol 12.5 Mg Tablet noxaparin 40 Mg ubcutaneous amotidine 20mg Tablets sulin Glargine Subcutaneous sulin Lispro Subcutaneous ultivitamin Oral Tablet olyethylene Glycol 17 G Packet enna-Docusate 8.6 Mg-50 Mg ablet amoxifen 20 Mg Tablets			s c c c c c c c c					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
25-May-2020	17823188	DIRECT	Υ					60 YR	Female	USA

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Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>N</u>	<u>Nfr</u>
Alanine Aminotransferas ncreased; Aspartate Aminotransferase ncreased		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 Rosuvastatin 20 Mg Tablet			%00000 00000					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
25-May-2020	178231	95 DIRECT	Υ		ÞΕ			68 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Anxiety; Encephalopath Hypoxia; Respiratory Distress; Respiratory Failure; Unresponsive T Stimuli	ōo	Zosyn Insulin Lispro & Insulin Glargine Albuterol Combivent Amlodipine Precedex Lovenox Gabapentin Seebri Levothyroxine Ativan Lopressor Dulera Percocet			s	Intravenous (not otherwise specified)				Not Reported
FDA Received Date		Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	178232	12 DIRECT	Υ	C	DΤ			73 YR	Male	USA

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Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	•
Glomerular Filtration R Decreased; Renal Impairment	npairment				S	Intravenous (notherwise spec			No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cor	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2020	178232	217 DIRECT	Υ					89 YR	Female	USA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	: -
Administration Site Extravasation		Remdesivir			S	Intravenous dr	ip	5 DAY	Gi	lead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cor	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	177927	758 EXPEDITED (15-D)	AY)		ОТ	CH-PFIZ 2020191		61 YR	Female	CHE
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Dermatitis Exfoliative		Nexium			S	Unknown	Unk		Ur	nknown
Generalised; Eosinoph Rash Erythematous	nilia;	Nexium			S	Unknown	Unk		Ur	nknown
Trasii Erytiiciiiatous		Temesta (Lorazepam)			S	Unknown	Unk		Pfi	zer
		Zithromax			S	Unknown	Unk		Pfi	zer
		Amlodipine Besilate			S	Unknown	Unk		Pfi	zer
		Haldol			S	Unknown	Unk		No	t Reported
		Quetiapine			S	Unknown	Unk		No	t Reported
		Lasix [Furosemide Sodium]			S	Unknown	Unk		No	t Reported
		Lasix [Furosemide Sodium]			S	Unknown	Unk		No	t Reported
		Lasix [Furosemide Sodium]			S	Unknown	Unk		No	ot Reported
		Ceftriaxone			S	Unknown	Unk			ot Reported
		Clarithromycine			S	Unknown	Unk			ot Reported
		Remdesivir			S	Unknown	Unk		No	t Reported
		Anxiolit			S	Unknown	Unk		No	t Reported
		Clexane			S	Unknown	40 Mg		No	t Reported

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Clexane	S	Unknown	40 Mg	Not Reported
Dafalgan	S	Unknown	Unk	Not Reported
Dafalgan	S	Unknown	Unk	Not Reported
Solu-Medrol	С	Unknown	Unk	Not Reported
Diamox [Acetazolamide]	С	Unknown	Unk	Not Reported
Diamox [Acetazolamide]	С	Unknown	Unk	Not Reported
Diamox [Acetazolamide]	С	Unknown	Unk	Not Reported
Distraneurin [Clomethiazole]	С	Unknown	Unk	Not Reported
Novorapid	С	Unknown	Unk	Not Reported
Ipramol	С	Unknown	Unk	Not Reported
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	С	Unknown	Unk	Not Reported
Hydrochloride] 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



							•				
	Propof	ol			С	Unknown	Unk			Ne	ot Reported
	Propot	ol			С	Unknown	Unk			Ne	ot Reported
	Propof	ol			С	Unknown	Unk			N	ot Reported
		onium [Rocuronium			С	Unknown	Unk			N	ot Reported
	Bromio Tracrit				С	Unknown	Unk			N	ot Reported
	Tracriu	ım			С	Unknown	Unk			Ne	ot Reported
	Tracriu	ım			С	Unknown	Unk			Ne	ot Reported
	Colisti	n			С	Unknown	Unk			Ne	ot Reported
	Colisti	n			С	Unknown	Unk			Ne	ot Reported
	Colisti	n			С	Unknown	Unk			N	ot Reported
	Tobrar	nycin			С		Unk			N	ot Reported
	Tobrar	nycin			С		Unk			N	ot Reported
	Tobrar	nycin			С		Unk			No	ot Reported
	Ampho	otericin B			С		Unk			N	ot Reported
	Ampho	otericin B			С		Unk			No	ot Reported
	Ampho	otericin B			С		Unk			No	ot 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
26-May-2020	17822479	EXPEDITED (15-DAY)		•	ОТ	DE-ABE 341649	3VIE-20K-062- 2-00			Unknown	DEU
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	Mf	<u>r</u>
Adverse Drug Reaction	n; Kaletra	a			S	Oral				N	ot Reported
Liver Disorder; Multiple Organ Dysfunction Syndrome; Renal Failu	Rema	esivir			S	Unknown				No	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17823907	DIRECT	Υ	(ОТ				76 YR	Male	USA
Preferred Term	Produ		Comp.	OTC	Role	Route	Dosage		<u>Duration</u>	Mf	



Condition Aggravated; Diarrhoea; Dyspnoea	Remo	desivir	Y		S	Intravenous (not otherwise specified))		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17823998	DIRECT	Υ	C	E			71 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>
Liver Function Test ncreased	Remo	desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824003	DIRECT	Υ	C	T			43 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>
Liver Function Test ncreased	Remo	desivir			S				N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824009	DIRECT	Υ	C	т			73 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>
Alanine Aminotransferancreased; Aspartate	ase Remo	desivir	Υ		S	Intravenous (not otherwise specified))		G	ilead
Aminotransferase ncreased	Milrin	darone 360 Mg/200 MI one 20 Mg/100 MI binephrine			C C C				N	ot Reported ot Reported ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824025	DIRECT	Υ	D	E			73 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>
Acute Respiratory Dist Syndrome; Pneumonia Renal Failure		desivir			S				N	ot Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control:	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824060	DIRECT	Υ		DE				76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>!</u>	<u>VIfr</u>
Cardio-Respiratory Ar	rest Remo	desivir			S	Intravenous (not otherwise specified)		quency:Total;			Gilead
	Cefe	oime			С						Not Reported
	Enox	aparin			C C C						Not Reported
	Famo	otidine			С						Not Reported
	Fenta	anyl			С						Not Reported
	Hepa	rin			C C						Not Reported
	Insuli	n Lispro			С						Not Reported
	Meth	ocarbamol			С						Not Reported
	Meth	ylprednisolone Sodium			С						Not Reported
		zolam			0000						Not Reported
		pinephrine			С						Not Reported
		abalin			С						Not Reported
	Propo				С						Not Reported
	Vanc			С						Not Reported	
	Vaso	Vasopressin			С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824081	DIRECT	Υ						38 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Heart Rate Decreased	d Remo	desivir			S	Intravenous (not otherwise specified))				Gilead
	Acety	lcysteine			С	•	=				Not Reported
		rbic Acid			Č						Not Reported
		roline			Č						Not Reported
		aparin			Č						Not Reported
		n Regular			C						Not Reported
		ylprednisolone			C						Not Reported
		oprazole			C C C						Not Reported
		ethylene Glycol			Č						Not Reported
	Senn				C						Not Reported
					C						
	Fenta	aliyi			U						Not Reported



	Propo	fol			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	17824084	DIRECT	Υ					59 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>
Bradycardia	Remo	lesivir			S	Intravenous (not otherwise specified)		5 DAY		Gilead
	Atorva Citalo Enoxa Famo	aparin tidine pentin nix			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
26-May-2020	17824086	DIRECT	Υ	0	Γ			69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Aspartate Aminotransferase Increased	Famo Senno Docus Insulin Epopi Asprir Aceta Norep Hepai Methy Midoc Ampio Metol	erol Ipratropium tidine osides sate n Lispro ostenol n minophen oinephrine rin Drip r/prednisone drine sillin Sulbactam			% 00000000000000000	Intravenous drip				Gilead Not Reported

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						Detailed No	Sport			
	Furos Potas	zolamide			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
26-May-2020	17824087	DIRECT	Υ	Н	O, OT			80 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Burning Sensation; Clinical Trial Participant; Condition Aggravated; Covid-19 Pneumonia; Product Use In Unapproved Indication; Respiratory Disorder	Remd;	esivir			S					Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824088	DIRECT	Υ					85 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participant; Decreased Appetite; Product Use In Unapproved Indication	; Remd (Eua))	esivir (Eua) (Remdesivir)			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
26-May-2020	17824089	DIRECT	Υ	DI	E			82 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Cardiac Arrest; Clinical Trial Participant; Produc	Remd	esivir	Υ		S	Intravenous (not otherwise specified))			Gilead
Use In Unapproved Indication	Famo Enoxa				C C					Not Reported Not Reported

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	Lo Ce Di Gı As Ao Mi	iralax orazepam eftriaxone laudid uiafenesin spirin cetaminophen ylanta Suspension ethylprednisolone			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	17824090	DIRECT	Υ	0	Т			65 YR	Male	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participar Ischaemic Stroke; Pro Use In Unapproved Indication; Vertebral A Occlusion	duct	emdesivir	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
26-May-2020	17824149	DIRECT	Υ	RI	I			68 YR	Male	USA
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; A Kidney Injury; Clinical Participant; Product Usunapproved Indication	Trial (E se In	emdesivir (Eua) (Remdesivir ua))			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
26-May-2020	17824205	DIRECT	Υ					67 YR	Female	USA
Preferred Term	<u>P</u> i	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Procedural Hypotension	Az In:	emdesivir zithromycin sulin Aspart mlodipine			S C C C					Gilead Not Reported Not Reported Not Reported

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						Dotanoa itt	port			
	Bume Ceftria D5/Ns Fenta Gemfi Hepar Midaz Norep Panto Sodiu	s nyl brozil in			00000000000					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
26-May-2020	17824219	DIRECT	Υ	НС	O, OT			43 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Dyspnoea	Remd	esivir	Υ		S	Intravenous bolus	Other Frequency:One Time;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824509	DIRECT	Υ	НС	O, OT			73 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Pneumonia; Sepsis	Remd (Eua)	esivir (Eua) (Remdesivir			S					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824895	DIRECT	Υ	ОТ	Γ			62 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Renal Impairment; Therapy Cessation	Album Ascor	minophen	Y		S C C C	Intravenous bolus				Gilead Not Reported Not Reported Not Reported Not Reported

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							, p = 1			
		Chlorothiazide Enoxaparin Fentanyl Heparin Lidocaine Patch Metronidazole Norepinephrine Pantoprazole Propofol Vecuronium Zinc Sulfate			00000000000					Not Reported
FDA Received Date	Case #	Case Type	<u>Hea</u>	<u>lth Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178248	99 DIRECT	Υ		НО			62 YR	Female	USA
Preferred Term		Product	Com	<u>o.</u> <u>OT</u>	C Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased; Therapy Cessation		Remdesivir Eua Chlorhexidine 0.12% Sol Enoxaparin Famotidine Heparin Ipratropium-Albuterol Multivitamin Rocuronium Sennosides-Docusate Hydromorphone Lorazepam Norepinephrine	Y ution		8 00000000000	Intravenous bolus				Gilead Not Reported
FDA Received Date	Case #	Case Type	<u>Hea</u>	Ith Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	178249	26 DIRECT	Υ		ОТ			52 YR	Male	USA
Preferred Term		Product	Com	<u>o.</u> <u>OT</u>	C Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Inflammato Marker Increased;	ry	Remdesivir Acetaminophen Tab Azithromycin Iv Ceftriaxone Iv Benzonatate			s C C C	Intravenous bolus				Gilead Not Reported Not Reported Not Reported Not Reported

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Therapy Cessation	Famo Metoj Potas Phos	aparin otidine Iv prolol Iv ssium & Sodium phates Packet ssium Chloride Tab			0000 0					Not Reported Not Reported Not Reported Not Reported
		omycin Iv			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	17824932	DIRECT	Υ		ОТ			69 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme	Remo	desivir	Υ		S	Intravenous bolus				Gilead
Increased	Aspiri Atorv Ceftri Diphe Doxyi Enox: Etom Fenta Levot Norep Potas Propo Succi	astatin axone enhydramine cycline aparin idate anyl thyroxine binephrine ssium Chloride inylcholine			00000000000000					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	17824939	DIRECT	Υ		DE			39 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased	Remo	desivir	Υ		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
26-May-2020	17824944	DIRECT	Υ		DE			76 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cardiac Arrest; Dyspn Emphysema; Interstitia Lung Disease; Respira Failure; Tachycardia	al Eatory EA BA LA PA AA	emdesivir noxaparin lbuterol rovana noro Ellipta asix rednisone sulin rotonix torvastatin letformin	Y		» 0000000000	Intravenous (not otherwise specified)				Not Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	<u>Sex</u>	Country
26-May-2020	17824950	DIRECT	Y		ОТ		-	46 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	R	emdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	E F Ir L S A Z S	oriconazole Iv noxaparin luconazole luticasone Nasal Spray sulin Lispro evothyroxine enna scorbic Acid inc Sulfate odium Chloride 0.9% W/ 20 eq Kcl			000000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
	В	cetaminophen enzonatate pamidol			C C C					Not Reported Not Reported Not Reported

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						Detailed IV	Сроге			
	P V	Ondansetron Promethazine W/ Codeine Vancomycin Piperacillin-Tazobactam			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
26-May-2020	1782495	6 DIRECT	Υ	0	Т			72 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; B Creatinine Increased; Dose Calculation Error Glomerular Filtration R Decreased; Incorrect D Administered By Produ Sepsis	r; A tate C Dose C uct; C F Z C	Remdesivir ascorbic Acid Po azithromycin Iv Ceftriaxone Iv Cholecalciferol Cimetidine Po Turosemide Ivp And Gtt Cinc Gluconate Po Cisatricurium Epoprostenol Inhaled Cropofol	1		s	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
26-May-2020	1782496	0 DIRECT	Υ	Н	0			46 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	F	Remdesivir	Υ		S	Intravenous (not otherwise specified	3)	2 DAY		Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	1782496	6 DIRECT	Υ	Ľ	T, OT			79 YR	Male	USA
Preferred Term	<u> </u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Blood Creatinine Increased; Blood Urea		Remdesivir	Υ		S	Intravenous (not otherwise specified	i)	5 DAY		Gilead

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Increased; Dialysis	F A F A F E II C N	Cocilizumab Cefepime Azithromycin Centanyl Continuous Infusion Midazolam Infusion Propofol Infusion Albumin 25 Gm Infusion Camotidine 20 Mg Po Aspirin 81 Mg Curosemide 40 Mg Iv Choxaparin 40 Mg Sq Choxalin Infusion Cisatracurium Infusion Meropenem Cimovastatin 20 Mg Mitamin D 2000 Units			00000000000000000					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-May-2020	1782497	0 DIRECT	Υ	(ОТ			56 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine Increased	F	Remdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Daily After 200mg;			Gilead
	A C C E F	Ascorbic Acid Po 1000mg Bio Atorvastatin 10mg Po Daily Ceftriaxone 1gm Iiv Daily Clopidogrel 75mg Po Daily Enoxaparin 90mg Sq Q12hrs Famotidine 20mg Iv Daily Insulin Lispro Sq Sliding Scale			000000					Not Reported
	L	oratadine 10mg Po Daily Methylprednisolone 125mg lv			C					Not Reported Not Reported
	Z N F	linc 220mg Oral Bid Jorco 5/325mg Po Q6hrs Prn Tentanyl Variable Rate Continuous Iv	ı		C C					Not Reported Not Reported Not Reported
	N	Joritindous IV Jorepinephrine Variable Rate Continuous IV Propofol Variable Rate	•		C C					Not Reported Not Reported



	Con	tinuous Iv								
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	17824973	DIRECT	Υ		ОТ			41 YR	Male	USA
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Asthenia; Chromaturia Fatigue; Therapy Cessation	Azith	ndesivir nromycin epime	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
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Rash; Rash Maculo- Papular	Rem	ndesivir			S	Intravenous (not otherwise specified)				Not Reported
	Strib Prez Love Solu	zista			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	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Rem	ndesivir	Υ		S	Intravenous (not otherwise specified)	1			Gilead
		nromycin 250mg Iv assium Chloride Er 40meq			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
26-May-2020	17824984	DIRECT	Υ	0	Т				51 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme	Remo	desivir			S	Intravenous drip					Gilead
Increased; Therapy Interrupted	Aceta Aspiri Enoxa	zumab ıminophen 325 Mg ın 81mg Ec aparin 40mg Sc Bid ıprazole 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 O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824989	DIRECT	Υ	D	E				85 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Arrhythmia; Creatinine Renal Clearance Decreased; Encephalopathy; Respiratory Failure; Sudden Cardiac Death	Moda Trazo Queti				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>	<u>Sex</u>	Country
26-May-2020	17824990	DIRECT	Υ						60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Aspartate	Remo	desivir	Υ		S	Intravenous drip					Gilead
Aminotransferase Increased	Tocili	zumab			С						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020	17824991	DIRECT	Υ	0	Т				69 YR	Female	e USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		Mfr

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Aspartate	Remde	sivir	Υ		S	Intravenous bolus				Gilead
Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Liver Function Test Increased	Metock Polyeth				C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date C	ase#	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 17	7824992	DIRECT	Υ	I	НО			45 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury	Remde	sivir Injection			S	Intravenous drip				Gilead
		sivir For Injection, ized Powder, 100 Mg Vial			С					Not Reported
FDA Received Date C	ase#	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 17	7824993	DIRECT	Υ					79 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Administration Site Extravasation	Remde	sivir			S	Intravenous drip		5 DAY		Gilead
FDA Received Date C	ase #	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 17	7825230	EXPEDITED (15-DAY)								
		,			DE, OT	US-SA-2020SA	135575		Male	USA
Preferred Term	Produc		Comp.	OTC	·		135575 Dosage Text	<u>Duration</u>	Male	USA <u>Mfr</u>
Covid-19; Disseminated	Loveno	<u>et</u>	Comp.		·			<u>Duration</u>	Male	
Covid-19; Disseminated Intravascular Coagulation Intra-Abdominal	Loveno	ct x	Comp.		Role	Route	Dosage Text	<u>Duration</u>	Male	Mfr
Covid-19; Disseminated Intravascular Coagulation Intra-Abdominal Haemorrhage; Retroperitoneal	Loveno	ct x sivir	Comp.		Role S	Route Subcutaneous Intravenous (not	Dosage Text 40 Mg, Qd	<u>Duration</u>	Male	Mfr Sanofi
Covid-19; Disseminated Intravascular Coagulation Intra-Abdominal Haemorrhage; Retroperitoneal Haemorrhage; Septic	Lovence Remde Ascorb Heparii	ct x sivir ic Acid	Comp.		Role S S	Route Subcutaneous Intravenous (not otherwise specified)	Dosage Text 40 Mg, Qd Unk	<u>Duration</u>	Male	Mfr Sanofi Not Reported Not Reported Not Reported
Covid-19; Disseminated Intravascular Coagulation Intra-Abdominal Haemorrhage; Retroperitoneal	Lovence Remde Ascorb	ct x sivir ic Acid	Comp.		Role S S	Route Subcutaneous Intravenous (not otherwise specified) Unknown	Dosage Text 40 Mg, Qd Unk Unk	<u>Duration</u>	Male	Mfr Sanofi Not Reported Not Reported



	Sodiu	ım Chloride			С	Unknown	Unk				Not Reported
	Sitagl	iptin			С	Unknown	Unk				Not Reported
	Midaz	zolam			С	Unknown	Unk				Not Reported
	Panto	prazole			С	Unknown	Unk				Not Reported
	Nph I	nsulin			С	Unknown	Unk				Not Reported
		n Human;Insulin Human ion, Isophane			С	Unknown	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
26-May-2020	17826568	EXPEDITED (15-DAY)			HO, OT	US-GILEAD-20 0467857)20-		73 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	յ, 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
26-May-2020	17826572	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0467950)20-		70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	<u>Route</u>	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Renal Tubular Necrosi	s Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg	ı, Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Tocilia	zumab			С		400 Mg	J			Not Reported
		rin aparin thobenzamide			C C C		200 Mg	ı, Once			Not Reported Not Reported Not Reported
	Aceta Onda Levot	n Lispro Iminophen nsetron hyroxine crynic Acid Drolol			0000000		Unk				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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	Tra	adipitant			С		Unk			N	ot Reported
FDA Received Date C	Case #	Case Type	Health	Prof Ou	itcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020 1	17826584	EXPEDITED (15-DAY)				US-GILEAD-2 0467774	2020-			Female	USA
Preferred Term	Pr	oduct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Product Storage Error	Re	mdesivir			S	Unknown	Unk			G	ilead
FDA Received Date	Case #	Case Type	Health	Prof Ou	itcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2020 1	17827902	DIRECT	Y	DS	S, HO, LT				67 YR	Female	USA
<u>Preferred Term</u>	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Crystal Nephropathy;	Re	mdesivir			S	Intravenous drip				G	ilead
Hydronephrosis; Renal Tubular Necrosis; Respiratory Disorder; Urine Analysis Abnormal	Du An	etominophen onebs niodarone 150mg Iv Bolus ce			C C C	·				N	ot Reported ot Reported ot Reported
	Az Ce Po	ithromycin 500mg Iv Once fepime 2gm Iv tassium Chloride 20meq Iv cilizumab 400mg Iv			C C C					N N	ot Reported ot Reported ot Reported 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
26-May-2020 1	17827908	DIRECT	Υ	ТО	-				59 YR	Male	USA
<u>Preferred Term</u>	Pr	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Alanine Aminotransferas Increased; Aspartate	se Re	mdesivir			S	Intravenous (not otherwise specified	4)			G	ilead
Aminotransferase Increased; Blood Alkaline	^	orvastatin			С	- п	/				ot Reported
Phosphatase Increased;	LO	venox			С						ot Reported
Condition Aggravated;	11111	odium sartan			C C						ot Reported ot Reported
Enteritis		ntoprazole			Č						ot Reported
	Ph	osphorus			С					N	ot Reported
	To	radol			С					N	ot Reported

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						Detailed IN	•			
	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				Ċ					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>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control i	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	<u>Pr</u>	oduct	Comp.	OTO	Role	Route	Dosage Text	Duration	Mfr	
Transaminases Increa	sed Re	emdesivir Injection	Υ		S	Intravenous drip		3 DAY	Gile	ead
	All As Be De De Cr Do Er Fa Gu Or	tetaminophen 500 Mg puterol 90 Mcg Hfa porterol 90 Mcg Hfa porterol 90 Mcg Hfa porterol 90 Mcg provided State 100 Mg porterol 90 Mg porterol							Not Not Not Not Not Not Not Not Not Not	Reported
FDA Received Date		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2020	17829758	DIRECT	Υ		ОТ			48 YR	Female	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Acute Kidney Injury; Ischaemic Hepatitis; M Organ Disorder; Thera Interrupted	lulti-	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>	oduct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Blood Creatine	Re	emdesivir Injection			S	Intravenous (not	Other Frequency:Once;		Gile	ead



Phosphokinase Increase	sed;					otherwise specifi	ed)			
Therapy Cessation	F	Remdesivir			S	Intravenous (not otherwise specific		6 DAY		Gilead
		torvastatin 40 Mg Tablet			С					Not Reported
		Ceftriaxone 1 Gm Injection			С					Not Reported
		noxaparin 100 Mg Injection			С					Not Reported
		urosemide 40 Mg Injection			С					Not Reported
		lydromorphone 1 Mg Injection			С					Not Reported
	Т	lydroxychloroquine 200 Mg ablet			С					Not Reported
		orazepam 2 Mg Injection			С					Not Reported
		Meropenem 1 Gm Injection			С					Not Reported
		Pantoprazole 40 Mg Injection			С					Not Reported
		otassium Chloride Injection			С					Not Reported
		opiramate 100 Mg Tablet			С					Not Reported
		ancomycin 1 Gm Injection			С					Not Reported
		Propofol 10 Mg/MI Injection			С					Not Reported
		Sodium Bicarbonate Injection			С					Not Reported
		ecuronium Injection			C C					Not Reported
		cetaminophen Tablet								Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol # 503E	B Facility Age	<u>Sex</u>	<u>Country</u>
27-May-2020	1783012	5 EXPEDITED (15-DAY)				US-GILEAD 0468001	D-2020-	52 YR	Male	USA
Preferred Term	E	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duratio</u>	<u>on</u>	<u>Mfr</u>
Product Dose Omissio	n R	Remdesivir			S	Unknown	200 Mg			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol # 503E	B Facility Age	<u>Sex</u>	Country
27-May-2020	1783084	3 EXPEDITED (15-DAY)		(ОТ	CH-JNJFO 202005146		61 YR	Female	e CHE
Preferred Term	E	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duratio</u>	<u>on</u>	<u>Mfr</u>
TCICITCA TCITII		1-1-1-1			S	Unknown				Janssen
<u> </u>	H	laldol								NI (B)
<u> </u>		naidoi Ceftriaxone			S	Unknown				Not Reported
Rash Erythematous	C				S S	Unknown Unknown				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



							•			
	Propo Propo Propo Propo	ofol ofol ofol ronium ium ium			00000000					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	17831674	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468136	20-	52 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Hypertension	Remo	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Digox	in			С		Unk			Not Reported
	Enox	aparin			С		Unk			Not Reported
	Furos	emide			С		Unk			Not Reported
	Hydra	alazine			С		Unk			Not Reported
	Losar	tan			С		Unk			Not Reported
	[Meth	/lprednisolon ylprednisolone]			С		Unk			Not Reported
	Nebiv				С		Unk			Not Reported
	Hydro	exychloroquine			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
27-May-2020	17831684	EXPEDITED (15-DAY)			DE, HO, OT	US-GILEAD-20 0468502	20-	73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Alanine	ress Remo	lesivir			S	Unknown	200 Mg			Gilead



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

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833395	DIRECT	Υ	DE	=			63 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Death	Remo	desivir	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	<u>Prod</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Liver Function Test Increased	Remo	desivir	Y		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
27-May-2020	17833410	DIRECT	Υ	0	Γ			67 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>
Alanine Aminotransfer	rase Remo	desivir Injection	Υ		S	Intravenous drip				Gilead
Increased; Aspartate Aminotransferase Increased; Therapy Cessation	Asco Ceftri Dexa Doxy Hepa Hydra Lope	aminophen rbic Acid iaxone methasone cycline irin alazine ramide ssium Chloride			000000000	·				Not Reported

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Sodium Chloride C								=			
Preferred Term			Multivitamin Ondansetron Dextromethorphan-Guaifenesii Zinc Sulfate Docusate-Senna			C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Preferred Term	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>
Acute Respiratory Distrest Syndrome; Acute Respiratory Failure; Amiodarone Infusion C C C C C C C C C	27-May-2020	178334	14 DIRECT	Υ		ОТ			53 YR	Male	USA
Syndrome; Acute Respiratory Failure; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Aspartate Robitation Increased; Blood Alkaline Phosphatase Increased; Blood Alkaline Robitation Increased; Blood Creatinine Increased; Hypoxia; Shock; Viral Cardiomyopathy FDA Received Date Preferred Term Remdesivir Respiratory Failure; Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; Hypoxia; Shock; Viral Cardiomyopathy Respiration Resported Rota Respiration Respiration Resported Rota Respiration Rota Respiration Rota Resported Rota Respiration Rota Resported Rota Respiration Rota Resported Rota Respiration Rota Resported Rota Respiration Rota Resported Rota Respiration Rota Respiration Rota Respiration Rota Resported Rota Respiration Rota Resported R	Preferred Term		Product	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		Mfr
27-May-2020 17833420 DIRECT Y DE 64 YR Male USA Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Hypotension Remdesivir S Gilead FDA Received Date Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country	Syndrome; Acute Respiratory Failure; Alanine Aminotransfel Increased; Aspartate Aminotransferase Increased; Blood Alka Phosphatase Increase Blood Bilirubin Increase Blood Creatinine Increased; Hypoxia; Shock; Viral	rase aline ed; sed;	Amiodarone Infusion Ceftriaxone Dobutamine Infusion Doxycycline Iv Enoxaparin 40mg Q12 Famotidine 20mg Iv Q12 Fentanyl Infusion Hydrocortisone 50mg Iv Q6hr Midazolam Infusion Norepinephrine Infusion Phenylephrine Infusion Propofol Infusion Sodium Bicarbonate Inusion Vasopressin Infusion			00000000000000					Not Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Hypotension Remdesivir S Gilead FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country	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
Hypotension Remdesivir S Gilead FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country	27-May-2020	178334	20 DIRECT	Υ		DE			64 YR	Male	USA
FDA Received Date	Preferred Term		Product	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
	Hypotension		Remdesivir			S					Gilead
27-May-2020 17833421 DIRECT Y OT 24 YR Female USA	FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
	27-May-2020	178334	21 DIRECT	Υ		ОТ			24 YR	Femal	e USA

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Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Epigastric Discomfort; Nausea	Remo	lesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
	Atorv Azithı Ceftri	bic Acid astatin romycin axone aparin ol			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 #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833426	DIRECT	Υ		DE			51 YR	Female	e USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Pressure Decreased; Cardiac	Remo	desivir Solution			S	Intravenous (not otherwise specified)				Gilead
Arrest; Lethargy; Pneumothorax; Respiratory Failure	Remo	lesivir			S	Intravenous (not otherwise specified)				Gilead
itoopiiatory i aliaro	Albut	erol			С					Not Reported
		bic Acid			С					Not Reported
		astatin			С					Not Reported
	Aztre				С					Not Reported
	Bisac				С					Not Reported
	Buspi				С					Not Reported
	Carbi	dopa-Levodopa			C C					Not Reported Not Reported
		nex izepam			C					Not Reported
	Digox				C					Not Reported
	Digoz				C					Not Reported
	Lover				Č					Not Reported
	Fenta				Č					Not Reported
		enesin Er			Č					Not Reported
	Meto				Č					Not Reported
	Propo				С					Not Reported
		ridone			С					Not Reported
		edetomindine Additive			С					Not Reported
		phrine			С					Not Reported
	Fenta	lnyl			С					Not Reported

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	Var	ncomycin			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-May-2020	17833433	DIRECT	Υ		ОТ			57 YR	Male	USA
Preferred Term	Pro	oduct	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	Ace Alb Asc Asp Ato Azi Buc Cel Cho Doc End Ins Ins Lini Pal Pol Sel Tra	mdesivir Injection etaminophen uterol Hfa corbic Acid birin ervastatin thromycin desonide-Formoterol ftriaxone olecalciferol xamethasone cusate-Senna bxaparin ulin Lispro ulin Glargine agliptin inopril ntoprazole yethylene Glycol inexor imadol c Sulfate	Y		» 000000000000000000000000000000000000	Intravenous drip				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
27-May-2020	17833438	DIRECT	Υ					43 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypokalaemia	Cel End Ace	mdesivir fepime oxaparin etylcysteine Inh. Solution 20% uterol-Ipratropium Inh.			s C C C	Intravenous bolus		10 DAY		Gilead Not Reported Not Reported Not Reported Not Reported

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		Solution Amlodipine Enteral Nutrition (Vital Hp) Famotidine Piperacillin/Tazobactam Vancomycin Fentanyl Insulin Lispro Propofol			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
27-May-2020	178334	50 DIRECT	Υ					52 YR	Female	e USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		Mfr
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	178334	53 DIRECT	Υ	C	T			49 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransfer	ase	Remdesivir	Υ		S	Intravenous bolus	Other Frequency:Once;	1 DAY		Gilead
Increased		Remdesivir	Υ		S	Intravenous bolus	• • •	1 DAY		Gilead
		Acetaminophen Prn Albuterol Hfa Mdi Ascorbic Acid (Vitamin C) 1000mg Po Tid			C C					Not Reported Not Reported Not Reported
		Bisacodyl Supp Daily Prn Enoxaparin 40mg Subq Q12hr Guaifenesin/Codeine Prn Cough Tussionex Po Bid Solu-Medrol 40mg Iv Q12hr	1		00000					Not Reported Not Reported Not Reported Not Reported Not Reported
		Morphine Iv Prn Sodium Chloride Iv Solution Thiamine 100mg Tablet Po Daily Zinc Sulfate 220mg Po Daily	/		C C C C					Not Reported Not Reported Not Reported Not Reported

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						Dotalioa 110	PO: 1			
	Famo Mupi Bid	hexidine Swish/Spit Bid otidine 20mg Po Bid rocin 2% Ointment Nasal			C C C					Not Reported Not Reported Not Reported
	Thiar	nine 100mg Iv Daily			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
27-May-2020	17833459	DIRECT	Υ	0	Т			45 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Alanine Aminotransfer Increased; Glomerular Filtration Rate Increas	-	desivir			S	Intravenous (not otherwise specified))			Gilead
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17833468	DIRECT	Υ	0	Т			71 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Pyrexia	Atorv Bume Carve Dexa Fame Insuli Insuli Mela	methasone otidine n Aspart n Detemir tonin penem arin			80000000000					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	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Hepatic Enzyme Increased	Remo	desivir			S	Intravenous (not				Gilead

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

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						otherwise specified)				
	Aztre Leva Prava Siroli	astatin			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 i	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833477	DIRECT		0	Γ			71 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Pulmonary Embolism	Remo	desivir			S	Intravenous (not otherwise specified)				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>	<u>Country</u>
27-May-2020	17833483	DIRECT	Υ	DI	=			61 YR	Female	USA
<u>Preferred Term</u>	Prod	<u>luct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Respiratory Arrest	Remo	desivir	Υ		S	Intravenous drip	Other Frequency:Once;			Gilead
	Covid	d-19 Convalescent Plasma			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
27-May-2020	17833489	DIRECT	Υ	DI	≣			83 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Hepatic Failure;	Remo	desivir			S	Intravenous bolus				Gilead
Diarrhoea; Malaise; Pyrexia		aminophen			С					Not Reported
i yichia	Apixa Ceftri	aban iaxone			C C					Not Reported Not Reported
		rhexidine Oral Solution			С					Not Reported
	Enox	aparin			С					Not Reported
		semide apentin			C C					Not Reported Not Reported
		ADCHUH I			$\overline{}$					TAOL INCOULED

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						Detailed Re	port				
	Latan Magn Metro Moda Monte Morpl Potas Sertra Sodiu	etasone/Formoterol elukast hine ssium Chloride			000000000000						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Control #	<u> 50</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833490	DIRECT	Υ	DE	Ē				76 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>
Acidosis; Acute Respiratory Failure; Cough; Dyspnoea; Hypoxia; Renal Impairment; Sepsis	Norm Enoxa Fenta Hepa Hydro Triad Insulin Lacta Lactu Magn Melat Metro Midaz Morpl Norep	erol in bime hexidine Oral Solution osol-R aparin in coortisone Iv Paste Wound Dressing in (Glargine, Regular) ted Ringers lose lesium Sulfate Iv onin onidazole zolam			» 000000000000000000000000000000000000	Intravenous bolus					Gilead Not Reported



FDA Received Date Case	# Case	е Туре	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020 17833	3492 DIRI	ECT		C	T				57 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Blood Creatinine Increased; Creatinine Renal Clearance Decreased	Remdesivir				S	Intravenous (not otherwise specified	I)			No	t Reported
FDA Received Date Case	# Case	<u>e Type</u>	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020 17833	3505 DIRI	ECT	Υ	C	T				56 YR	Female	USA
Preferred Term	<u>Product</u>		Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; General Physical Health Deterioration; Haemoglobin Decreased; Intestinal Dilatation; Intestinal Ischaemia; Lactic Acidosis; Neutrophil Count Decreased; Platelet Count Decreased; Septic Shock; Supraventricular Tachycardia; Tissue Infiltration	Amiodarone Albumin Cyanocobalar Folic Acid Heparin Sq Enoxaparin Sc Famotidine Hydrocortison Succinate Midodrine Multivitamin Nicotine Trans Thiamine Dobutamine In Epineprhrine I Fentanyl Infus Ketamine Infu Norepinephrine	q ne Sodium sdermal nfusion Infusion sion usion ne Infusion	Y		» 0000000 0000000000	Intravenous (not otherwise specified))			No No No No No No No No No No No No No N	t Reported 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
27-May-2020	17833510	DIRECT	Υ	С	T			50 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	lesivir			S	Intravenous drip	Other Frequency:Once;	1 DAY		Gilead
	Remo	lesivir			S	Intravenous drip				Gilead
	Cefep Enoxa Furos Insulia Insulia Levof Methy Panto Sertra Vanca Fenta Midaz	um Gluconate pime aparin emide n Glargine n Lispro loxacin prednisolone prazole aline pmycin nyl colam pinephrine			000000000000000000000000000000000000000					Not Reported
FDA Received Date		Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	Age	<u>Sex</u>	Country
27-May-2020	17833527	DIRECT	Υ	C	T			69 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Acute Kidney Injury; Rhabdomyolysis	Remo	lesivir			S	Intravenous (not otherwise specified))	4 DAY		Not Reported
	Sinen				С	<u>-</u>				Not Reported
	Fenta				С					Not Reported
	Regla				C C					Not Reported
	Midoo				С					Not Reported
		pinephrine			С					Not Reported
	Propo				С					Not Reported
	Pepci	d			С					Not Reported



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

	Lover Solun	nox nedrol			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
27-May-2020	17833532	DIRECT	Υ		ОТ				68 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfer Increased	rase Remo	desivir	Υ		S						Gilead
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	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	<u>Dosage</u>	Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Liver Function Test Increased	Remo	desivir			S	Intravenous (not otherwise specified	d)		1 DAY	I	Not Reported
	Zithro				С						Not Reported
	Roce Lover	-			C C						Not Reported Not Reported
	Solun Huma	nedrol alog			C					1	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-May-2020	17833539	DIRECT	Y		НО				82 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Blood Pressure Increa Headache; Heart Rate Increased; Migraine; Myalgia; Pain; Pruritus Rash Papular	9	desivir Injection	Υ		S	Iontophoresis	Other F	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
27-May-2020	17833545	DIRECT	Υ		ОТ				65 YR	Male	USA



Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u> </u>	<u>Mfr</u>
Blood Creatine Increas Glomerular Filtration R Decreased	,	esivir	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
27-May-2020	17833603	DIRECT	Υ	H	HO, LT			48 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Bacterial Infection; Wh Blood Cell Count Increased	Aspiri Atorva Famo Furos Loraz Sodiu Vanco Hepai Insulir	n 81mg astatin 10mg tidine 20mg emide 20mg epam 2mg m Chloride omycin			80000000000					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	17833610	DIRECT	Υ	(T			69 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>
Condition Aggravated; Pyrexia; Ventricular	; Remd	esivir			S	Intravenous (not otherwise specified)			Gilead
Tachycardia	Amloo Apixal Aspiri Atorva	oan n Ec astatin ropine dilol oroex pezil			000000000					Not Reported

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	Guaif Insuli Insuli Ipratr Lorat Meth Succi Mont Ibrutii Panto Also:	elukast			0000000 0000					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
27-May-2020	17833630	DIRECT	Υ					66 YR	Male	USA
Preferred Term	Prod	uct	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 C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833637	DIRECT	Υ	[ÞΕ			73 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Death	Meth	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 C	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833642	DIRECT	Υ	L	.T			26 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; Pulseless Electrical	Remo	desivir			S	Intravenous (not otherwise specified)	1 DAY		Gilead

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Activity; Transaminases Increased	Ce Cal End Me Pal Zin Ace On Fer	thromycin fepime lcium Gluconate oxaparin thylprednisolone ntoprazole c Sulfate etaminophen dansetron ntanyl lazolam			00000000000					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
27-May-2020	17833647	DIRECT	Y					42 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chills; Tremor	Re	mdesivir			S	Intravenous drip	Other Frequency:Once;			Gilead
	Ins	oxaparin ulin Glargine (Lantus) ulin Lispro			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
27-May-2020	17833652	DIRECT	Υ		HO, OT			80 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfera Increased; Aspartate	ase Re	mdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once;			Unknown
Aminotransferase Increased; Internationa Normalised Ratio Increased; Liver Disord Prothrombin Time Prolonged	ll Pla Cei Do: Vai Vit Tor Ca Lip Pro	semide rdizem			00000000000					Not Reported

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	Pred	nisone			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
27-May-2020	17833668	DIRECT	Υ					40 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Liver Function Test Increased	Rem	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
27-May-2020	17833677	DIRECT	Υ	D	E			77 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	Mfr	
Condition Aggravated; Dyspnoea; Hypoxia; Lethargy; Respiratory Disorder		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>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Infusion Site Extravasa	ation Rem	desivir	Y		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>	<u>Country</u>
27-May-2020	17833738	DIRECT	Υ					1 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
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

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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	17833753	DIRECT		D	E			80 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Covid-19		desivir desivir			S C					lead ot Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2020	17833766	DIRECT		0	Т			62 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Liver Function Test Increased		desivir desivir			S C					nt Reported nt 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	17839011	DIRECT	Υ						Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Liver Function Test Increased		desivir desivir			S C	Intravenous drip				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
28-May-2020	17812574	EXPEDITED (15-DAY)		D	E, OT	GB-PFIZER IN 2020198894	C-		Male	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Acute Kidney Injury; Multiple Organ	•	nolactone			S	Oral	50 Mg, Bid (100mg Per Day)		Pfi	zer
Dysfunction Syndrome	Furos	semide			S	Intravenous (not otherwise specified)	40 Mg, Bid (80 Mg Per		No	t Reported
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		No	t Reported
	Atorv	astatin			С		Unk		No	t Reported

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	Ipratropium Azithromycin			C C		Unk			lot Reported lot Reported
	Co-Amoxiclav [Amoxicillin;Clavulanate Potassium]			С		Unk		٨	lot Reported
	Lansoprazole			С		Unk		N	lot Reported
	Paracetamol			С		Unk		N	lot Reported
	Midazolam			С		Unk		N	lot Reported
	Metoclopramide			С		Unk		N	lot Reported
	Morphine			С		Unk		N	lot Reported
	Salbutamol			С		Unk		N	lot Reported
	Noradrenaline [Norepinephrine]			С		Unk		N	lot Reported
	Rocuronium			С		Unk		N	lot Reported
	Piperacilin/Tazobactam			С		Unk		N	lot Reported
	Erythromycin			С		Unk		N	lot Reported
	Heparin			С		Unk		N	lot Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Out	comes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020 1783	3859 DIRECT	Υ	ОТ				78 YR	Male	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Disturbance In Attention; Lethargy; Oxygen Saturation Decreased; Palpitations; Tremor; Ventricular Tachycardia	Remdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:Once (Loading Dose;		G	bilead
FDA Received Date Case	# Case Type	<u>Health</u>	Prof Out	comes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020 1783-	4192 DIRECT	Υ	ОТ				92 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury; Alanine Aminotransferase	Remdesivir Remdesivir			S C					ilead lot Reported



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

FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834582	DIRECT	Y	D	_	mir Gondior	<u>ooob raomty</u>	78 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Нурохіа	Remo	desivir	Y		S	Intravenous (not otherwise specified)				Gilead
	Metoj Enoxi Insuli Diltiaz Fenta Morpi Allopi Dexm Loraz	opium prolol aparin n zem anyl hine			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
28-May-2020	17834588	DIRECT	Υ	D	E, OT			61 YR	Female	e USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer	ase Remo	desivir			S	Intravenous drip				Gilead
Increased; Aspartate Aminotransferase Increased; Febrile Neutropenia; Respirate Failure		zumab			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-May-2020 1	7834593	DIRECT	Υ		LT			86 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Alanine Aminotransferas Increased; Aspartate Aminotransferase Increased; Therapy Interrupted		emdesivir orvastatin	Υ		S C	Intravenous bolus				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
28-May-2020 1	7834597	DIRECT	Υ		DE			38 YR	Female	e USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bradycardia; Condition Aggravated; Hypotensior Inflammatory Marker Increased; Ventricular Fibrillation	n; Ac Ce De Inf En Etc Ins Ins Mic Pro Ro Va	emdesivir etaminophen 650mg Tablet efepime 2g lvpb exmedetomidine 1.4mg/Kg/Hr usion exaparin 40mg Bid emidate 20mg Once entanyl 100mcg Once sulin Glargine 5 Units Bid esulin Lispro Sliding Scale erazepam 1mg Inj Once esulin Regular Sliding Scale dazolam 5mg Inj Once epofol Infusion ecuronium Infusion encomycin 1250mg Q6h egnesium Oxide 400mg Bid etassium Chloride 40meq Daily	Y		% 000 000000000000	Intravenous bolus				Gilead 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-May-2020 1	7834603	DIRECT	Υ		DS			51 YR	Male	USA



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Preferred Term	<u>F</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
Acute Kidney Injury; Blo Creatinine Increased;	ood F	Remdesivir	Υ		S	Intravenous bolus	Other Frequency:1 Time & 100 Daily;	\$		Gilead
Blood Pressure Decreased; Blood Urea ncreased	1 E F L III L P F L	Lovenox 40mg Docusate With Senna Famotidine Lantus Insulin Lispro Lisinopril Acetaminophen Fentanyl Drip Lactated Ringers Norepinephrine Propofol Rocuronium			000000000000		Too Bany,			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	1783460	7 DIRECT		[DE			92 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Acute Kidney Injury		Remdesivir Remdesivir			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
28-May-2020	1783461	3 DIRECT	Υ	[DE			86 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
General Physical Healt	h F	Remdesivir	Υ		S	Intravenous bolus				Gilead
Deterioration; Hypoxia		Convalescent Plasma Tocilizumab			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
28-May-2020	1783462	3 DIRECT	Υ	(ТС			70 YR	Female	USA
Preferred Term	Ē	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>

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						Detailed Ke	port			
Fransaminases Increase	ed F	Remdesivir	Y		S	Intravenous (not otherwise specified)			ı	Gilead
	Δ	cetaminophen			С	,				Not Reported
		inoxaparin			Č					Not Reported
		entanyl			Č					Not Reported
	F	urosemide			С					Not Reported
	li	nsulin			С					Not Reported
		inezolid			С					Not Reported
		Meropenem			С					Not Reported
		orazepam			С					Not Reported
		Phenylephrine			C C					Not Reported
		Propofol								Not Reported
	Case #	Case Type	Health		utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	1783464	6 DIRECT	Υ	0	T			70 YR	Male	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>∕\fr</u>
Atrial Fibrillation; Clinica Frial Participant; Produc Jse In Unapproved ndication		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
28-May-2020	1783465	1 DIRECT	Υ	D	E			61 YR	Female	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>∕/fr</u>
Acute Kidney Injury; Clinical Trial Participant;		Remdesivir			S	Intravenous (not otherwise specified)		2 DAY		Gilead
Liver Function Test	N	lorepinephrine Infusion			С	,				Not Reported
ncreased; Multiple Orga	an _E	Phenylephrine Infusion			Č					Not Reported
Dysfunction Syndrome;		asopressin Infusion			С					Not Reported
Product Use In Unapproved Indication; Shock	E	pinephrine Infusion			С					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	1783488	5 DIRECT	Υ	D	E			83 YR	Male	USA

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Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Clinical Trial Participant; Product Use In	Remde	esivir			S	Intravenous (not otherwise specified)			Gilead
Unapproved Indication; Respiratory Failure		omycin acillin/Tazobactam			C C		,			Not Reported Not Reported
FDA Received Date Cas	e #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020 178	34887	DIRECT	Υ	D	ÞΕ			66 YR	Femal	e USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participant; Palliative Care; Product	Remd	esivir			S	Intravenous (not otherwise specified)			Gilead
Use In Unapproved Indication; Therapy Cessation	Conva	alescent Plasma			С	oniorwise specifica	,			Not Reported
FDA Received Date Cas	<u>e #</u>	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020 178	34892	DIRECT	Υ	C	DΤ			56 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Clinical Trial Participant; Dysphagia; Headache; Product Use In Unapproved Indication	Remde Conva	esivir Ilescent Plasma			S C					Not Reported Not Reported
FDA Received Date Cas	e #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020 178	34894	DIRECT	Υ	C	T			74 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Clinical Trial Participant; Product Use In Unapproved Indication	Remdo Amlod Ibupro	lipine			S 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
28-May-2020	17834895	DIRECT	Υ	(ТС			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hepatic Enzyme Increased; Therapy Cessation	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
28-May-2020	17834911	DIRECT	Υ					54 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	Υ		S	Intravenous bolus				Gilead
Increased	Hydro	oic Acid oxychloroquine romycin			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
28-May-2020	17834946	DIRECT	Υ	(ОТ			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; R Tubular Necrosis	enal Remo	desivir			S	Intravenous (not otherwise specified))			Gilead
	Sodiu Sodiu Potas Magn Dexm Zinc S Cefep	eb ose 50% Im Chloride Flush Im Chloride 250 MI ssium Chloride lesium Sulfate nedetomidine Sulfate			00000000000					Not Reported

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	B M Ir C V Ir	antoprazole umetanide lethylprednisolone isulin Lispro hlorothiazide ancomycin isulin Detemir ocilzumab			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	1783496	5 DIRECT	Υ	0	Т			49 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Acute Kidney Injury; Therapy Interrupted	R	emdesivir			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
28-May-2020	17834973	B DIRECT	Υ	0	Т			53 YR	Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Liver Function Test Increased; Therapy Interrupted	R	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>	<u>Country</u>
28-May-2020	17834979	DIRECT	Υ					84 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Anaemia; Platelet Cou Increased; White Bloo		emdesivir			S	Intravenous (not otherwise specified)			(Gilead
Cell Count Decreased	A A C	cyclovir 400 Mg Po Bid Ilopurinol 300 Mg Po Daily spirin 325 Mg Po Daily holecalciferol 2000 Units Po aily			C C C	ss. mee epecinion)			1 1	Not Reported Not Reported Not Reported Not Reported
	F	urosemide 20 Mg Po Bid			С				ı	Not Reported

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	M Ri	evothyroxine 88 Mcg Po Daily eropenem 1 Gram Iv Q12h uxolitinib eparin Iv Infusion			C C C		<u>-</u>				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
28-May-2020	17835864	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468283	20-		38 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Aspartate Aminotransferase	Re	emdesivir			S	Intravenous (not otherwise specified)	200 M	g, Qd			Gilead
Increased; Aspartate Aminotransferase	C	eftriaxone			С	. ,	Unk				Not Reported
Increased; Septic Sho	ck He	eparin			С		Unk				Not Reported
	In	sulin			С		Unk				Not Reported
	М	idazolam			С		Unk				Not Reported
	No	orepinephrine			С		Unk				Not Reported
	Az	zithromycin			С		Unk				Not Reported
	To	ocilizumab			С		Unk				Not Reported
	Va	ancomycin			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	1	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17835865	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468246	20-		70 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	<u>Route</u>	Dosage	<u>Text</u>	Duration	<u>N</u>	<u>Mfr</u>
Alanine Aminotransfera Abnormal; Aspartate	ase Ro	emdesivir			S	Intravenous (not otherwise specified)		g, Once			Gilead
Aminotransferase Abnormal	At	orvastatin			С	. ,	Unk				Not Reported
Abrioffiai	Pr	ropofol			С		Unk				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	17835872	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468272	20-		46 YR	Female	USA

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Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Seizure	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Tociliz	zumab			С		Unk				Not Reported
	Zinc				С		Unk				Not Reported
	Quetia	apine			С		Unk				Not Reported
	Methy	/lprednisolone			С		Unk				Not Reported
	Melate	onin			С		Unk				Not Reported
	Levet	iracetam			С		Unk				Not Reported
	Atorva	astatin			С		Unk				Not Reported
	Ascor	bic Acid			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	Sex	Country
28-May-2020	17835873	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468468)20-		75 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	Duration		Mfr
Atrial Fibrillation	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg	, Qd			Gilead
	Aceta	minophen			С		Unk				Not Reported
	Amloo	dipine			С		Unk				Not Reported
	Apixa	ban			С		Unk				Not Reported
	Doxaz	zosin			С		Unk				Not Reported
	Hydra	lazine			С		Unk				Not Reported
	Loraz	epam			С		Unk				Not Reported
	Comb	ivent Respimat			С		Unk				Not Reported
	Ascor	bic Acid			С		Unk				Not Reported
	Chole	calciferol			С		Unk				Not Reported
	Levot	hyroxine			С		Unk				Not Reported
	Zinc S	Sulfate			С		Unk				Not Reported
	Tylen	ما			С						Not Reported

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facili	ty <u>Age</u>	<u>Sex</u>	Country
28-May-2020	17835874	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468237	20-	23 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Rem	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Acet	aminophen			С	Oral	1000 Mg Q5h			Not Reported
	Dext	romethorphan			С	Oral	30 Mg			Not Reported
	Enox Aspi Ibup Vitar Zinc Hydr Pred	conatate caparin rin [Acetylsalicylic Acid] rofen nin C [Ascorbic Acid] Sulfate oxychloroquine nisone terol Hfa			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	<u>Outcomes</u>	Mfr Control #	503B Facili	ty <u>Age</u>	<u>Sex</u>	Country
28-May-2020	17835876	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468482	20-	49 YR	Female	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfer Abnormal; Blood Alkal	ine	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
Phosphatase Increase Hypotension	ed; Ator	astatin //			С		Unk			Not Reported
туротоплогі	Cefti	iaxone			С		Unk			Not Reported
	Desv	renlafaxine			С		Unk			Not Reported
	Fnor	etin Alfa			С		Unk			Not Reported
	-рос	7.111 7 411 C			^		Unk			Not Reported
	•	otidine			С		Olik			
	•	otidine			С		Unk			Not Reported
	Fam Hepa Hydr	otidine								•

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							•				
	Insu	lin Lispro			С		Unk				Not Reported
	Met	nadone			С		Unk				Not Reported
	Met	oprolol			С		Unk				Not Reported
	Pota	assium Chloride			С		Unk				Not Reported
	Preg	gabalin			С		Unk				Not Reported
	Azitl	nromycin			С		Unk				Not Reported
	Hyd	roxychloroquine			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17835882	EXPEDITED (15-DAY)			ОТ	US-GILEA 0468290	D-2020-		67 YR	Female	e USA
Preferred Term	<u>Pro</u>	duct	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Dysphagia; Swelling;	Rem	ndesivir			S	Unknown	200 M	lg			Gilead
Throat Irritation	Albu	iterol Hfa			С		Unk				Not Reported
	Nys	tatin			С		Unk				Not Reported
		cocet [Oxycodone			С		Unk				Not Reported
		rochloride;Paracetamol] toprazole			С		Unk				Not Reported
	Zinc				С		Unk				Not Reported
	Vita	min D [Colecalciferol]			С		Unk				Not Reported
	Vita	min C [Ascorbic Acid]			С		Unk				Not Reported
	Asp	irin [Acetylsalicylic Acid]			С		Unk				Not Reported
	Met	nylprednisolone			С		Unk				Not Reported
	Dipr	idamole			С		Unk				Not Reported
	Insu	lin Lispro			С		Unk				Not Reported
	Letr	ozole			С		Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17837784	EXPEDITED (15-DAY)			ОТ	US-GILEA 0468230	D-2020-		60 YR	Male	USA
<u>Preferred Term</u>	Pro	<u>duct</u>	Comp.	OTO	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>

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Acute Kidney Injury;

S Remdesivir Unk Unknown

Medication Error; Prod Jse Issue	luct					OTIKIOWIT	OTIK			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
28-May-2020	17837791	EXPEDITED (15-DAY)			DS, HO, LT,	OT US-GILEAD-20 0469042	20-	67 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Hydronephrosis; Necro	osis; Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg		G	Silead
Respiratory Disorder	Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		G	Gilead
	Aceta	minophen			С		Unk		N	lot Reported
	Duone	eb			С		Unk		N	lot Reported
	Azithr	omycin			С		Unk		N	lot Reported
	Amioo	larone			С		Unk		N	lot Reported
	Cefep	ime			С		Unk		N	lot Reported
	Potas	sium Chloride			С		Unk		N	lot Reported
	Tociliz	zumab			С		Unk		N	lot Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17837798	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0468927	20-	76 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Remd	esivir			S	Intravenous (not otherwise specified)	300 Mg, Total		G	Gilead
	Cefep	ime			С		Unk		N	lot Reported
	Enoxa	parin			С		Unk		N	lot Reported
	Famo	tidine			С		Unk		N	lot Reported
	Fenta	nyl			С		Unk		N	lot Reported
	Hepar	rin			С		Unk		N	lot Reported

Gilead



						Dotalioa 110	роп			
	Insul	in Lispro			С		Unk		١	Not Reported
	Meth	ocarbamol			С		Unk		١	lot Reported
	Meth	ylprednisolone			С		Unk		١	lot Reported
	Mida	zolam			С		Unk		١	lot Reported
	Nore	pinephrine			С		Unk		١	lot Reported
	Preg	abalin			С		Unk		١	lot Reported
	Prop	ofol			С		Unk		١	lot Reported
	Vano	omycin			С		Unk		١	lot Reported
	Vaso	pressin			С		Unk		١	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facil	lity Age	<u>Sex</u>	<u>Country</u>
28-May-2020	17838503	DIRECT	Υ		ОТ			57 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Hypotension; Renal	Rem	desivir			S	Intravenous drip			١	Not Reported
Impairment	Aspir Atorv Mida	omycin			C C C C C				1 1 1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facil	lity Age	<u>Sex</u>	Country
28-May-2020	17838778	DIRECT	Υ		ОТ			51 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>
Blood Creatine Phosphokinase Increa		desivir			S	Intravenous (not otherwise specified)			(Gilead
	Ceftr Enox Furos Guai	rastatin Tablet iaxone Injection aparin Injection semide Injection fenesin Tablet oxychloroquine Tablet			00000				1 1 1	Not Reported

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	L M F V P A	ansoprazole Capsule evothyroxine Tablet Methylprednisolone Injection Pantoprazole Tablet Cancomycin Injection Propofol Injection Acetaminophen Tablet Orazepam Injection			00000000				N N N N N 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
28-May-2020	1783893	B DIRECT	Υ					33 YR	Female	USA
Preferred Term	E	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>'r</u>
Alanine Aminotransfera Increased; Aspartate Aminotransferase Increased	ase R	demdesivir	Y		S	Intravenous drip			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
28-May-2020	1783894	5 DIRECT	Υ	ОТ	Г			60 YR	Male	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Transaminases Increas	sed R	temdesivir			S	Intravenous (not otherwise specified))		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
28-May-2020	1783894	9 DIRECT	Υ					90 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Glomerular Filtration R Decreased; Therapy	tate R	temdesivir	Υ		S	Intravenous (not otherwise specified))		G	ilead
Cessation	V	ancomycin			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
28-May-2020	17838954	DIRECT	Υ	C	T			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Renal Failure	Remo	desivir	Υ		S	Intravenous drip				Gilead
	Cefer Vanc	ex romycin			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 C	<u>Dutcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838955	DIRECT	Υ	C	OT			63 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; Ischaemic Hepatitis; Transaminases Increa	sed Azithi Ceftri Dexa Enox Famo Fenta Insuli Insuli Phen Piper Propo Rocu	n Glargine n Lispro ylephrine acillin/Tazobactam			8 000000000000	Intravenous (not otherwise specified)	Other Frequency: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
28-May-2020	17838959	DIRECT	Υ	H	HO, LT			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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Acute Kidney Injury; Haemodialysis	Rem	desivir			S	Intravenous (not otherwise specified	l)			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	17838962	DIRECT	Υ					73 YR	Male	USA
Preferred Term	Proc	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Aspartate Aminotransferase Increased	Cefe Fent Prop Aripi Gab Mirta Meth Enox Aspi Fam Praz	ofol prazole apentin azapine aylprednisolone kaparin rin otidine			s 0000000000000	Oral				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
28-May-2020	17838968	DIRECT	Υ					82 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
International Normalise Ratio Increased		desivir iis 2.5mg Q12h	Υ		s C	Intravenous drip				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
28-May-2020	17838972	DIRECT	Υ		_T			34 YR	Male	USA
Preferred Term	Prod	duct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Ventricular Tachycardi	a Rem	desivir	Υ		S	Intravenous drip				Gilead



FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	l#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838976	DIRECT	Y						71 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Chills; Hypotension; Infusion Site Extravasation; Infusior Site Reaction; Nausea	1	desivir			S	Intravenous drip				(Gilead
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838982	DIRECT	Υ		ОТ				62 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration F Decreased	;	desivir			S	Intravenous drip				(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
28-May-2020	17838987	DIRECT	Υ						91 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Glomerular Filtration F Decreased	Rate Rem	desivir	Υ		S	Intravenous (not otherwise specified	d)			(Gilead
	Vano	omycin			С					ı	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	17838988	DIRECT	Υ		ОТ				49 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased		desivir			S	Intravenous drip	Othe	r Frequency:Once;		(Gilead

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Glomerular Filtration Ra Decreased	ate										
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
28-May-2020	17838991	DIRECT	Υ	(ОТ				74 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Acute Kidney Injury; Creatinine Renal Clearance Decreased; Glomerular Filtration Ra Decreased; Therapy Cessation	Remo	lesivir			S	Intravenous drip				G	ilead
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838994	DIRECT	Υ						77 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Acute Kidney Injury; Blo Creatine Increased; Creatinine Renal Clearance Decreased; Glomerular Filtration Ra Decreased		esivir			S	Intravenous drip				G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17838997	DIRECT	Υ						32 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	<u>fr</u>
Hepatotoxicity	Remo	esivir			S	Intravenous drip				G	ilead
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839001	DIRECT	Υ	I	LT, OT				78 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>

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Acute Kidney Injury	I	Remdesivir			S	Intravenous drip				Gilead
	; 	Rocuronium Sodium Bicarbonate 50 Meq Fentanyl nsulin Drip Morphine Propofol Zosyn Azithromycin Bumex			00000000					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	1783900	4 DIRECT	Υ		ОТ			82 YR	Female	e USA
Preferred Term	1	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
White Blood Cell Coun Decreased	t I	Remdesivir	Υ		S	Intravenous (not otherwise specified)				Not Reported
		Acetaminophen			С					Not Reported
		Allopurinol			С					Not Reported
		Amiodarone Aspirin			C C					Not Reported Not Reported
		Aspiriri Atorvastatin			C					Not Reported
		Cardidopa-Levodapa			Č					Not Reported
		Diltiazem			C C					Not Reported
	I	Enoxaparin			С					Not Reported
		urosemide			С					Not Reported
		Hydrocodone-Acetaminophen			C C					Not Reported
		nsulin Aspart			C					Not Reported
		nsulin Glargine			С					Not Reported
		Methylprednisolone Metoprolol Tartrate			C C					Not Reported Not Reported
		Sertraline			Č					Not Reported
		Горіramate			Č					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	<u>Sex</u>	Country
28-May-2020	1783902	3 DIRECT	Υ		DE			73 YR	Male	USA
Preferred Term]	<u>Product</u>	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>

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Ventricular Fibrillation	Rem	desivir			S	Intravenous drip	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
28-May-2020	17839025	DIRECT	Υ					54 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Rem	desivir			S	Intravenous bolus	Other Frequency:Once;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2020	17839026	DIRECT	Υ		DE			88 YR	Female	e AFG
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Hypotension; Hypoxia;	; Rem	desivir			S	Intravenous drip				Gilead
Skin Discolouration		romycin			C	·				Not Reported
		eonam iaxone			C C					Not Reported Not Reported
		ozyne			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
28-May-2020	17839552	DIRECT	Υ		HO, RI, OT			94 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Thrombocytopenia	Rem	desivir 100mg/20ml			S	Intravenous (not otherwise specified	l)			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	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Liver Function Test Increased	Rem	desivir	Υ		S	Intravenous drip				Not Reported

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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	17839763	DIRECT	Υ					76 YR	Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Ventricular Tachycardi	ia Rem	desivir Injection			S	Intravenous bolus	Other Frequency:200mg X1;			Gilead
	Enox Meto Praz	odipine kaparin oprolol XI osin enecid			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	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17839790	DIRECT	Υ	[DE			81 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Dialysis; Renal Failure Tachypnoea	Aceta Amlo Aspir Atory Benz Norm Enox Fenta Furos Guai Hepa Hydr Insul Regu Labe Lacta	vastatin conatate nosol-R caparin anyl semide fenesin/Codeine arin ochlorothiazide omorphone in (Glargine, Lispro And ular)			8 00000000000000 0000	Intravenous bolus				Gilead Not Reported



	Magr Morp	esium Sulfate hine			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
29-May-2020	17839798	DIRECT	Υ	[DE			74 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury; Haemodialysis;	Remo	desivir			S	Intravenous (not otherwise specified)			Gilead
Pneumothorax; Pseudomonal Bacteraemia		alecent Plasma zumab Or Matching bo			C C	onioimos specimes.	,			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
29-May-2020	17839805	DIRECT	Υ	I	DE			75 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Fluid Overload; Hypotension	Remo	desivir Solution			S	Intravenous (not otherwise specified)			Gilead
	Conv	alescent Plasma			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	17839841	DIRECT	Υ	(TC			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 React		desivir			S	Intravenous (not otherwise specified	Other Frequency:Once Then 100mg X4;			Gilead
FDA Received Date	Case #	Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	Sex	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 Aminotransfera	ase Remo	desivir			S	Intravenous drip				Not Reported

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							- 1			
Increased; Therapy Cessation	Azithı Ceftri Enox	minophen romycin axone aparin omycin			0000				N N	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 Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840013	DIRECT	Υ	DE	Ī			67 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Death	Remo	desivir			S	Intravenous drip	Other Frequency:Once;		(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
29-May-2020	17840020	DIRECT	Υ	07	Γ			34 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Blood Alkal Phosphatase Increase Hyperhidrosis; Liver Function Test Increase Therapy Cessation	line ed;	desivir			S				١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17840027	DIRECT	Υ	07	Г			65 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Acute Kidney Injury; B Creatinine Increased; Dialysis; Disease Progression	Aspiri Atova Calcii Cefaz Cefep	statin um Citrate/Vitamin D zolin	Y		800000				1 1 1	Gilead Not Reported



	Hydro Lanso Nalox Multiv Tacro Tenof Atracı Dexm Fenta Norep Propo	ritamin limus ovir urium edetomidine nyl pinephrine			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
29-May-2020	17840033	DIRECT	Υ	0	Т			55 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Continuous Haemodiafiltration; Creatinine Renal Clearance Decreased; Endotracheal Intubatio Renal Impairment; Therapy Cessation		lesivir			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-May-2020	17840034	DIRECT	Υ	DI	E			71 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Respiratory Dist Syndrome; Cardiac Ar Cardio-Respiratory Arr Pulse Absent; Shock	rest;	lesivir	Y		S	Intravenous drip	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
29-May-2020	17840052	DIRECT	Υ	0	Т			55 YR	Male	XQZ



Preferred Term	<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Blood Bilirubin Increased	Remdesiv	⁄ir			S	Intravenous drip				Not Reported
	Rocuroni	um			С	•				Not Reported
	Propofol				С					Not Reported
	Norepine				С					Not Reported
	Midazola				С					Not Reported
	Hydromo				С					Not Reported
	Fluoxetin	е			С					Not Reported
	Fentanyl				С					Not Reported
	Ceftriaxo Heparin	ne			C					Not Reported Not Reported
FDA Received Date Case		Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	Age	Sex	Country
						Will Colludia	<u>JOSE I acinty</u>			_
29-May-2020 17840	058	DIRECT	Y	0	Т			64 YR	Male	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Blood Creatinine	Remdesiv	vir			S	Intravenous bolus				Gilead
Increased; C-Reactive Protein Increased; Fibrin D Dimer Increased:	Acetylcys Solution	teine 20% Oral			С					Not Reported
Glomerular Filtration Rate	Aztreona				С					Not Reported
Decreased; Haematuria;	Furosemi				С					Not Reported
Interleukin Level	Levofloxa				С					Not Reported
Increased; Seizure	Tocilizum				С					Not Reported
	Acetamin	ophen			С					Not Reported
	Albuterol	10/ (Onally)			С					Not Reported
	Clopidogi	1% (Orally)			C C					Not Reported Not Reported
	Docusate				C					Not Reported
	Heparin S				C					Not Reported
	Levothyro				C					Not Reported
	Midazola				C					Not Reported
	Norepine				C					Not Reported
	Pantopra				Č					Not Reported
	Propofol				Č					Not Reported
EDA Bassissal Data Casa	#	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date Case	_									

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Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Off Label Use	Remo	esivir	Υ		S					Gilead
FDA Received Date	Case #	Case Type	Health	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	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Disease Progression; Hypoxia; Respiratory Failure; Severe Acute Respiratory Syndrome		lesivir 100mg/20 Ml			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)				Gilead
	Azithr Carbio Donej Enoxa Etomi Lispro Insulir Metop Monte Solife	astatin omycin dopa-Levodopa pezil aprin date orolol			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
29-May-2020	17840213	DIRECT	Υ	D	E			68 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Distributive Shock; Dru Ineffective	ug Remo	lesivir 100mg/20 MI Eua			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Frequency 4x			Gilead
	Colac Eliqui: Huma Insulir	s log			C C C					Not Reported Not Reported Not Reported Not Reported

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		zotanou rtoport	
Lantus Pepcid Miralax Seroquel	C C C		Not Reported Not Reported Not Reported Not Reported
Seroquei Singulair Zofran Acetaminophen	C C C		Not Reported Not Reported Not Reported Not Reported
Piperacillin Tazobactam Azithromycin Diclofenac Propofol	C C C C		Not Reported Not Reported Not Reported Not Reported
Norepinephrine Fentanyl Exmedetomidine	C C C		Not Reported Not Reported Not Reported
FDA Received Date	Health Prof Outcome	s Mfr Control # 503B Facility	Age Sex Country
29-May-2020 17840266 DIRECT	Y ОТ		67 YR Male USA
Preferred Term Product	Comp. OTC Role	Route Dosage Text	<u>Duration</u> <u>Mfr</u>
Acute Kidney Injury; Blood Remdesivir Bilirubin Increased; Blood	Y S	Intravenous (not otherwise specified)	Gilead
Creatinine Increased; Dehydration; Hypotension; Transaminases Increased Fentanyl Drip Norepinephrine Drip Rocurronium Drip Turnamida Inc. Mar.	C C		Not Reported Not Reported Not Reported
Furosemide Ivp X1 Gabapentin Lovenox Famotidine	C C C C		Not Reported Not Reported Not Reported Not Reported
Lactated Ringers Acetaminophen Ketamine Propofol	C C C		Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Health Prof Outcome	s Mfr Control # 503B Facility	Age Sex Country
29-May-2020 17840269 DIRECT	Y OT		77 YR Female USA
Preferred Term Product	Comp. OTC Role	Route Dosage Text	<u>Duration</u> <u>Mfr</u>
Blood Creatinine Remdesivir	S	Intravenous (not	Gilead

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Increased						otherwise specified)				
		semide Iv semide Po			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
29-May-2020	17841424	EXPEDITED (15-DAY)		•	ОТ	US-GILEAD-20 0468719	20-	56 YR	Male	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Acute Kidney Injury	Remo	desivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Nore	pinephrine			С		2-10 Mcg/Min			Not Reported
	Albur Azith Bume Ceftri Clona Desn Docu Enox Epop Famo Fenta Furos Hepa Hydro Ketar Insuli	romycin etanide iaxone azepam nopressin isate aparin orostenol otidine anyl semide arin omorphone mine			00000000000000000000		25-50 Mcg/Min			Not Reported
		ronium osides			C C C		1-7 Mcg/Kg/Min			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
29-May-2020	17841427	EXPEDITED (15-DAY)		(OT	US-GILEAD-2 0468705	2020-		69 YR	Male	USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Acute Kidney Injury; Blo Creatinine Increased; Blood Urea Increased	ood Ren	ndesivir			S	Intravenous (not otherwise specified	100 M	g, Qd			Gilead
blood Orea Increased	Metrocisal North Property Pentrocisal North Pent	atonin irin [Acetylsalicylic Acid] osemide olazone ılin Glargine			000000000000000000						Not Reported
FDA Received Date		vastatin <u>Case Type</u>	Health	Prof (C Outcomes	Mfr Control	#	503B Facility	Age	Sex	Not Reported Country
	17841756	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-2 0468849			68 YR	Female	USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>]	<u>Mfr</u>
Acute Respiratory Failu Covid-19	ıre; Ren	ndesivir			S	Intravenous (not otherwise specified	Unk d)				Gilead
	Zos	yn			С		Unk				Not Reported
	Albu	iterol [Salbutamol]			С		Unk				Not Reported
	Ingi	ılin Lispro			С		Unk				Not Reported



								-				
		Insulin Gl	argine			С		Unk				Not Reported
		Combiver	nt			С		Unk				Not Reported
		Amlodipin	e			С		Unk				Not Reported
		Precedex				С		Unk				Not Reported
		Lovenox [Enoxaparin Sodium]			С		Unk				Not Reported
		Gabapent	tin			С		Unk				Not Reported
		Seebri				С		Unk				Not Reported
		Levothyro	oxine			С		Unk				Not Reported
		Ativan				С		Unk				Not Reported
		Lopresso	r			С		Unk				Not Reported
		Dulera				С		Unk				Not Reported
		Percocet	[Oxycodone oride;Paracetamol]			С		Unk				Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	178424	483	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468473	20-		59 YR	Female	e USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Transaminases Increa	sed	Remdesiv	vir			S	Intravenous (not otherwise specified)		lg, Once			Gilead
		Remdesiv	rir			S	Intravenous (not otherwise specified)		lg, Qd			Gilead
		Vitamin D	ophen ndansetron] 3 Calcium Carbonate] Gluconate			0000000						Not Reported
		Lovenox [Miralax	Enoxaparin Sodium] [Diphenhydramine oride]			0000						Not Reported Not Reported Not Reported Not Reported Not Reported

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	Magnes	sium Sulfate			С					No	t Reported
	Potassi	um Chloride			С					No	t Reported
	Clozaril				C C C						t Reported
	Propofo										t Reported
		e [Etomidate]			0000000						t Reported
	Quelicir				С						t Reported
	Fentany	/l			С						t Reported
	Versed				С						t Reported
		ne Regular			С						t Reported
	Humalo				С						t Reported
		Cefazolin Sodium]			С						t Reported
		k [Omeprazole]			С						t Reported
		Metronidazole]			C C C						t Reported
		in [Ceftriaxone]			C						t Reported
	Vancom				C						t Reported
	Zenpep				С						t Reported
		[Omeprazole]			С						t Reported
		um Bicarbonate			С						t Reported
	Zemuro				С						t Reported
	Levaqui	ın			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
29-May-2020	17842534	EXPEDITED (15-DAY)		0.	Г	US-G 0468	ILEAD-2020- 511		54 YR	Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased	ase Remde:	sivir			S	Unknown	Unk			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
29-May-2020	17842537	EXPEDITED (15-DAY)		DI	≣, OT	US-G 0468	ILEAD-2020- 948		85 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	
Death	Remdes	sivir			S	Unknown	Unk			Gil	ead



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17842544	EXPEDITED (15-DAY)		ОТ		US-GILEAD-20 0468274)20-	34 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Anxiety; Blood Pressu Increased; Body Temperature Abnorma Erythema; Heart Rate Increased; Hyperhidro Nausea; Oxygen Saturation Decreased; Respiratory Rate Increased	al; sis;	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once		G	ilead
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17844971	DIRECT	Υ					71 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Bradycardia	Remd	esivir			S	Intravenous drip	Other Frequency:Once;		N	ot Reported
	Guaife Hydro Loper Metop Omep Polyet Spiror Tamsi	entin line line lan oroex zine us Gluconate enesin xyzine amide orolol Succinate XI orazole thylene Glycol nolactone ulosin orol Tartrate			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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	Saline	9			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
29-May-2020	17844976	DIRECT	Υ		НО			27 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Liver Function Test Increased	Remo	lesivir			S	Intravenous (not otherwise specified)			G	ilead
		onin minophen aparin			C C C C	,			N N N	ot Reported ot Reported ot Reported 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
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>M</u> 1	<u>ir</u>
Atrial Fibrillation; Hear Rate Irregular	t 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
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>M</u> 1	<u>ir</u>
Disease Progression; Hyperhidrosis; Hypotension	Remo Lover	lesivir nox	Υ		S C	Parenteral				ilead 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
29-May-2020	17844998	DIRECT	Υ		НО			77 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	ir

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Acute Kidney Injury Remdesivir FDA Received Date Case # Case Type					S			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	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	<u>Health</u>	Prof O	utcomes	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 1	<u> ext</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Alanine Aminotransfera	ase Remo	desivir			S					1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>l#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	17845007	DIRECT	Υ	0	Т				75 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>ext</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Renal Impairment	Remo	desivir			S	Intravenous drip				(Gilead
	Osmo	olite 1.5 Cal Liquid			С	·				1	Not Reported
		astatin 10mg At Bedtime			С						Not Reported
		hexidine Mouthwash			С						Not Reported
		pin 10mg			С						Not Reported
		re Clnical Health			С						Not Reported
		romycin Opth Ointment Daily			С					Γ	Not Reported
		semide 40mg Iv Once			С					ı	Not Reported
		rin In D5w 25000 Unit Bag			Č						Not Reported
		ofol 1000mg Titration			Č						Not Reported
		ım Chloride 0.9% @			C						Not Reported
	50ml/										-
		aminophen 325mg Tablet			C						Not Reported
		repam 1mg Injection Once			С						Not Reported
		inephrine 4mg In 500ml			С					1	Not Reported
		ose 5% oxychloroquine 200mg			C					,	Not Reported
		n Lispro Per Sliding Scale			C C						Not Reported
		thyroxine 137mcg Per Dose			C						Not Reported
		ylprednisolone 125mg lv			C						Not Reported
		/ 6 Hrs			-						
		ga 3 Fatty Acid 2000mg			С					1	Not Reported
		e Daily									•

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							Dotalioa 110	γροιτ			
		Pantor Daily	orazole 40mg lv Twice			С					Not Reported
		Propra	anolol 40mg Twice Daily line 25mg Daily			C C					Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	178450	012	DIRECT	Υ	НС), OT			44 YR	Female	USA
Preferred Term		<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Alanine Aminotransfera Increased; Aspartate	ase	Remde	esivir			S	Intravenous (not otherwise specified)				Gilead
Aminotransferase Increased; Blood Alkali		Cobici	stat/ gravir/Emtracitabine			С					Not Reported
Phosphatase Increase Blood Creatinine Increased; Therapy	Atorvastatin Creatinine Doxycycline ased; Therapy Omnipaque		statin ycline			CCC					Not Reported Not Reported
Interrupted;		Ceftria				C C C					Not Reported Not Reported
Transaminases Increas	sed		inephrine			Č					Not Reported
			carium			C					Not Reported
			calciferol			С					Not Reported
		Folic A	oic Acid			C C					Not Reported Not Reported
		Multivi				C					Not Reported
			ne-Guifenesin			C					Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2020	178450	018	DIRECT	Υ	LT				70 YR	Male	USA
Preferred Term		<u>Produ</u>	<u>ıct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Angioedema; Therapy		Remde	esivir	Υ		S C					Gilead
Interrupted		Azithro				С					Not Reported
		Duone				С					Not Reported
		Ascort Budes	oic Acid			C					Not Reported
			onide iexadine			C C C					Not Reported Not Reported
		Enoxa				Č					Not Reported
		Lasix	•			Č					Not Reported
		Lantus	3			С					Not Reported



						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			0000				N N	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
29-May-2020	17845068	DIRECT	Υ					61 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Infusion Site Extravasation; Periphe Swelling		desivir	Y		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
29-May-2020	17846418	DIRECT	Y		RI, OT			63 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Atrial Fibrillation	Remo	desivir 100mg/20ml			S	Intravenous (not otherwise specified)			(Gilead
	Remo	desivir 100mg/20ml			S	Intravenous (not otherwise specified)			(Gilead
	Remo	desivir 100mg/20ml			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
29-May-2020	17846473	DIRECT	Υ		RI, OT			76 YR	Female	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; Atrial Fibrillation; Blood Crea Phosphokinase Increa Blood Lactate	atine	desivir 100mg/20ml Vial			S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)			(Gilead

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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>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845070	DIRECT	Υ		DE, HO, LT			68 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Death	Emer	rgency Use Remdesivir	Υ		S	Intravenous (not otherwise specified)	Other Frequency:X1 Loading Dose;		G	ilead
	Emer	rgency Use Remdesivir	Υ		S	Intravenous (not otherwise specified)			G	ilead
	Aceto	ominopohen			С				N	ot Reported
	Amlo	pidine			С					ot Reported
		trozole			С					ot Reported
	Asco	rbic Acid			С					ot Reported
		astatin astatin			С					ot Reported
		romycin			С					ot Reported
	Cefe				С					ot Reported
	•	dogrel			С					ot Reported
		bivent Respimat			С					ot Reported
		pazine			C C					ot Reported
		ecalciferol			C					ot Reported
	Cloni				C					ot Reported
	Core				C C					ot Reported
		ocobalamin			C					ot Reported
		sate Senna			C					ot Reported
		pezil			С					ot Reported
		aparin			С					ot Reported
		otidine			С					ot Reported
		ous Sulfate			С					ot Reported
	Folic	Acid			С					ot Reported
	Gaba	apentin			С				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
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	Case #	Case Type	Health	Prof O	utcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17845128	DIRECT							48 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		Mfr
ntercepted Product Preparation Error; Prod Preparation Error	Remo duct	lesivir			S						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
30-May-2020	17845130	DIRECT	Υ	Н	O, OT				70 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>
Bradycardia	Remo	lesivir	Υ		S	Intravenous (not otherwise specified)					Gilead
		rlprednisolone aparin pril			C C C	o					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
30-May-2020	17846348	DIRECT		Н	0					Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
nfusion Site Pain	Remo	lesivir (Eua)			S						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2020	17846639	EXPEDITED (15-DAY)		DI	E, OT	US-GILEAD-20 0469017)20-		82 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	Duration		Mfr
Death; Hypoxia	Remo	lesivir			S	Intravenous (not otherwise specified)	100 Mg	g, Qd			Gilead
	Famo	tidine			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-May-2020	17845136	DIRECT	Y					63 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Acute Kidney Injury; Chronic Kidney Diseas		esivir (Eua)	Υ		S	Intravenous (not otherwise specified)			C	Gilead
	Remd	esivir (Eua)			С				N	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-May-2020	17845140	DIRECT	Υ					57 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Haemorrhage; Thrombocytopenia	Remd	esivir			S	Intravenous drip			N	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
01-Jun-2020	17844495	EXPEDITED (15-DAY)			ОТ	US-GILEAD-20 0468824	20-	26 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Liver Function Test Increased; Oxygen	Remd	esivir			S	Intravenous (not otherwise specified)	200 Mg, Once		C	Gilead
Consumption Decreas Renal Impairment	ed; Remd	esivir			S	Intravenous (not otherwise specified)	100 Mg, Qd		C	Gilead
	Remd	esivir			S	Intravenous (not otherwise specified)	Unk		C	Silead
	Coval	escent Plasma			С		Unk		N	lot Reported
	Tociliz	zumab			С		Unk		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
01-Jun-2020	17846453	DIRECT	Y					61 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>

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Blood Creatinine Increased	Remo	lesivir			S	Intravenous (not otherwise specified	٦)				Gilead
	Losar Metfo Tociliz Aspiri Cefur Famo Gaba Guaife	rmin Er zumab n oxime tidine pentin enesin ocholorthiazide			0000000000	Otherwise specified	•)				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	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.	OTC	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>		<u>Mfr</u>
Alanine Aminotransfe Increased; Liver Func Test Increased	tion Tociliz Lover Onda Trama	zumab nox nsetron			S C C C C C	Intravenous (not otherwise specified	(k				Gilead Not Reported Not Reported Not Reported Not Reported 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
01-Jun-2020	17846480	DIRECT	Υ						51 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>		<u>Mfr</u>
Product Dose Omission	on Remo	lesivir			S	Intravenous (not otherwise specified	(k				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	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	ļ	<u>Mfr</u>
Alanine Aminotransfer Increased; Aspartate Aminotransferase Increased; Therapy Cessation	ase Remo	lesivir			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
01-Jun-2020	17846513	DIRECT			ОТ			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Hyperphosphataemia	Remo	lesivir			S	Intravenous (not otherwise specified)			Not Reported
	Ceftri	axone			С					Not Reported
		sate Sodium			C					Not Reported
	Etomi				С					Not Reported
	Famo				С					Not Reported
		emide			C C					Not Reported
		n Detemir			C					Not Reported
		n Humalog			С					Not Reported
		esium Sulfate			C C					Not Reported
	Metor	azone			C					Not Reported Not Reported
		a Liquid			C					Not Reported
		a Liquid tanide Drip			C C					Not Reported
		nyl Drip			C					Not Reported
		rin Infusion			C					Not Reported
		n Human Regular			Č					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	17846521	DIRECT			ОТ			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>]	<u>Mfr</u>
Thrombocytosis	Remo	lesivir			S	Intravenous (not otherwise specified)			Not Reported
		axone sate Sodium			C C					Not Reported Not Reported

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							P			
	Insulin I Magnes Metolaz Metopro Senna I Bumeta Fentany	dine mide Detemir Humalog sium Sulfate zone olol Liquid anide Drip			00000000000		<u>r</u>		No No No No No No No No No No No No No N	ot Reported
	Insulin	Human Regular			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
01-Jun-2020	17846712	DIRECT	N	С	ÞΕ			68 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Covid-19		esivir 5mg/Ml ntrated Solution	Υ		S	Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Dose Or Amount:		G	ilead
	Conval	escent Plasma 213 MI			С	,			N	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17847828	EXPEDITED (15-DAY)				US-GILEAD-20 0468846	20-	67 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Product Administration Error; Product Storage Error		sivir			S	Unknown	Unk		G	ilead
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17847986	EXPEDITED (15-DAY)		D	E, OT	US-GILEAD-20 0469172	20-	92 YR	Female	USA
				OTC	Role				Mf	



Acute Kidney Injury; D	eath Re	emdesivir			S	Unknown	Unk				Gilead
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	!	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2020	17848017	EXPEDITED (15-DAY)			LT, OT	US-GILEAD-20 0469288	20-		79 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		Mfr
Blood Creatinine Increased; Blood Urea		emdesivir			S	Intravenous (not otherwise specified)	200 Mg	I			Gilead
Increased	Re	emdesivir			S	Intravenous (not otherwise specified)	100 Mg	ı, Qd			Gilead
	Ce Az Fe Mi Pro All Fa As Fu En Cis Me Sir	cilizumab efepime ithromycin entanyl dazolam eppofol eumin emotidine epirin 81 rosemide exaparin esatracurium eropenem envastatin esamin D [Colecalciferol]			000000000000000						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	17848022	EXPEDITED (15-DAY)			HO, LT, OT	US-GILEAD-20 0469201	20-		48 YR	Female	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Endotracheal Intubation	on Re	emdesivir			S	Unknown	Unk				Gilead
	Ato Fa Fu	pirin [Acetylsalicylic Acid] orvastatin motidine rosemide razepam			00000						Not Reported Not Reported Not Reported Not Reported Not Reported

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	Vanc Hepa Insuli Insuli Nore	um Chloride comycin arin in Aspart in Detemir pinephrine iaxone			000000					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
01-Jun-2020	17848028	EXPEDITED (15-DAY)		DE	E, OT	US-GILEAD-20 0469174	20-	76 YR	Female	USA
Preferred Term	Prod	luct	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
	Albut	erol [Salbutamol]			С		Unk			Not Reported
	Aspir	in [Acetylsalicylic Acid]			С		Unk			Not Reported
	Cefe	pime			С		Unk			Not Reported
	Chlor	rhexidine			С		Unk			Not Reported
	Norm	nosol R			С		Unk			Not Reported
	Enox	aparin			С		Unk			Not Reported
	Fenta	anyl			С		Unk			Not Reported
	Нера	arin			С		Unk			Not Reported
	Hydro	ocortisone			С		Unk			Not Reported
	Triad				С		Unk			Not Reported
	Insuli	in Glargine			С		Unk			Not Reported
	Insuli	in Regular Hm			С		Unk			Not Reported
	Lacta	ated Ringers			С		Unk			Not Reported
	Lactu	ulose			С		Unk			Not Reported
	Magr	nesium Sulfate			С		Unk			Not Reported
	Mela	tonin			С		Unk			Not Reported



						Detailed IX	cport				
	Metro	onidazole			С		Unk				Not Reported
	Midaz	zolam			С		Unk				Not Reported
	Midoo	drine			С		Unk				Not Reported
	Morpl	hine Sulfate			С		Unk				Not Reported
	Nore	oinephrine			С		Unk				Not Reported
	Panto	prazole			С		Unk				Not Reported
	Phen	ylephrine			С		Unk				Not Reported
	Prism Prism Propo Simva Sodiu	astatin ım Bicarbonate omycin			00000000						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	17848032	EXPEDITED (15-DAY)		0.	Т	US-GILEAD-2 0468530	2020-		57 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u>e Text</u>	Duration		<u>Mfr</u>
Bilirubin Conjugated Increased	Remo	desivir			S	Unknown	Unk				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	17848037	EXPEDITED (15-DAY)		0	Т	US-GILEAD-2 0468536	2020-		55 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; Infusion Related Reaction	Remo	desivir			S	Intravenous (not otherwise specified	200 M d)	lg, Qd			Gilead
	Remo	desivir			S	Intravenous (not otherwise specified	100 M d)	lg 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
01-Jun-2020	17848039	EXPEDITED (15-DAY)			DE, OT	US-GILEAD-20 0469173	20-	82 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Afr</u>
Death	Remd	lesivir			S	Intravenous (not otherwise specified)	200 Mg, Once			Gilead
	Remd	lesivir			S	Intravenous (not otherwise specified)	100 Mg, Qd			Gilead
	Acetai	minophen			С		Unk			Not Reported
	Apixal	ban			С		Unk			Not Reported
	Ceftria	axone			С		Unk			Not Reported
	Enoxa	aparin			С		Unk			Not Reported
	Furose	emide			С		Unk			Not Reported
	Gabar	pentin			С		Unk			Not Reported
	Insulir	n Lispro			С		Unk			Not Reported
	Insulir	n Regular Hm			С		Unk			Not Reported
	Lactat	ted Ringers			С		Unk			Not Reported
	Latano	oprost			С		Unk			Not Reported
	Magne	esium Sulfate			С		Unk			Not Reported
	Metop	orolol Tartrate			С		Unk			Not Reported
	Metro	nidazole			С		Unk			Not Reported
	Modaf	finil			С		Unk			Not Reported
	Mome	etasone			С		Unk			Not Reported
	Formo	oterol			С		Unk			Not Reported
	Monte	elukast			С		Unk			Not Reported
	Morph	nine			С		Unk			Not Reported
	Potass	sium Chloride			С		Unk			Not Reported
	Sertra	lline			С		Unk			Not Reported
	Sodiu	m Chloride 0.9%			С		Unk			Not Reported

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	Vancomycin OA Received Date					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-Jun-2020	178480	43 EXPEDITED	(15-DAY)			DE, OT	US-GILEAD-20 0469167)20-		61 YR	Female	USA
Preferred Term		<u>Product</u>		Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>N</u>	<u>Mfr</u>
Respiratory Arrest		Remdesivir				S	Intravenous (not otherwise specified)	200 Mg	, Once			Gilead
		Convalescent Plasma				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-Jun-2020	178480	44 EXPEDITED	(15-DAY)			DE, OT	US-GILEAD-20 0469503)20-		45 YR	Male	USA
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage	<u>Text</u>	Duration	<u>N</u>	<u>Afr</u>
Blood Creatinine Increased; Cardiac Arr		Remdesivir				S	Intravenous (not otherwise specified)	200 Mg	, Once		1	Gilead
Glomerular Filtration R Decreased; Liver Func Test Increased		Remdesivir				S	Intravenous (not otherwise specified)	100 Mg	, Qd		1	Gilead
		Acetaminophen				С						Not Reported
		Norco Albuterol [Salbutamol]				C C						Not Reported Not Reported
		Amiodarone				C						Not Reported
		Amlodipine				Ċ						Not Reported
		Aspirin [Acetylsalicylic	Acidl			C C						Not Reported
		Atorvastatin				С						Not Reported
		Calcium Carbonate				С						Not Reported
		Calcium Gluconate				C C						Not Reported
		Ceftriaxone				С						Not Reported
		Chlorhexidine Glucona	te			С						Not Reported
		Cholecalciferol				С						Not Reported
		Cisatracurium				C C						Not Reported
		Dexmedetomidine				C						Not Reported
		Digoxin				C C						Not Reported Not Reported
		Doxycycline Enoxaparin				C						Not Reported Not Reported
		Heparin				C						Not Reported

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	Insi	ulin Glargine			С						Not Reported		
Insulin Lispro					C C						Not Reported		
	Famotidine Fentanyl Furosemide Losartan Meropenem				C						Not Reported		
					С				Not Reported				
					000000						Not Reported		
					C						Not Reported		
			C						Not Reported				
	Metformin				C						Not Reported		
	Methylprednisolone Metoprolol Midazolam Nitroglycerin Norepinephrine				C						Not Reported		
					C						Not Reported Not Reported		
					C						Not Reported		
				C C C C							Not Reported		
				C							Not Reported		
Nortriptyline Phenylephrine			C								Not Reported		
Prienylepriline Propofol Tocilizumab Warfarin				C							Not Reported		
					Ċ						Not Reported		
					Č						Not Reported		
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		
01-Jun-2020	17848077	EXPEDITED (15-DAY)		(TC	US-GILEAD-2020- 0468738			71 YR	Male	USA		
Preferred Term	eferred Term Product		Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>		<u>Mfr</u>		
Platelet Count Increase	ed Rer	mdesivir			S	Intravenous (not otherwise specified)	100 Mg, (Qd			Gilead		
		max [Tamsulosin drochloride]			С		Unk				Not Reported		
	Vita	min C [Ascorbic Acid]			С		Unk				Not Reported		
	Zin				С		Unk				Not Reported		
Allopu		purinol			С		Unk				Not Reported		
	Azi	thromycin			С		Unk				Not Reported		
	Ber	nzonatate			С		Unk				Not Reported		
	Cef	triaxone			С		Unk				Not Reported		
	Dip	yridamole			С		Unk				Not Reported		
	End	oxaparin			С		Unk				Not Reported		
	Inst	С			Unk					Not Reported			



				Dotanou Roport											
	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	te Case # Case Type		Health Prof		Outcomes	Mfr Control #		<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country			
02-Jun-2020	17794	570 EXPEDITE	ED (15-DAY)		DE, HO, LT		OT NL-BRISTOL-M SQUIBB COMP/ BMS-2020-0372		PANY-		66 YR Male		NLD		
Preferred Term		Product		Comp.	OTO	Role	Rou	<u>te</u>	Dosage	e Text	Duration		<u>Mfr</u>		
Covid-19; Haematoma Muscle; Lactic Acidosis Off Label Use; Renal Failure; Respiratory Failure; Subcutaneous Abscess	ì	Apixaban				S	Unkn	own	Unk				Bristol Myers Squibb		
	s;	Remdesivir	r			S	Intrav	venous (not wise specified)	200 M	illigram, Qd			Not Reported		
	3	Remdesivir				S		venous (not wise specified)	100 M	illigram, Qd			Not Reported		
		Nadroparine				S	Unkn	own	Unk				Not Reported		
		Pravastatine [Pravastatin Sodium]				С	Unkn	own	Unk				Not Reported		
		Metoclopramide			С	Unknown Unknown		Unk				Not Reported			
		Nifedipine			С			Unk				Not Reported			
		Perindopril				С	Unkn	own	Unk				Not Reported		
		Oxycodone [Oxycod Hydrochloride]	lone			С	Unkn	own	Unk				Not Reported		
		Fenoterol;Ipratropius	m			С	Unkn	own	Unk				Not Reported		
		Cotrimaxazol			С	Unkn	own	Unk				Not Reported			
		Valaciclovir Allopurinol Paracetamol Pantoprazol [Pantoprazole] Flucloxacillin				C C	Unknown Unknown Unknown		Unk				Not Reported		
									Unk				Not Reported		
						С			Unk				Not Reported		
						С	Unkn	own	Unk				Not Reported		
						С	Unkn	own	Unk				Not Reported		
		Folic Acid			С	Unkn	own	Unk				Not Reported			

Date - Time: 03-Jun-2020 09:54:23 AM EST

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

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2020	17852138	352138 EXPEDITED (15-DAY)		DE, HO, OT		FR-VALIDUS PHARMACEUTICALS LLC-FR- 2020VAL000437				Unknown	FRA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Te	<u>ext</u>	Duration	Mfr	
Coronavirus Infection; Pancreatitis	Furose	emide			S	Intravenous (not otherwise specified)	Unk			Val	idus
	Remde			S	Intravenous (not otherwise specified)	100 Mg, C	Qd		Not	Reported	
	Karde	gic			С		Unk			Not	Reported
	Couma	adine			С		Unk			Not	Reported
	Perfalgan				С		Unk			Not	Reported
	Triated	Triatec /00885601/ Piperacillin			С		Unk			Not	Reported
	Pipera				С		Unk			Not	Reported
	Cordarone				С		Unk			Not	Reported
	Rovam	mycine /00074401/			С		Unk			Not	Reported
	Cefota	xime			С		Unk			Not	Reported
	Hepari	n Al			С		Unk			Not	Reported
	Ciprofloxacin				С		Unk			Not	Reported
	Tazoba	Tazobactam			С		Unk			Not	Reported
	Solupred /00016217/				С		Unk			Not	Reported
	Bisoce				С		Unk			Not	Reported