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

Selection Criteria:

Product Name:	.;HARVONI
Product Active Ingredient:	·
Active Ingredient	·
Active Moiety:	·
FDA Received Date:	From: 10-OCT-2014 To: 15-MAR-2015
MedDRA® Version* :	17.1
Total Cases**:	759
Number of Pages:	216

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

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

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

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

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

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting Direct: submitted “directly” to FDA by healthcare professionals, patients and other consumers
Health Professional	Indicates whether the initial source who provided information about the event is a health professional (HP). 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.
Manufacturer Control #	The Manufacturer Control Number is the manufacturer’s unique identifier associated with the case. Also referred to as the Company Report Number.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).
Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.

Field Heading	Definition
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 therapeutic 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.
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.
Manufacturer	The manufacturer of the product, as indicated in the report.

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Oct-2014	10555873	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0120484	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swelling face	HARVONI	S	UNKNOWN	UNK		GILEAD
	VIBRANCE GREEN	C				
	PLANT FUSION WITH PROTEIN POWDER	C				
	MORINGA	C				
	SEA VEG	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Nov-2014	10564309	EXPEDITED (15-DAY)			US-GILEAD-2014-0120470	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Nov-2014	10567735	DIRECT	Y			49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	by mouth		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Nov-2014	10569133	EXPEDITED (15-DAY)			US-GILEAD-2014-0121190		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrointestinal motility disorder	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2014	10574244	EXPEDITED (15-DAY)			US-GILEAD-2014-0121768	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Erythema	HARVONI	S	UNKNOWN	UNK		GILEAD
Pruritus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Nov-2014	10574606	EXPEDITED (15-DAY)			US-GILEAD-2014-0122062	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD
Abdominal discomfort						
Diarrhoea						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Nov-2014	10577680	EXPEDITED (15-DAY)			US-GILEAD-2014-0122164		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD
	TRUVADA	C				GILEAD
	TIVICAY	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Nov-2014	10580238	EXPEDITED (15-DAY)			US-GILEAD-2014-0122382		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lymphadenopathy	HARVONI	S	UNKNOWN			GILEAD
Blister						
Lymphadenopathy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2014	10582222	EXPEDITED (15-DAY)			US-GILEAD-2014-0121897		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN			GILEAD
Abdominal discomfort						
Poor quality sleep						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2014	10582315	EXPEDITED (15-DAY)			US-GILEAD-2014-0122431		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	UNKNOWN			GILEAD
	ADCIRCA	C				
	SPIRONOLACTONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Nov-2014	10582504	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0122112	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure acute	HARVONI	S	UNKNOWN	UNK		GILEAD
Presyncope	PLAVIX	C				
Dehydration	COLCHICINE	C		UNK, BID		
Diarrhoea	ULORIC	C				
Dysphagia	METOPROLOL	C				
Sensation of foreign body	LIPITOR	C				
Chest pain	ASPIRIN / 00002701/	C		81 mg, UNK		
Vomiting	ESOMEPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2014	10584733	EXPEDITED (15-DAY)			US-GILEAD-2014-0122459		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Off label use	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2014	10585030	EXPEDITED (15-DAY)			US-GILEAD-2014-0122564		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Protein urine present	HARVONI	S	UNKNOWN			GILEAD
Urine protein/creatinine ratio increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2014	10585940	EXPEDITED (15-DAY)			US-GILEAD-2014-0122925		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hot flush	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Nov-2014	10587619	EXPEDITED (15-DAY)			US-GILEAD-2014-0122993		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrointestinal sounds abnormal	HARVONI	S	UNKNOWN			GILEAD
Diarrhoea						
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Nov-2014	10588065	EXPEDITED (15-DAY)			US-GILEAD-2014-0122913		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vitreous floaters	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Nov-2014	10588079	EXPEDITED (15-DAY)			US-GILEAD-2014-0122982		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	UNKNOWN			GILEAD
Abdominal pain						
Influenza like illness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Nov-2014	10591545	EXPEDITED (15-DAY)			US-GILEAD-2014-0123020		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Nov-2014	10595171	DIRECT	Y			61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	HARVONI	S	ORAL			GILEAD
Back pain						
Feeling abnormal						
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2014	10596714	EXPEDITED (15-DAY)			US-GILEAD-2014-0123522	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nail infection	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Nov-2014	10596782	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2014-0123538	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure congestive	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2014	10599901	EXPEDITED (15-DAY)			US-GILEAD-2014-0123398		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dose omission	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2014	10599930	EXPEDITED (15-DAY)			US-GILEAD-2014-0123613		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastric disorder	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2014	10599932	EXPEDITED (15-DAY)			US-GILEAD-2014-0123668		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ear infection	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2014	10599933	EXPEDITED (15-DAY)			US-GILEAD-2014-0123685	69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN			GILEAD
Diarrhoea	METFORMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2014	10603181	EXPEDITED (15-DAY)			US-GILEAD-2014-0123622		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2014	10603283	EXPEDITED (15-DAY)			US-GILEAD-2014-0123630	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle spasms	HARVONI	S	UNKNOWN	UNK		GILEAD
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2014	10603286	EXPEDITED (15-DAY)			US-GILEAD-2014-0123837		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	UNKNOWN	2 DF, QD		GILEAD
	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2014	10603290	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0123734		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	HARVONI	S	UNKNOWN			GILEAD
Diarrhoea						
Insomnia						
Migraine						
Pain						
Phantom pain						
Retching						
Unevaluable event						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Nov-2014	10606830	DIRECT				59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL			GILEAD
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Nov-2014	10615690	DIRECT	Y	HO		51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	1 QD Oral		GILEAD
	METFORMIN	C				
	OMPERAZOLE	C				
	GLYBURIDE	C				
	DICYCLOMINE	C				
	LYRICA	C				
	BUPRENORPHINE	C				
	VITAMIN B1	C				
	AMLODIPINE	C				
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Nov-2014	10611592	EXPEDITED (15-DAY)			US-GILEAD-2014-0124327		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Dec-2014	10617853	EXPEDITED (15-DAY)			US-GILEAD-2014-0124412		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2014	10620623	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2014-0124551	50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pancreatitis	HARVONI	S	UNKNOWN			GILEAD
Chest pain						
Paraesthesia oral						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2014	10620628	EXPEDITED (15-DAY)			US-GILEAD-2014-0124462		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Joint swelling	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue	ATENOLOL	C				
	AMBIEN	C				
	D3	C				
	MULTIVITAMINS	C				
	ALA /00213801/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2014	10622428	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vaginal odour	HARVONI	S	ORAL			GILEAD
Vaginal discharge						
Vaginal infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2014	10622456	DIRECT	Y			80 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Visual impairment	HARVONI	S	ORAL	1 tablet		GILEAD
Blood pressure increased						
Hearing impaired						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2014	10622475	DIRECT	Y			57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 TABLET DAILY PO		GILEAD
Depression						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2014	10588049	EXPEDITED (15-DAY)			US-GILEAD-2014-0122699		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bone pain	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal discomfort						
Diarrhoea						
Headache						
Pain						
Vision blurred						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2014	10623275	EXPEDITED (15-DAY)			US-GILEAD-2014-0124798	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2014	10623279	EXPEDITED (15-DAY)			US-GILEAD-2014-0124725		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus generalised	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2014	10623292	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0125129	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pancytopenia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2014	10623359	EXPEDITED (15-DAY)			US-GILEAD-2014-0124754	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dose omission	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Dec-2014	10636192	DIRECT	Y			62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abnormal dreams	HARVONI	S	ORAL			GILEAD
Somnolence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Dec-2014	10627291	EXPEDITED (15-DAY)			US-GILEAD-2014-0125103		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Balance disorder	HARVONI	S	UNKNOWN	UNK		GILEAD
Feeling abnormal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2014	10636131	EXPEDITED (15-DAY)			US-GILEAD-2014-0125282		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatinine increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Glomerular filtration rate decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2014	10636133	EXPEDITED (15-DAY)			US-GILEAD-2014-0125275		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Increased appetite	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Feeling cold						
Hypoglycaemia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2014	10636146	EXPEDITED (15-DAY)		HO	US-GILEAD-2014-0125102		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	HARVONI	S	UNKNOWN			GILEAD
Dyspnoea						
Headache						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2014	10636150	EXPEDITED (15-DAY)			US-GILEAD-2014-0125482		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2014	10636151	EXPEDITED (15-DAY)			US-GILEAD-2014-0125488	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Dec-2014	10636153	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0125677		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lung infection	HARVONI	S	UNKNOWN	UNK		GILEAD
Sputum discoloured						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Dec-2014	10641134	DIRECT	Y			58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	HARVONI	S	ORAL	HARVONI 90-400 MG DAILY PO		GILEAD
Abdominal distension						
Chest discomfort						
Decreased appetite						
Dyspnoea						
Psychomotor hyperactivity						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2014	10641994	EXPEDITED (15-DAY)			US-GILEAD-2014-0125400		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2014	10641995	EXPEDITED (15-DAY)			US-GILEAD-2014-0125483		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN	UNK		GILEAD
Drug dose omission						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2014	10641997	EXPEDITED (15-DAY)			US-GILEAD-2014-0125493	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2014	10641998	EXPEDITED (15-DAY)			US-GILEAD-2014-0125902		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	UNKNOWN	UNK		GILEAD
Diarrhoea						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Dec-2014	10643191	DIRECT	Y			80 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2014	10643497	EXPEDITED (15-DAY)		OT	DE-GILEAD-2014-0124918		Female	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Angioedema	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2014	10644615	EXPEDITED (15-DAY)			US-GILEAD-2014-0125989		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Viral infection	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Dec-2014	10644991	DIRECT	Y			51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neuropathy peripheral	HARVONI	S	ORAL	1, daily, po		GILEAD
Disease recurrence						
Fibrosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2014	10646827	EXPEDITED (15-DAY)			US-GILEAD-2014-0126179	82 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hot flush	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2014	10646857	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0126042		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ascites	HARVONI	S	ORAL	UNK, QD		GILEAD
Back pain	LACTULOSE	C				
Asthenopia						
Blood glucose decreased						
Blood pressure fluctuation						
Dysarthria						
Fatigue						
Feeling abnormal						
Headache						
Hunger						
Hypoglycaemia						
Insomnia						
Joint stiffness						
Muscle spasms						
Peripheral swelling						
Speech disorder						
Yellow skin						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2014	10646866	EXPEDITED (15-DAY)			US-GILEAD-2014-0126189		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chills	HARVONI	S	UNKNOWN			GILEAD
Pyrexia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2014	10646891	EXPEDITED (15-DAY)			US-GILEAD-2014-0126255	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	UNKNOWN			GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2014	10647564	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0126408		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic failure	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal pain						
Abdominal rigidity						
Bladder pain						
Chest pain						
Congenital cystic kidney disease						
Diarrhoea						
Fatigue						
Headache						
Paraesthesia						
Peripheral swelling						
Platelet count abnormal						
Splenomegaly						
Vasodilatation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2014	10647597	EXPEDITED (15-DAY)			US-GILEAD-2014-0126199	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza like illness	HARVONI	S	UNKNOWN	UNK		GILEAD
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2014	10651558	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypersensitivity	HARVONI	S	ORAL			GILEAD
Eye discharge						
Eye pruritus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10653039	EXPEDITED (15-DAY)			US-GILEAD-2014-0126301		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	HARVONI	S	UNKNOWN	UNK		GILEAD
Back pain						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10653196	EXPEDITED (15-DAY)			US-GILEAD-2014-0126500		Female	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Off label use	HARVONI		S	UNKNOWN	UNK		GILEAD
	PRILOSEC 00661201/	/	C	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10653198	EXPEDITED (15-DAY)			US-GILEAD-2014-0126272	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mood swings	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Anxiety						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10653245	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0127263		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cognitive disorder	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10653267	EXPEDITED (15-DAY)			US-GILEAD-2014-0126176	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Dec-2014	10653296	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0127261		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cognitive disorder	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10599334	EXPEDITED (15-DAY)			US-GILEAD-2014-0123390		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrooesophageal reflux disease	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache	PROTONIX	C		40 mg, QD		
	AMBIEN	C		10 mg, QHS		
	VALIUM	C		15 mg, QHS		
	CLONIDINE	C		0.2 mg, BID		
	ZOLOFT	C		50 mg, QD		
	METOPROLOL TARTRATE	C		50 mg, BID		
	OXYCONTIN	C		40 mg, BID		
	OXYCODONE	C		30 mg, Q4Hr		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10656489	EXPEDITED (15-DAY)			US-GILEAD-2014-0127197		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10656518	EXPEDITED (15-DAY)			US-GILEAD-2014-0127255		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10656524	EXPEDITED (15-DAY)			US-GILEAD-2014-0127391		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Migraine	HARVONI	S	UNKNOWN			GILEAD
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10656563	EXPEDITED (15-DAY)		OT	US-GILEAD-2014-0127353	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10658854	DIRECT		HO			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S				
	E PIVIR HBV	C				
	HARVONI	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2014	10659156	DIRECT		OT		63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness postural Headache	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10659483	EXPEDITED (15-DAY)			US-GILEAD-2014-0127233		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10659536	EXPEDITED (15-DAY)			US-GILEAD-2014-0127495	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blister Rash Rash pustular	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10660550	EXPEDITED (15-DAY)			US-GILEAD-2014-0127561	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary tract infection	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10660611	EXPEDITED (15-DAY)			US-GILEAD-2014-0127708		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neuropathy peripheral	HARVONI	S	UNKNOWN	UNK		GILEAD
Pruritus						
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10661419	DIRECT	Y			62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hallucination, visual	HARVONI	S	ORAL	1 tablet, QD, Oral		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Dec-2014	10661488	DIRECT	Y			63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	one tablet, QD, Oral		
	APAP	C				
	IMITREX	C				
No therapeutic response						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2014	10599907	EXPEDITED (15-DAY)			US-GILEAD-2014-0123542	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arthralgia	HARVONI	S	UNKNOWN	UNK		GILEAD
	ATENOLOL CHLORTHALIDONE	C	ORAL	1 DF, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2014	10662829	EXPEDITED (15-DAY)			US-GILEAD-2014-0126318	62 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urticaria	HARVONI	S	UNKNOWN			GILEAD
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2014	10663302	EXPEDITED (15-DAY)			US-GILEAD-2014-0127797	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bronchitis	HARVONI	S	UNKNOWN	UNK		GILEAD
Influenza						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2014	10663305	EXPEDITED (15-DAY)			US-GILEAD-2014-0127887		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain lower	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2014	10663307	EXPEDITED (15-DAY)			US-GILEAD-2014-0128091	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2014	10666221	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2014-0127533	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Clostridium difficile colitis	HARVONI	S	UNKNOWN	UNK		GILEAD
	LISINOPRIL	C	UNKNOWN	20 mg, QD		
	TOPROL	C	UNKNOWN	100 mg, QD		
	NEURONTIN	C	UNKNOWN	300 mg, BID		
	TRIAMTERENE AND HYDROCHLOROTHIAZID	C	UNKNOWN	1 DF, QD		
	LANTUS	C		30 units, QD		
	LIPITOR	C	ORAL	10 mg, QHS		
	PRILOSEC / 00661201/	C	UNKNOWN	UNK, QD		
	RESTASIS	C	UNKNOWN	gtts, QD		
	OSCAL D / 07451701/	C	UNKNOWN	UNK		
	ASA	C	UNKNOWN	81 mg, QD		
	GABAPENTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2014	10667241	DIRECT		OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	HARVONI	S	ORAL	1 tablet daily by mouth		GILEAD
Dyspnoea						
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Dec-2014	10668065	DIRECT		OT		57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	HARVONI	S	ORAL	1 tab		GILEAD
	METFORMIN	C				
	LISINOPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10603282	EXPEDITED (15-DAY)			US-GILEAD-2014-0123620	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abnormal dreams	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10620625	EXPEDITED (15-DAY)			US-GILEAD-2014-0124433	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10642000	EXPEDITED (15-DAY)			US-GILEAD-2014-0125829	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Drug dose omission						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10669941	EXPEDITED (15-DAY)			US-GILEAD-2014-0128010		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD
Eye pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10669951	EXPEDITED (15-DAY)			US-GILEAD-2014-0127984		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pollakiuria	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10671699	EXPEDITED (15-DAY)			US-GILEAD-2014-0128412		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD
Dyspnoea						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10671720	EXPEDITED (15-DAY)			US-GILEAD-2014-0128449		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Loss of libido	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2014	10673094	EXPEDITED (15-DAY)			US-GILEAD-2014-0128282	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Dec-2014	10679010	DIRECT	Y	HO		70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal distension	HARVONI	S	ORAL	1 tablet once daily by mouth		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Dec-2014	10682900	DIRECT				59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI	S	ORAL	One Tablet		
Chills						
Cough						
Headache						
Pyrexia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Dec-2014	10682921	DIRECT	Y	OT		68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 Tablet		GILEAD
Chest pain	CERTIRIZINE	C				
	DILTIAZEM	C				
	DORZOLAMIDE	C				
	FINASTERIDE	C				
	LEVOTHYROXINE	C				
	LISINOPRIL	C				
	OXYCODONE	C				
	TIMOLOL	C				
	WARFARIN	C				
Blood pressure increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Dec-2014	10685425	DIRECT				64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL			GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2014	10685667	EXPEDITED (15-DAY)		HO	US-GILEAD-2014-0128129		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2014	10685969	EXPEDITED (15-DAY)			US-GILEAD-2014-0127574	62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2014	10687524	DIRECT				57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	90-400, daily, po		GILEAD
Influenza like illness	RIBAVIRIN	C				
	SOVALDI	C				
Diarrhoea						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2014	10687592	DIRECT	Y			37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	one tablet		
Amenorrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2014	10687969	DIRECT	Y			56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 tablet (400mg/90mg) daily po		GILEAD
Chills						
Headache						
Hyperhidrosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10620644	EXPEDITED (15-DAY)			US-GILEAD-2014-0124563		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug screen positive	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10636118	EXPEDITED (15-DAY)			US-GILEAD-2014-0125284	84 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	ORAL	24 DF, UNK		GILEAD
	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10653077	EXPEDITED (15-DAY)			US-GILEAD-2014-0127123		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN			GILEAD
Cough	WELLBUTRIN	C				
Dysphonia						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688296	EXPEDITED (15-DAY)			US-GILEAD-2014-0128477		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pollakiuria	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688302	EXPEDITED (15-DAY)			US-GILEAD-2014-0128660		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Musculoskeletal pain	HARVONI	S	UNKNOWN			GILEAD
Arthralgia						
Headache						
Myalgia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688313	EXPEDITED (15-DAY)			US-GILEAD-2014-0128367	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Furuncle	HARVONI	S	ORAL	1 DF, QD		GILEAD
Depression						
Fatigue						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688315	EXPEDITED (15-DAY)			US-GILEAD-2014-0128371	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
	TRAMADOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688322	EXPEDITED (15-DAY)			US-GILEAD-2014-0128428	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	1 DF, QD		GILEAD
Depression						
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688325	EXPEDITED (15-DAY)			US-GILEAD-2014-0128452		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688326	EXPEDITED (15-DAY)			US-GILEAD-2014-0128467	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688354	EXPEDITED (15-DAY)			US-GILEAD-2014-0128542		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Energy increased	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688355	EXPEDITED (15-DAY)			US-GILEAD-2014-0128652		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arthropod bite	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688358	EXPEDITED (15-DAY)			US-GILEAD-2014-0128655		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Constipation	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Jan-2015	10688359	EXPEDITED (15-DAY)			US-GILEAD-2014-0128654	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691704	EXPEDITED (15-DAY)			US-GILEAD-2014-0128820		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C RNA	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691705	EXPEDITED (15-DAY)			US-GILEAD-2014-0128892		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Eye discharge	HARVONI	S	UNKNOWN	UNK		GILEAD
Skin lesion						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691708	EXPEDITED (15-DAY)			US-GILEAD-2014-0129262	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Chills						
Cough						
Headache						
Pyrexia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691710	EXPEDITED (15-DAY)			US-GILEAD-2014-0129059		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain	HARVONI	S	ORAL	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691712	EXPEDITED (15-DAY)			US-GILEAD-2014-0128967		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hot flush	HARVONI	S	UNKNOWN	UNK		GILEAD
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691713	EXPEDITED (15-DAY)			US-GILEAD-2014-0128965	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI	S	UNKNOWN			GILEAD
Nausea						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691714	EXPEDITED (15-DAY)			US-GILEAD-2014-0128917	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691715	EXPEDITED (15-DAY)			US-GILEAD-2014-0129163		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aspartate aminotransferase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Alanine aminotransferase increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691717	EXPEDITED (15-DAY)			US-GILEAD-2014-0129726	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Agitation	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						
Fatigue						
Insomnia						
Poor quality sleep						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691721	EXPEDITED (15-DAY)			US-GILEAD-2014-0129853	37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Menstruation irregular	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691722	EXPEDITED (15-DAY)			US-GILEAD-2014-0129765	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oropharyngeal pain	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691723	EXPEDITED (15-DAY)			US-GILEAD-2014-0129782	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastroenteritis viral	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Insomnia						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691725	EXPEDITED (15-DAY)			US-GILEAD-2014-0129829	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritable bowel syndrome	HARVONI	S	UNKNOWN	UNK		GILEAD
Diarrhoea						
Dysgeusia						
Dyspepsia						
Stomatitis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10691726	EXPEDITED (15-DAY)			US-GILEAD-2015-0130142	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus generalised	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2015	10692674	DIRECT		OT		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood urine present Nephrolithiasis	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2015	10695099	DIRECT	Y	HO		61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain Hypertension	HARVONI	S	ORAL	one tablet		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Jan-2015	10697365	DIRECT	Y	OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swelling face Dyspnoea Muscular weakness	HARVONI	S	ORAL	1 tablet daily po		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699158	EXPEDITED (15-DAY)			US-GILEAD-2014-0129933	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue Diarrhoea Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699159	EXPEDITED (15-DAY)			US-GILEAD-2015-0130341		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental exposure to product	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699160	EXPEDITED (15-DAY)			US-GILEAD-2015-0130343	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	HARVONI	S	ORAL	1 DF, QD		GILEAD
Pruritus	PROPRANOLOL	C				
	XANAX	C				
	PRISTIQ	C				
	ALDACTONE / 00006201/	C				
	CHANTIX	C				
	OMEPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699164	EXPEDITED (15-DAY)			US-GILEAD-2015-0130363	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699209	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0130012	50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haematemesis	HARVONI	S	UNKNOWN	UNK		GILEAD
	OCTREOTIDE	C		UNK		
	MIDAZOLAM	C		UNK		
	FENTANYL	C				
	ZOSYN	C		UNK		
	ACETAMINOPHEN	C		UNK		
	PANTOPRAZOLE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699214	EXPEDITED (15-DAY)			US-GILEAD-2015-0130061	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urine odour abnormal	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue	URSODIOL	C		300 mg, BID		
Visual impairment	PROMACTA	C		50 mg, QD		
Dizziness	NADOLOL	C		20 mg, QD		
	SPIRONOLACTONE	C		100 mg, QD		
	L-THYROXINE / 00068001/	C		50 µg, QD		
	SUCRALFATE	C		1 DF, QID		
	MULTIVITAMIN / 07504101/	C		1 DF, QD		
	HYDROXYZINE HYDROCHLORIDE	C		25 mg, TID		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10699293	EXPEDITED (15-DAY)			US-GILEAD-2015-0130068	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Jan-2015	10700642	DIRECT	Y	HO		49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	RIBAVIRIN (RIBATAB) 600 MG RIBATAB	S	ORAL			UNKNOWN
Agitation	DIAZEPAM(VALIUM)	C				
	LITHIUM CARBONATE	C				
	NAPROXEN(NAPROSYN)	C				
	LEDIPAAVIR-SOFOSBUVIR	C				
Depressed level of consciousness						
Intentional overdose						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2015	10699313	EXPEDITED (15-DAY)			US-GILEAD-2015-0130219		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal pain upper						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2015	10699324	EXPEDITED (15-DAY)			US-GILEAD-2015-0130282		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2015	10699330	EXPEDITED (15-DAY)			US-GILEAD-2015-0130318	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight decreased	HARVONI	S	ORAL	1 DF, QD		GILEAD
Decreased appetite						
Dizziness						
Fatigue						
Headache						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2015	10704582	DIRECT				29 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2015	10704608	DIRECT				64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus generalised	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jan-2015	10706258	DIRECT	Y	DE			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2015	10706907	DIRECT	Y			57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nightmare	HARVONI	S	ORAL	1 tablet QD Oral		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2015	10707112	DIRECT				58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle spasms	HARVONI	S	ORAL	1; once daily	8 WEEK	GILEAD
Impaired work ability						
Muscle spasms						
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2015	10707172	DIRECT				56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	ORAL			GILEAD
Dyspnoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2015	10707617	DIRECT				59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 tablet qd oral		GILEAD
	ENALAPRIL	C				
Dizziness	HZTZ	C				
Blood pressure increased	VALACYCLOVIR	C				
	GAVILYTE	C				
	DIAZEPAM	C				
	AZITHROMYCIN	C				
	CLONIDINE	C				
	FOLIC ACID	C				
	MAGNESIUM	C				
	VITAMIND	C				
Pain in extremity						
Tinnitus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jan-2015	10707626	DIRECT				66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	ORAL			GILEAD
	PROPECIA	C				
	EFFEXOR	C				
	ASPIRIN	C				
	IRBESARTAN	C				
	METOPROLOL	C				
	AMLOPIPINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2015	10709641	DIRECT	Y			42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL			GILEAD
Headache						
Stomatitis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10644526	EXPEDITED (15-DAY)			US-GILEAD-2014-0126123	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Nausea						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10669942	EXPEDITED (15-DAY)			US-GILEAD-2014-0128077	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatine phosphokinase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Muscle strain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10669950	EXPEDITED (15-DAY)			US-GILEAD-2014-0128047		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pregnancy	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10691727	EXPEDITED (15-DAY)			US-GILEAD-2014-0129937	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sleep disorder	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711473	EXPEDITED (15-DAY)			US-GILEAD-2015-0130435		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arthralgia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711528	EXPEDITED (15-DAY)			US-GILEAD-2015-0130509		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Panic attack	HARVONI	S	UNKNOWN			GILEAD
Dyspnoea						
Headache						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711863	EXPEDITED (15-DAY)			US-GILEAD-2015-0130736	73 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mouth ulceration	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711864	EXPEDITED (15-DAY)			US-GILEAD-2015-0130838		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cough	HARVONI	S	UNKNOWN	UNK		GILEAD
Asthenia						
Fatigue						
Platelet count increased						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711865	EXPEDITED (15-DAY)			US-GILEAD-2015-0130741	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mouth ulceration	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711866	EXPEDITED (15-DAY)			US-GILEAD-2015-0130803		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sinusitis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711887	EXPEDITED (15-DAY)			US-GILEAD-2015-0130894	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10711890	EXPEDITED (15-DAY)			US-GILEAD-2015-0130895	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10712044	EXPEDITED (15-DAY)			US-GILEAD-2014-0127992		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
C-reactive protein increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Red blood cell sedimentation rate increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10712079	EXPEDITED (15-DAY)			US-GILEAD-2015-0130993	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrooesophageal reflux disease	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10712086	EXPEDITED (15-DAY)			US-GILEAD-2015-0131063		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	UNKNOWN	UNK		GILEAD
	PEPTO-BISMOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10712799	DIRECT				60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL			GILEAD
	VITAMIN C	C				
	CYMBALTA	C				
	MULTI VITAMIN	C				
	PANTOPRAZOLE	C				
	TRAZODONE	C				
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jan-2015	10712952	DIRECT	Y	OT		48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abnormal dreams	HARVONI	S	ORAL	1 tablet		GILEAD
Crying						
Nightmare						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Jan-2015	10714871	EXPEDITED (15-DAY)			US-GILEAD-2014-0128356		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S				GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10717632	EXPEDITED (15-DAY)			US-GILEAD-2015-0131135		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrooesophageal reflux disease	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10717639	EXPEDITED (15-DAY)			US-GILEAD-2015-0131184	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cold sweat	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal pain upper						
Abnormal faeces						
Nausea						
Retching						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10717651	EXPEDITED (15-DAY)			US-GILEAD-2015-0131185	58 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nightmare	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10717660	EXPEDITED (15-DAY)		OT	CA-GILEAD-2015-0131419	58 YR	Male	CAN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrolithiasis	HARVONI	S	UNKNOWN	UNK		GILEAD
Chromaturia	ROSUVASTATIN	S	UNKNOWN	UNK		
Cough						
Diarrhoea						
Influenza						
Muscle spasms						
Oropharyngeal pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10717664	EXPEDITED (15-DAY)			US-GILEAD-2015-0131227	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Localised intraabdominal fluid collection	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10717672	EXPEDITED (15-DAY)			US-GILEAD-2015-0131240	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chills	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10723560	DIRECT	Y	DE		59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	HARVONI	S	ORAL	1-2-15 only		GILEAD
Cardiac arrest						
Respiratory failure						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2015	10723792	DIRECT		LT,OT		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	ORAL	1 QD Oral		GILEAD
Hypoaesthesia oral	CARVEDILOL	C				
Dizziness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10721645	EXPEDITED (15-DAY)			US-GILEAD-2015-0132046		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Therapeutic response changed	HARVONI	S	UNKNOWN			GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10721777	EXPEDITED (15-DAY)			US-GILEAD-2015-0131289		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	UNKNOWN			GILEAD
Feeling abnormal	PLAQUENIL SULFATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10722176	EXPEDITED (15-DAY)		DE,OT	IE-GILEAD-2015-0132637	50 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Lactic acidosis	TRUVADA	C		UNK		GILEAD
Pulmonary embolism	COPEGUS	C		UNK		
Cardiac arrest	SEPTRIN	C		UNK		
	THIAMINE	C				
	CENTRUM / 02217401/	C				
	FLORINEF	C				
	HYDROCORTONE / 00028601/	C				
	ISENTRESS	C				
	LAXOSE	C				
	SENOKOT / 00142201/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10722222	EXPEDITED (15-DAY)			US-GILEAD-2015-0131551		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fungal infection	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10722231	EXPEDITED (15-DAY)			US-GILEAD-2015-0131402	58 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hordeolum	HARVONI	S	UNKNOWN	UNK		GILEAD
Arthralgia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10722361	EXPEDITED (15-DAY)			US-GILEAD-2015-0131837		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10722366	EXPEDITED (15-DAY)			US-GILEAD-2015-0131881	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jan-2015	10722375	EXPEDITED (15-DAY)			US-GILEAD-2015-0131937		Male	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Rash erythematous	HARVONI		S	UNKNOWN			GILEAD
Pruritus	PLAQUENIL 00072602/	/	C				
Sleep disorder due to a general medical condition							

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2015	10669939	EXPEDITED (15-DAY)			US-GILEAD-2014-0128008	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	UNKNOWN	2 DF, QD		GILEAD
	HARVONI	S	UNKNOWN	1 UNK, UNK		GILEAD
	FERROUS SULFATE	C		UNK		
	VITAMIN B COMPLEX	C		UNK		
	ZESTORETIC	C		UNK		
	KEPPRA	C		UNK		
	RIVASTIGMINE	C		UNK		
	SPIRONOLACTONE	C		UNK		
	METFORMIN	C		UNK		
	FUROSEMIDE	C		UNK		
	LEXAPRO	C		UNK		
	FOLIC ACID	C		UNK		
	COGENTIN	C		UNK		
	XANAX	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2015	10711479	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0130448		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	HARVONI	S	UNKNOWN	UNK		GILEAD
Drug interaction	DIGOXIN	S	UNKNOWN	UNK		

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2015	10726267	DIRECT				65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight decreased	HARVONI	S	ORAL	1 tablet daily po		GILEAD
Constipation						
Dehydration						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2015	10726581	DIRECT				46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	ORAL	1 tablet, daily, po		GILEAD
Dizziness						
Visual impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Jan-2015	10730466	DIRECT				60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	ORAL	1 pill once daily taken by mouth		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2015	10647571	EXPEDITED (15-DAY)			US-GILEAD-2014-0126407	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain	HARVONI	S	ORAL	1 DF, QD		GILEAD
Dry skin	PROTONIX	C				
Rash	GABAPENTIN	C				
Pruritus	PREMARIN	C				
Pruritus generalised	LYRICA	C				
	PROVIGIL 01265601/ /	C				
	VYVANSE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2015	10729433	DIRECT	Y	OT		59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	ORAL	Harvoni QD Oral		
	METOPROLOL TARTRATE	C				
	AMLOPIDINE	C				
	CLONAZEPAM	C				
	TACROLIMUS	C				
	MYCOPHENOLATE MOFETIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2015	10729525	DIRECT	Y			63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL			GILEAD
Fatigue						
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2015	10729585	DIRECT				67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2015	10729830	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oral candidiasis	HARVONI	S	ORAL	1, qd, oral		GILEAD
Stomatitis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10687986	EXPEDITED (15-DAY)			US-GILEAD-2014-0127854		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aggression	HARVONI	S				GILEAD
Gastrooesophageal reflux disease						
Insomnia						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10731118	EXPEDITED (15-DAY)			US-GILEAD-2015-0132274	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10731125	EXPEDITED (15-DAY)			US-GILEAD-2015-0131976	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10731128	EXPEDITED (15-DAY)			US-GILEAD-2015-0132052	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10731129	EXPEDITED (15-DAY)			US-GILEAD-2015-0132827	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10731172	EXPEDITED (15-DAY)			US-GILEAD-2015-0132243		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jan-2015	10736151	DIRECT		OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	ORAL	1 tab daily po		GILEAD
Aphagia						
Headache						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10734163	EXPEDITED (15-DAY)			US-GILEAD-2015-0132187	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10736427	DIRECT	Y	DE		60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic failure	HARVONI	S	ORAL	1		GILEAD
	CITALOPRAM	C				
	FUROSEMIDE	C				
	LACTULOSE	C				
	MULTIVITAMIN	C				
	NADOLOL	C				
	NORCO	C				
	PANTOPRAZOLE	C				
	SPIRONOLACTONE	C				
	VITAMIN B12	C				
	VITAMIN C	C				
	VITAMIN D	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10738282	DIRECT		OT		68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain in extremity	HARVONI	S	ORAL			GILEAD
Palpitations						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10738312	DIRECT		OT		49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Peripheral swelling	HARVONI	S				GILEAD
Peripheral swelling	AMITIZA	C				
	MORPHINE	C				
	LOSARTAN	C				
	ONDANSETRON	C				
	ALPRAZOLAM	C				
	NITROFURANTOIN	C				
	AMIODIPINE	C				
	TIZANIDINE	C	ORAL			
Local swelling						
Peripheral swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10738326	DIRECT	Y	OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Platelet count decreased	HARVONI	S	ORAL	one tablet, QD, Oral		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10738363	DIRECT	Y	OT		56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	HARVONI	S	ORAL	one tablet		GILEAD
Back pain						
Chest discomfort						
Fatigue						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10740758	DIRECT	Y			61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
White blood cell count decreased	HARVONI	S	ORAL	one tablet		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10741259	DIRECT		HO		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalopathy	LEDIPASVIR-SOFOSBUVIR (HARVONI) 90-400MG GILEAD SCIENCES, INC.	S	ORAL			GILEAD
Treatment noncompliance	ELAVIL	C				
	CHOLECALCIFEROL	C				
	NEXIUM	C				
	LASIX	C				
	XODOL	C				
	ZOFRAN	C				
	ALDACTONE	C				
	ROXICODONE	C				
Ammonia increased						
Condition aggravated						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10741736	DIRECT	Y			58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure fluctuation	HARVONI	S	ORAL	one tablet QD Oral		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2015	10742327	DIRECT		HO,LT		63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	HARVONI	S	ORAL	once daily		
Hypotension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10669954	EXPEDITED (15-DAY)			US-GILEAD-2014-0128334	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10681308	EXPEDITED (15-DAY)		HO	US-GILEAD-2014-0128650		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lung disorder	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash generalised	RIBAVIRIN	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10717652	EXPEDITED (15-DAY)			US-GILEAD-2015-0131186	55 YR	Male	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Vision blurred	HARVONI		S	ORAL	1 DF, QD		GILEAD
Visual acuity reduced	LASIX	/00032601/	C	UNKNOWN	UNK		
	SPIRONOLACTONE		C	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10737993	EXPEDITED (15-DAY)			US-GILEAD-2015-0132575		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arthropathy	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738319	EXPEDITED (15-DAY)			US-GILEAD-2015-0132150	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tinnitus	HARVONI	S	ORAL	1 DF, QD		GILEAD
Dizziness						
Headache						
Irritability						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738442	EXPEDITED (15-DAY)			US-GILEAD-2015-0132312		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Arthritis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738452	EXPEDITED (15-DAY)			US-GILEAD-2015-0133864	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Therapeutic response changed						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738939	EXPEDITED (15-DAY)			US-GILEAD-2015-0132490		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chromaturia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738941	EXPEDITED (15-DAY)			US-GILEAD-2015-0132334	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nightmare	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738946	EXPEDITED (15-DAY)			US-GILEAD-2015-0132348		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Photophobia	HARVONI	S	UNKNOWN			GILEAD
	BRIMONIDINE	C				
	PREDNISOLONE	C				
	DORZOLAMIDE	C				
	LATANOPROST	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738947	EXPEDITED (15-DAY)			US-GILEAD-2015-0132285		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Night sweats	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						
Somnolence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10738958	EXPEDITED (15-DAY)			US-GILEAD-2015-0132494	50 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739035	EXPEDITED (15-DAY)			US-GILEAD-2015-0132351	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739053	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0133443		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739067	EXPEDITED (15-DAY)			US-GILEAD-2015-0132396		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pallor	HARVONI	S	UNKNOWN			GILEAD
Heart rate irregular						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739082	EXPEDITED (15-DAY)			US-GILEAD-2015-0132455	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritability	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739098	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0133396	33 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicidal ideation	HARVONI	S	UNKNOWN	UNK		GILEAD
Abnormal behaviour						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739108	EXPEDITED (15-DAY)			US-GILEAD-2015-0132664	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739114	EXPEDITED (15-DAY)			US-GILEAD-2015-0133313	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739116	EXPEDITED (15-DAY)			US-GILEAD-2015-0133333	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739127	EXPEDITED (15-DAY)			US-GILEAD-2015-0133009	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Stress	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						
Depressed mood						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739193	EXPEDITED (15-DAY)			US-GILEAD-2015-0133187	30 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739206	EXPEDITED (15-DAY)			US-GILEAD-2015-0133251	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739208	EXPEDITED (15-DAY)			US-GILEAD-2015-0133215	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739226	EXPEDITED (15-DAY)			US-GILEAD-2015-0133135	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Body temperature decreased	HARVONI	S	ORAL	1 DF, QD		GILEAD
Feeling cold						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739239	EXPEDITED (15-DAY)			US-GILEAD-2015-0133261	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dehydration	HARVONI	S	UNKNOWN	UNK		GILEAD
Blood creatinine increased	LIRAGLUTIDE	C				
Creatinine renal clearance decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739249	EXPEDITED (15-DAY)			US-GILEAD-2015-0133308		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hordeolum	HARVONI	S	UNKNOWN	UNK		GILEAD
Arthralgia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739259	EXPEDITED (15-DAY)			US-GILEAD-2015-0133331		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oral candidiasis	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739284	EXPEDITED (15-DAY)			US-GILEAD-2015-0133379		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal pain upper						
Diarrhoea						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739291	EXPEDITED (15-DAY)			US-GILEAD-2015-0133314	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739297	EXPEDITED (15-DAY)			US-GILEAD-2015-0133611		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pyrexia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739301	EXPEDITED (15-DAY)			US-GILEAD-2015-0133392		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue	RIBAVIRIN	C		UNK		
Asthenia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739307	EXPEDITED (15-DAY)			US-GILEAD-2015-0133424	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739312	EXPEDITED (15-DAY)			US-GILEAD-2015-0133650		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood count abnormal	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue	RIBAVIRIN	C				
Unevaluable event						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10739345	EXPEDITED (15-DAY)			US-GILEAD-2015-0133875	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10744699	DIRECT	Y			61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain in extremity	HARVONI	S	ORAL	1 TABLET, DAILY, PO		GILEAD
Peripheral swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10744726	DIRECT				64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight decreased	HARVONI	S	ORAL			
	LISINOPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10744750	DIRECT	Y			52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90MG-400MG	S	ORAL	1 TAB, QD, PO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jan-2015	10745442	DIRECT	Y	HO		53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fluid retention	HARVONI	S	ORAL	1		
Localised oedema						
Scrotal oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10741839	EXPEDITED (15-DAY)			US-GILEAD-2015-0133145		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Facial paresis	HARVONI	S	UNKNOWN			GILEAD
Abdominal discomfort						
Hyperhidrosis						
Lacrimation increased						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10741884	EXPEDITED (15-DAY)			US-GILEAD-2015-0133281	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysgeusia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Sleep disorder	RIBAPAK	C				
Decreased appetite						
Fatigue						
Memory impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10741904	EXPEDITED (15-DAY)			US-GILEAD-2015-0133305	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10742008	EXPEDITED (15-DAY)			US-GILEAD-2015-0133651	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	ORAL	1 DF, QD		GILEAD
Blood glucose increased						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10742770	EXPEDITED (15-DAY)			US-GILEAD-2015-0133969		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	UNKNOWN	2 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10742796	EXPEDITED (15-DAY)			US-GILEAD-2015-0133518	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Limb discomfort	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10743109	EXPEDITED (15-DAY)			US-GILEAD-2015-0133413		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S	UNKNOWN			GILEAD
	VITAMINS NOS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10743161	EXPEDITED (15-DAY)			US-GILEAD-2015-0133895		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Epistaxis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10743226	EXPEDITED (15-DAY)			US-GILEAD-2015-0133896		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Epistaxis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10743232	EXPEDITED (15-DAY)			US-GILEAD-2015-0134117		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling abnormal	HARVONI	S	UNKNOWN	UNK		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10743256	EXPEDITED (15-DAY)			US-GILEAD-2015-0133905	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pyrexia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Sinusitis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2015	10745791	DIRECT		OT		51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10745790	EXPEDITED (15-DAY)		OT	CA-GILEAD-2015-0133678		Male	CAN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary retention	HARVONI	S	UNKNOWN	UNK		GILEAD
Peripheral swelling	TRUVADA	C				
Somnolence	ATAZANAVIR W/RITONAVIR	C				
	METHADONE	C				
	ZOPLICONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746519	EXPEDITED (15-DAY)			US-GILEAD-2015-0134101	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tooth infection	HARVONI	S	UNKNOWN			GILEAD
	RIBAVIRIN	C				
	CLINDAMYCIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746521	EXPEDITED (15-DAY)			US-GILEAD-2015-0134056	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746523	EXPEDITED (15-DAY)			US-GILEAD-2015-0134412	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746525	EXPEDITED (15-DAY)			US-GILEAD-2015-0134390	49 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	400 mg, QD		GILEAD
Depression						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746526	EXPEDITED (15-DAY)			US-GILEAD-2015-0134324		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN	UNK		GILEAD
Tinnitus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746527	EXPEDITED (15-DAY)		HO,OT	IE-GILEAD-2015-0134165	70 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ascites	HARVONI	S	ORAL	1 DF, QD		GILEAD
Pneumonia	RIBAVIRIN	S	ORAL	1 DF, QD		
Cellulitis	OMEPRAZOLE	C				
	FLUOXETINE	C				
	CEFUROXIME	C				
	CO-TRIMOXAZOLE	C				
	SPIRONOLACTONE	C				
	TEMAZEPAM	C				
	FRUSEMIDE / 00032601/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746528	EXPEDITED (15-DAY)			US-GILEAD-2015-0134273	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
	ALBUTEROL SULFATE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746532	EXPEDITED (15-DAY)			US-GILEAD-2015-0134102	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10746533	EXPEDITED (15-DAY)			US-GILEAD-2015-0133817		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood thyroid stimulating hormone increased	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jan-2015	10748880	DIRECT	Y	OT		52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aortic stenosis	HARVONI 90MG-400MG	S	ORAL	1 tablet, qd, oral		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2015	10748385	EXPEDITED (15-DAY)			US-GILEAD-2015-0133545	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	ORAL	1 DF, QD		GILEAD
	TACROLIMUS	C				
	CARVEDILOL	C		12.5 mg, UNK		
	LOSARTAN	C				
	CREON	C				
	FISH OIL	C				
	LANTUS	C				
	CALCIUM	C				
	PRAVASTATIN	C				
	NOVOLOG	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2015	10750839	DIRECT					Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	HARVONI 90-400MG TAB GILEAD SCIENCES	S	ORAL			GILEAD
Abdominal pain upper						
Dyspepsia						
Dyspnoea						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jan-2015	10751165	DIRECT				64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Constipation	HARVONI 90/400MG GILEAD	S	ORAL	90/400mg (1 tablet) once daily by mouth		GILEAD
Ear disorder						
Tinnitus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10739253	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0133332	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cognitive disorder	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						
Feeling abnormal						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10750533	EXPEDITED (15-DAY)		HO	IE-ROCHE-1528362	61 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemoglobin decreased	Copegus	S	UNKNOWN	400 mg in the morning and and 600 mg in the evening		
Blood phosphorus decreased	HARVONI	S	ORAL			
Blood potassium decreased	TRUVADA	C				
	PREZISTA	C				
	NORVIR	C				
	LANSOPRAZOLE	C				
	SEPTRIN	C				
	METHADONE	C				
	LAXOSE	C				
	FUROSEMIDE	C				
	Diazepam	C	UNKNOWN			
	THIAMINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10752227	EXPEDITED (15-DAY)		HO,OT	IE-GILEAD-2015-0134166	45 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ascites	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
	RIBAVIRIN	S	ORAL	1 DF, QD		
	RIFAXIMIN	C				
	TRANEXAMIC ACID	C				
	DOVOBET	C				
	URSOFALK	C				
	CIPROFLOXACIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10754234	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	HARVONI 90/400 MG GILEAD	S	ORAL	1 tablet		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10754771	DIRECT		OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
Feeling abnormal	THYROID (ARMOUR) 2G (120 MG) TABS	C				
Gastrooesophageal reflux disease	PRILOSEC	C				
Feeling abnormal	CITALOPRAM	C				
Condition aggravated						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10755150	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
	ATORVASTATIN	C				
	FLUVIRIN MULTIDOSE VIAL	C				
	METFORMIN ER	C				
	INCIVEK	C				
	FISH OIL	C				
	PEGASYS	C				
	GLUCOSAMINE CHONDROITIN	C				
	RIBAVIRIN	C				
	FIN FISH OIL X/S ENT CD	C				
	CALCIUM	C				
	VITAMIN D	C				
	DESONIDE	C				
	CONTOUR NEXT TEST STRIPS	C				
	MICROLET COLORED LANCETS	C				
Constipation						

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Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jan-2015	10755225	DIRECT				57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
	VICODIN	C				
Mood altered	VIVELLE-DOT	C				
Decreased appetite	CALCIUM	C				
Rash erythematous	AMBIEN	C				
	IMITREX	C				
Crying						
Fatigue						
Migraine						
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2015	10704986	EXPEDITED (15-DAY)		DE,HO,OT	US-GILEAD-2015-0131119	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	HARVONI	S	UNKNOWN	UNK		GILEAD
Acute hepatic failure						
Disease progression						
Hepatic cirrhosis						
Jaundice						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2015	10753861	EXPEDITED (15-DAY)		HO,OT	IE-ROCHE-1528375	70 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ascites	Ribavirin	S	ORAL			
Pneumonia	HARVONI	S	ORAL			
Cellulitis	OMEPRAZOLE	C				
	FLUOXETINE	C				
	CEFUROXIME	C				
	COTRIMOXAZOLE	C				
	SPIRONOLACTONE	C				
	TEMAZEPAM	C				
	FRUSEMIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2015	10756335	EXPEDITED (15-DAY)			US-GILEAD-2015-0133426		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2015	10756337	EXPEDITED (15-DAY)			US-GILEAD-2015-0133959	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
	CARVEDILOL	C		3.25 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2015	10756430	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0134496	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal impairment	HARVONI	S	UNKNOWN	UNK		GILEAD
Blood creatinine increased						
Blood urea increased						
Decreased appetite						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2015	10756440	EXPEDITED (15-DAY)			US-GILEAD-2015-0134533		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Thyroid function test abnormal	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Product packaging quantity issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10739185	EXPEDITED (15-DAY)			US-GILEAD-2015-0133065	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasal congestion	HARVONI	S	UNKNOWN			GILEAD
Cough						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10739209	EXPEDITED (15-DAY)			US-GILEAD-2015-0132862		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Peripheral swelling	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10743237	EXPEDITED (15-DAY)			US-GILEAD-2015-0134052	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dry mouth	HARVONI	S	UNKNOWN	UNK		GILEAD
Epigastric discomfort						
Fatigue						
Insomnia						
Oral disorder						
Product measured potency issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759377	EXPEDITED (15-DAY)			US-GILEAD-2015-0133057	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash erythematous	HARVONI	S	UNKNOWN	UNK		GILEAD
Peripheral swelling	AMITIZA	C		UNK		
	IRBESARTAN	C		UNK		
	MORPHINE	C		UNK		
	OXYCODONE	C				
	MACROGOL	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759397	EXPEDITED (15-DAY)			US-GILEAD-2015-0134317		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oropharyngeal pain	HARVONI	S	UNKNOWN	UNK		GILEAD
Cough						
Social problem						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759399	EXPEDITED (15-DAY)			US-GILEAD-2015-0134213		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cough	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759415	EXPEDITED (15-DAY)			US-GILEAD-2015-0133977		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose decreased	HARVONI	S	UNKNOWN			GILEAD
Dizziness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759502	EXPEDITED (15-DAY)			US-GILEAD-2015-0134016	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759518	EXPEDITED (15-DAY)			US-GILEAD-2015-0134121	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759524	EXPEDITED (15-DAY)			US-GILEAD-2015-0132966	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759529	EXPEDITED (15-DAY)			US-GILEAD-2015-0134442		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759537	EXPEDITED (15-DAY)			US-GILEAD-2015-0134450		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Chills						
Headache						
Influenza						
Pyrexia						
Upper respiratory tract congestion						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759631	EXPEDITED (15-DAY)			US-GILEAD-2015-0134443		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	HARVONI	S	UNKNOWN	UNK		GILEAD
Feeling drunk						
Vertigo						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759648	EXPEDITED (15-DAY)			US-GILEAD-2015-0134290	71 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Back disorder	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759657	EXPEDITED (15-DAY)			US-GILEAD-2015-0134596	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Spinal pain	HARVONI	S	ORAL	1 DF, QD		GILEAD
Arthralgia						
Decreased interest						
Depression						
Fatigue						
Neck pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759695	EXPEDITED (15-DAY)			US-GILEAD-2015-0134463		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759703	EXPEDITED (15-DAY)			US-GILEAD-2015-0134484		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chills	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Arthralgia						
Fatigue						
Joint swelling						
Myalgia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759734	EXPEDITED (15-DAY)			US-GILEAD-2015-0134488	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759735	EXPEDITED (15-DAY)			US-GILEAD-2015-0134498		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gout	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759758	EXPEDITED (15-DAY)			US-GILEAD-2015-0134611		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10759773	EXPEDITED (15-DAY)			US-GILEAD-2015-0134497		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain upper	HARVONI	S	UNKNOWN			GILEAD
	ZANTAC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10761129	DIRECT	Y	OT		55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL			GILEAD
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Feb-2015	10761221	DIRECT	Y	OT		46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lip swelling	HARVONI	S	ORAL	1 tablet Once daily By mouth		GILEAD
Eye swelling						
Rash generalised						
Type IV hypersensitivity reaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10717186	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0131160	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ascites	HARVONI	S	ORAL	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10731121	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0131973	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hallucination, auditory	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Agitation						
Distractibility						
Insomnia						
Soliloquy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763101	EXPEDITED (15-DAY)			US-GILEAD-2015-0134794	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763129	EXPEDITED (15-DAY)			US-GILEAD-2015-0135033	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	UNKNOWN	2 DF, Once		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763148	EXPEDITED (15-DAY)			US-GILEAD-2015-0134942	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Disturbance in attention	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763160	EXPEDITED (15-DAY)			US-GILEAD-2015-0135140		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sinusitis	HARVONI	S	UNKNOWN	UNK		GILEAD
Nasopharyngitis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763167	EXPEDITED (15-DAY)			US-GILEAD-2015-0135198	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763185	EXPEDITED (15-DAY)			US-GILEAD-2015-0135196	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763198	EXPEDITED (15-DAY)			US-GILEAD-2015-0135130		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Viral load	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763209	EXPEDITED (15-DAY)			US-GILEAD-2015-0135474		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN	UNK		GILEAD
	SUBOXONE	C		UNK		
	AMBIEN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10763888	EXPEDITED (15-DAY)			US-GILEAD-2015-0135304	49 YR	Female	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI		S	ORAL	1 DF, QD		GILEAD
Headache	ADVIL	/00109201/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10764030	EXPEDITED (15-DAY)			US-GILEAD-2015-0134974	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10764077	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0134424	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rheumatoid arthritis	HARVONI	S	ORAL	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10764084	EXPEDITED (15-DAY)			US-GILEAD-2015-0134745	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	ORAL	1 DF, UNK		GILEAD
	AMLODIPINE	C	ORAL	1 DF, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10764090	EXPEDITED (15-DAY)			US-GILEAD-2015-0135496		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Increased appetite	HARVONI	S	UNKNOWN	UNK		GILEAD
Weight increased	TIZANIDINE	S	UNKNOWN	4 mg, QD		
Drug effect decreased	MORPHINE SULFATE	C		UNK		
Abdominal pain upper						
Fatigue						
Headache						
Irritability						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10764955	DIRECT					Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2015	10765810	DIRECT	Y	HO		46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI 90/400MG GILEAD	S	ORAL	one tablet		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10699069	EXPEDITED (15-DAY)			US-GILEAD-2015-0130799	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bronchitis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Potentiating drug interaction	Z-PAK	S	UNKNOWN	UNK		
Fatigue	XIFAXAN	C				
Chest discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10699322	EXPEDITED (15-DAY)		DE,HO,OT	US-GILEAD-2015-0130275	59 YR	Male	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Cardiac arrest	HARVONI		S	UNKNOWN	1 DF, UNK		GILEAD
Convulsion	AMIODARONE		C				
Hyponatraemia	NADOLOL		C				
Hypoalbuminaemia	PRAMIPEXOLE		C				
Hepatic enzyme increased	OMEPRAZOLE		C				
Leukocytosis	LASIX	/00032601/	C				
Thrombocytopenia	SILYBUM MARIANUM		C				
Coagulopathy							

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10759646	EXPEDITED (15-DAY)			US-GILEAD-2015-0134194	51 YR	Male	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI		S	ORAL	1 DF, QD		GILEAD
Nausea	LASIX	/00032601/	C				
Headache	ADVIL	/00109201/	C				
Fatigue							

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10767721	EXPEDITED (15-DAY)			US-GILEAD-2015-0135061		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gingival disorder	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Back disorder						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10767744	EXPEDITED (15-DAY)			US-GILEAD-2015-0135325	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10767745	EXPEDITED (15-DAY)			US-GILEAD-2015-0135385	31 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10767764	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0135639	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic cirrhosis	HARVONI	S	UNKNOWN	UNK		GILEAD
Gastrointestinal haemorrhage	PROTONIX	C		UNK		
Anaemia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2015	10776155	DIRECT		OT		58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90/400 MG GILEAD	S	ORAL	1 tab daily oral		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10746524	EXPEDITED (15-DAY)			US-GILEAD-2015-0133695	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10770915	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0135848		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dermatitis bullous	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10771816	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0135510	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10771949	EXPEDITED (15-DAY)			US-GILEAD-2015-0135709		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C virus test positive	HARVONI	S		UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10771981	EXPEDITED (15-DAY)			US-GILEAD-2015-0135713		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C virus test positive	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10772027	EXPEDITED (15-DAY)			US-GILEAD-2015-0135561	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD
	HARVONI	S		UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10772120	EXPEDITED (15-DAY)			US-GILEAD-2015-0135683	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10772269	EXPEDITED (15-DAY)		DE,OT	US-GILEAD-2015-0136217		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	HARVONI	S	UNKNOWN			GILEAD
	HARVONI	S				GILEAD
	COMPLERA	S	UNKNOWN			GILEAD
	COMPLERA	S				GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2015	10780312	DIRECT	Y			57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10717635	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0131149	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyperglycaemia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Drug interaction	LANTUS	S	UNKNOWN	50 IU, QHS		
	METFORMIN	S	UNKNOWN	500 Unknown, BID		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10727394	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0132493		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain	HARVONI	S	UNKNOWN	UNK		GILEAD
	RIBAVIRIN	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10738047	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0133623	73 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ascites	HARVONI	S	ORAL	1 DF, QD		GILEAD
Oedema	ABILIFY	C				
Atelectasis	ALDACTONE / 00006201/	C	UNKNOWN	25 mg, UNK		
Oedema peripheral	ALDACTONE / 00006201/	C	UNKNOWN	50 UNK, UNK		
Arthralgia	ASPIRIN / 00002701/	C				
	AVODART	C	UNKNOWN	0.5 mg, UNK		
	CRESTOR	C	UNKNOWN	UNK		
	KLONOPIN	C	UNKNOWN	UNK		
	LEXAPRO	C	UNKNOWN	UNK		
	VITAMIN D / 00107901/	C	UNKNOWN	UNK		
	B12 /00056201/	C	UNKNOWN	UNK		
	MULTIVITAMIN / 07504101/	C	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10763232	EXPEDITED (15-DAY)			US-GILEAD-2015-0135355	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Local swelling	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						
Pain of skin						
Pruritus						
Skin disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10776561	EXPEDITED (15-DAY)			US-GILEAD-2015-0135566	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10776941	EXPEDITED (15-DAY)		OT	DE-GILEAD-2015-0135391		Female	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Helminthic infection	HARVONI	S	UNKNOWN			GILEAD
Zoonosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10776968	EXPEDITED (15-DAY)			US-GILEAD-2015-0135615		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Balance disorder	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Balance disorder						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10776997	EXPEDITED (15-DAY)			US-GILEAD-2015-0135627	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Decreased interest	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777156	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0135716	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Retinal detachment	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777170	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0135721		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777375	EXPEDITED (15-DAY)			US-GILEAD-2015-0135674	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777392	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0135835	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrointestinal haemorrhage	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777511	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0135900	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Angioedema	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash generalised	LEVOTHYROXINE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777757	EXPEDITED (15-DAY)			US-GILEAD-2015-0135787	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	HARVONI	S	ORAL	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777760	EXPEDITED (15-DAY)			US-GILEAD-2015-0135865	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777796	EXPEDITED (15-DAY)			US-GILEAD-2015-0135937	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vertigo	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777878	EXPEDITED (15-DAY)			US-GILEAD-2015-0135893		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swollen tongue	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777880	EXPEDITED (15-DAY)			US-GILEAD-2015-0135918	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Stomatitis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						
Fatigue						
Headache						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777883	EXPEDITED (15-DAY)			US-GILEAD-2015-0135938		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pyrexia	HARVONI	S	UNKNOWN			GILEAD
Arthralgia						
Chills						
White blood cell count increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777894	EXPEDITED (15-DAY)			US-GILEAD-2015-0135958	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10777901	EXPEDITED (15-DAY)			US-GILEAD-2015-0135724		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Hypertension	OMEPRAZOLE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10778108	EXPEDITED (15-DAY)			US-GILEAD-2015-0136316		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash erythematous	HARVONI	S	UNKNOWN	UNK, QD		GILEAD
Inflammation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10778110	EXPEDITED (15-DAY)			US-GILEAD-2015-0136279	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nervousness	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10778131	EXPEDITED (15-DAY)			US-GILEAD-2015-0135658		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash pruritic	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10778154	EXPEDITED (15-DAY)			US-GILEAD-2015-0136236		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mouth swelling Speech disorder	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10778155	EXPEDITED (15-DAY)			US-GILEAD-2015-0136152		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Confusional state Disorientation	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10778156	EXPEDITED (15-DAY)			US-GILEAD-2015-0136013	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10781806	DIRECT	Y			65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL	90-400 mg		GILEAD
Condition aggravated						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10782719	DIRECT	Y	HO		54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rhabdomyolysis	HARVONI 90/400 MG GILEAD	S				GILEAD
Blood urine present						
Oral herpes						
Upper respiratory tract infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Feb-2015	10782755	DIRECT	Y	HO		57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug withdrawal convulsions	LEDIPASVIR-SOFOSBUVIR (HARVONI)	S	ORAL			GILEAD
Metabolic acidosis	ALPRAZOLAM (XANAX) 1MG/3X PER DAY	C				
	CARISOPRODOL (SOMA)	C				
	DEXTROAMPHETAMINE-AMPHETAMINE (AMPHETAMINE-DEXTROAMPHETAMINE)	C				
	ESCITALOPRAM (LEXAPRO)	C				
	OXYCODONE (ROXICODONE)	C				
	OXYMORPHONE (OPANA ER)	C				
	ZOLDIPEM (AMBIEN)	C				
Drug dose omission						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10712085	EXPEDITED (15-DAY)			US-GILEAD-2015-0131007	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VIIth nerve paralysis	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10781254	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0136136		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure acute	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10783670	EXPEDITED (15-DAY)			US-GILEAD-2015-0136138		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ill-defined disorder	HARVONI	S	UNKNOWN	UNK		GILEAD
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10783676	EXPEDITED (15-DAY)			US-GILEAD-2015-0136475	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lacrimation increased	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10783682	EXPEDITED (15-DAY)			US-GILEAD-2015-0136431	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nervousness	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Headache						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10783831	EXPEDITED (15-DAY)			US-GILEAD-2015-0136342	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Back pain						
Flushing						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10783832	EXPEDITED (15-DAY)			US-GILEAD-2015-0136347		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10785721	DIRECT				51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10785736	DIRECT				59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL	1 tab qd po		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10785961	DIRECT		OT		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
	LISINOPRIL	C				
	LEXAPRO	C				
	SPIROLACTONE	C				
	COREG	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2015	10786089	DIRECT		HO		68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure congestive	HARVONI 90/400MG GILEAD	S	ORAL			
	ASPIRIN	C				
	BYSTOLIC	C				
	CETIRIZINE	C				
	CREON	C				
	LORAZEPAM	C				
	SYMBICORT	C				
	LASIX	C				
	POTASSIUM ELIXIR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Feb-2015	10746294	EXPEDITED (15-DAY)		OT	IE-GILEAD-2015-0133932	39 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	S	ORAL	600 mg, BID		
	SEPTRIN	S	ORAL	960 mg, QD		
	SPIRONOLACTONE	C				
	RIFAXIMIN	C				
	THIAMINE	C				
	METHADONE	C				
	IRON	C				
	OMEPRAZOLE	C				
	LACTULOSE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10647567	EXPEDITED (15-DAY)			US-GILEAD-2014-0126535	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug eruption	HARVONI	S	ORAL	1 DF, QD		GILEAD
Rash	LOSARTAN	C				
Headache	FLUTICASONE	C				
	PROAIR / 00139502/	C				
	PRILOSEC / 00661201/	C				
	FLUOXETINE	C				
	CARVEDILOL	C				
	IBUPROFEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10790312	EXPEDITED (15-DAY)			US-GILEAD-2015-0135670	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10790513	EXPEDITED (15-DAY)			US-GILEAD-2015-0136688		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	HARVONI	S	UNKNOWN	UNK		GILEAD
Ammonia increased						
Hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10790654	EXPEDITED (15-DAY)			US-GILEAD-2015-0136105		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Joint injury	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10790684	EXPEDITED (15-DAY)			US-GILEAD-2015-0136717		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sciatica	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10790766	EXPEDITED (15-DAY)			US-GILEAD-2015-0136359	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10790969	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0136657		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neck pain	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10793493	DIRECT	Y	HO		52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Upper respiratory tract infection	HARVONI 90/400MG GILEAD SCIENCES	S	ORAL			GILEAD
Confusional state						
Encephalopathy						
Hallucinations, mixed						
Pneumonia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Feb-2015	10809141	DIRECT					Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asthenia	HARVONI	S	ORAL	1 Tablet QD PO		GILEAD
	ASPIRIN	C				
	CLONAZEPAM	C				
	TAMSULOSIN	C				
	LOSARTAN/HET	C				
	FLUOXETINE	C				
	METOPROLOL	C				
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10714885	EXPEDITED (15-DAY)		DE,OT	US-GILEAD-2015-0131279		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	HARVONI	S	UNKNOWN	UNK		GILEAD
Headache						
Overdose						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10717597	EXPEDITED (15-DAY)		DE,OT	US-GILEAD-2015-0132178	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Haemoglobin decreased						
Respiratory disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10743028	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0133022	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatinine increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Dysphagia	CHLORPROMAZINE	C		UNK		
	DAPTOMYCIN	C		UNK		
	ERTAPENEM	C		UNK		
	FINASTERIDE	C		UNK		
	FLECAINIDE	C		UNK		
	MIDODRINE	C		UNK		
	RIFAXIMIN	C		UNK		
	VANCOMYCIN	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10793689	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0136683	74 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood alkaline phosphatase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Glomerular filtration rate decreased	ATORVASTATIN	C		UNK		
Alanine aminotransferase increased	LISINOPRIL	C				
Aspartate aminotransferase increased	HCTZ	C				
Blood bilirubin increased	OMEPRAZOLE	C				
	NICOTINE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10793696	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0136573		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest discomfort	HARVONI	S	UNKNOWN	UNK		GILEAD
Chills						
Confusional state						
Cyanosis						
Fatigue						
Hyperhidrosis						
Throat tightness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10794616	EXPEDITED (15-DAY)		DE,HO,OT	US-GILEAD-2015-0137345	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sudden death	HARVONI	S	UNKNOWN	UNK		GILEAD
Depression	LISINOPRIL	C	UNKNOWN	UNK		
Abdominal pain	LEXAPRO	C	UNKNOWN	UNK		
Diarrhoea						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10794698	EXPEDITED (15-DAY)			US-GILEAD-2015-0136396		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoglycaemia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10794701	EXPEDITED (15-DAY)			US-GILEAD-2015-0136392	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2015	10812118	DIRECT	Y			56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain in extremity	HARVONI 90-400 MG	S	ORAL	1 tablet		GILEAD
Pain in extremity	ALBUTEROL	C				
Contusion	AMLODIPINE	C				
Fatigue	ASPIRIN	C				
	ATORVASTATIN	C				
	BUDESONIDE	C				
	CHOLECALCIFEROL	C				
	OMEPRAZOLE	C				
	SYMBICORT	C				
Decreased appetite						
Joint range of motion decreased						
Pain						
Peripheral swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10717636	EXPEDITED (15-DAY)			US-GILEAD-2015-0131161		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood bilirubin increased	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	C	ORAL	1200 mg, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10783799	EXPEDITED (15-DAY)			US-GILEAD-2015-0136410		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Retching	HARVONI	S	UNKNOWN	UNK		GILEAD
Headache						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798316	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0136497	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Epistaxis						
Tinnitus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798332	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137008	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798336	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137173	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pericarditis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798366	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137177	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pericarditis	HARVONI	S	UNKNOWN			GILEAD
Dyspnoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798739	EXPEDITED (15-DAY)			US-GILEAD-2015-0136398	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Psychomotor hyperactivity	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798754	EXPEDITED (15-DAY)		DE	IE-GILEAD-2015-0137044	41 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	HARVONI	S	ORAL	1 DF, UNK		GILEAD
	COPEGUS	C	UNKNOWN	400 mg, BID		
	TRUVADA	C		UNK		GILEAD
	ISENTRESS	C		400 mg, BID		
	PREZISTA	C		800 mg, QD		
	NORVIR	C		100 mg, QD		
	SEPTRIN	C		960 mg, QD		
	INDERAL	C		30 mg, BID		
	INDERAL	C				
	ALDACTONE / 00006201/	C		75 mg, QD		
	TARGAXAN	C		550 mg, BID		
	PANTOPRAZOLE	C		20 mg, QD		
	LAXOSE	C		15 ml, TID		
	MIRTAZAPINE	C		30 mg, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798757	EXPEDITED (15-DAY)			US-GILEAD-2015-0136696	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	UNKNOWN	UNK, BID		GILEAD
	HARVONI	S	UNKNOWN	UNK, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798759	EXPEDITED (15-DAY)			US-GILEAD-2015-0136715		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug level increased	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798893	EXPEDITED (15-DAY)			US-GILEAD-2015-0136908	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798908	EXPEDITED (15-DAY)			US-GILEAD-2015-0136952		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C virus test positive	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798909	EXPEDITED (15-DAY)			US-GILEAD-2015-0137130		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798912	EXPEDITED (15-DAY)			US-GILEAD-2015-0136892	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798918	EXPEDITED (15-DAY)			US-GILEAD-2015-0136986		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	HARVONI	S	UNKNOWN	UNK		GILEAD
Back pain						
Musculoskeletal chest pain						
Musculoskeletal stiffness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2015	10798932	EXPEDITED (15-DAY)			US-GILEAD-2015-0137306		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2015	10739242	EXPEDITED (15-DAY)			US-GILEAD-2015-0133205		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Viral test positive	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2015	10786032	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0136517	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Liver disorder	LETAIRIS	S	UNKNOWN	10 mg, QD		GILEAD
Malaise	LETAIRIS	S				GILEAD
	HARVONI	S	UNKNOWN			GILEAD
	ADCIRCA	C				
	VANCOMYCIN	C				
	HYDROCODONE	C				
	AMBIEN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2015	10803144	EXPEDITED (15-DAY)		DE,HO,OT	DE-GILEAD-2015-0137543	66 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebral haemorrhage	HARVONI	S	ORAL	1 DF, QD		GILEAD
	AGGRENOX	S	ORAL	2 DF, QD		
	PREDNISOLONE	C	ORAL	5 mg, QD		
	SANDIMMUN	C	ORAL	25 mg, UNK		
	AZATHIOPRINE	C	ORAL	50 mg, QD		
	DOCITON	C	ORAL	10 mg, TID		
	PANTOZOL / 01263204/	C	ORAL	20 mg, QD		
	SPIRONOLACTONE A L	C	ORAL	5 mg, QD		
	TORASEMID	C	ORAL	10 mg, QD		
	TAMSULOSIN	C	ORAL	0.4 mg, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10841344	DIRECT		OT		85 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL			GILEAD
Muscle spasms						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10853162	DIRECT	Y	OT		58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	HARVONI	S	ORAL	one tablet		GILEAD
Visual impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10853183	DIRECT	Y			60 YR	Male	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Peripheral coldness	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10853629	DIRECT		OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Constipation	HAVONI	S	ORAL			GILEAD
	CODEINE	C				
	VICODIN	C				
	PROTONIX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10853654	DIRECT	Y			59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10853655	DIRECT		OT		58 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dose omission	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10854826	DIRECT		HO		57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic encephalopathy	HARVONI	S	ORAL			GILEAD
Frequent bowel movements	LEXAPRO	C				
	FUROSEMIDE ORAL	C				
	LACTULOSE	C				
	NADOLOL	C				
	NEOMYCIN	C				
	PROMETHAZINE	C				
	RIFAXIMIN	C				
	SPIRONOLACTONE	C				
Anaemia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10854847	DIRECT				53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10860992	DIRECT	Y			44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza like illness	HARVONI 90-400MG TAB GILEAD SCIENCES	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10860998	DIRECT	Y			60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fluid imbalance	HARVONI	S	ORAL	1		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10861001	DIRECT	Y			65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90-400 MG	S	ORAL	one tablet		GILEAD
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10861094	DIRECT	Y				Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 pill, QD, Oral	4 WEEK	
Cough						
Sleep disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Feb-2015	10861175	DIRECT	Y	HO,LT		68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	HARVONI	S	ORAL	1		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10691200	EXPEDITED (15-DAY)			US-GILEAD-2014-0128242		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10737992	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0133092	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Orthostatic hypotension	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10739122	EXPEDITED (15-DAY)			US-GILEAD-2015-0132713	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal disorder	HARVONI	S	ORAL	1 UNK, UNK		GILEAD
Back pain						
Muscle strain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10756393	EXPEDITED (15-DAY)			US-GILEAD-2015-0133956	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alpha 1 foetoprotein decreased	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10798907	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137063		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Viral load increased	HARVONI	S	UNKNOWN			GILEAD
Drug ineffective						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10830645	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0131947	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pancytopenia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Glomerular filtration rate abnormal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10833299	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137835		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rheumatoid arthritis	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10833571	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0136100		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Multiple fractures	HARVONI	S	UNKNOWN	UNK		GILEAD
Road traffic accident						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10836026	EXPEDITED (15-DAY)			US-GILEAD-2015-0137107	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	ORAL	1 DF, BID		GILEAD
	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10836028	EXPEDITED (15-DAY)			US-GILEAD-2015-0137109	51 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10836029	EXPEDITED (15-DAY)			US-GILEAD-2015-0137007		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dose omission	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10836036	EXPEDITED (15-DAY)			US-GILEAD-2015-0137110	66 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tinnitus	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10836061	EXPEDITED (15-DAY)			US-GILEAD-2015-0137270	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10862796	DIRECT	Y	HO		39 YR	Male	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	HARVONI	S	ORAL			UNKNOWN
Tachycardia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10862821	DIRECT	Y			56 YR	Female	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	HARVONI	S	ORAL	1 tablet		GILEAD
Chest discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10862894	DIRECT	Y			58 YR	Male	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90/400 MG GILEAD	S	ORAL			GILEAD
Thirst						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10866431	DIRECT		HO		63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mental status changes	HARVONI	S	ORAL	1 pill QD Oral		GILEAD
Convulsion						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2015	10866437	DIRECT		HO		67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastric disorder	HARVONI	S	ORAL	1 QD Oral		
Clostridium difficile infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10712072	EXPEDITED (15-DAY)			US-GILEAD-2015-0130952	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10712097	EXPEDITED (15-DAY)			US-GILEAD-2015-0131130		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza like illness	HARVONI	S	UNKNOWN			GILEAD
Pyrexia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10717661	EXPEDITED (15-DAY)			US-GILEAD-2015-0131188	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Genital herpes	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abasia						
Back pain						
Lymphadenopathy						
Muscle spasms						
Nasopharyngitis						
Pain in extremity						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10739143	EXPEDITED (15-DAY)			US-GILEAD-2015-0133372	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling hot	HARVONI	S	ORAL	1 DF, QD		GILEAD
Irritability	NEXIUM / 01479302/	C	ORAL	20 mg, UNK		
Diarrhoea	ALEVE	C	ORAL	2 DF, prn		
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10777032	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0135860	24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dermatitis bullous	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Rash						
Rash erythematous						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10780827	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0130428		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	HARVONI	S	ORAL	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10844737	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137324		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal impairment	HARVONI	S	UNKNOWN			GILEAD
Blood glucose increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10844809	EXPEDITED (15-DAY)		DE,OT	US-GILEAD-2015-0138178		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	HARVONI	S	UNKNOWN			GILEAD
	RIBAVIRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846534	EXPEDITED (15-DAY)			US-GILEAD-2015-0137187		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846600	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0138134	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chronic hepatic failure	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846602	EXPEDITED (15-DAY)			US-GILEAD-2015-0137255	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846607	EXPEDITED (15-DAY)			US-GILEAD-2015-0137271	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846626	EXPEDITED (15-DAY)			US-GILEAD-2015-0137275	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846678	EXPEDITED (15-DAY)			US-GILEAD-2015-0137287	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10846681	EXPEDITED (15-DAY)			US-GILEAD-2015-0137362		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	ORAL	1 DF, BID		GILEAD
	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847206	EXPEDITED (15-DAY)			US-GILEAD-2015-0137394		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847217	EXPEDITED (15-DAY)			US-GILEAD-2015-0137582		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	UNKNOWN	UNK		GILEAD
	HARVONI	S	UNKNOWN	2 UNK, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847223	EXPEDITED (15-DAY)			US-GILEAD-2015-0137552	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	ORAL	df		GILEAD
Diarrhoea						
Dizziness postural						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847226	EXPEDITED (15-DAY)			US-GILEAD-2015-0137840		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrooesophageal reflux disease	HARVONI	S	UNKNOWN	UNK		GILEAD
Dyspepsia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847227	EXPEDITED (15-DAY)			US-GILEAD-2015-0137446	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Dyspepsia						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847241	EXPEDITED (15-DAY)			US-GILEAD-2015-0137587	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847245	EXPEDITED (15-DAY)			US-GILEAD-2015-0137592	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
	CHANTIX	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847247	EXPEDITED (15-DAY)			US-GILEAD-2015-0137848	65 YR	Male	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI		S	UNKNOWN	UNK		GILEAD
	INSULIN		C				
	COLACE		C				
	VASOTEC 00574902/	/	C				
	METHADONE		C				
	LASIX	/00032601/	C				
	ALDACTONE 00006201/	/	C				
	LACTULOSE		C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847251	EXPEDITED (15-DAY)			US-GILEAD-2015-0137448	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urticaria	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash	HYDROXYCHLOROQUINE	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847256	EXPEDITED (15-DAY)			US-GILEAD-2015-0137504	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847259	EXPEDITED (15-DAY)			US-GILEAD-2015-0137546		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aspartate aminotransferase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Alanine aminotransferase increased	LIPITOR	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847272	EXPEDITED (15-DAY)			US-GILEAD-2015-0137943	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847305	EXPEDITED (15-DAY)			US-GILEAD-2015-0137846	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	UNKNOWN	UNK		GILEAD
	PROPANOLOL / 00030001/	C				
	LACTULOSE	C				
	VENTOLIN / 00139501/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847312	EXPEDITED (15-DAY)			US-GILEAD-2015-0137953	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847369	EXPEDITED (15-DAY)			US-GILEAD-2015-0137965	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal distension	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847461	EXPEDITED (15-DAY)			US-GILEAD-2015-0137451	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847512	EXPEDITED (15-DAY)			US-GILEAD-2015-0137678		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Road traffic accident	HARVONI	S	UNKNOWN	UNK		GILEAD
Drug abuse						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847516	EXPEDITED (15-DAY)			US-GILEAD-2015-0137558	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847529	EXPEDITED (15-DAY)			US-GILEAD-2015-0137888	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Skin lesion	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847575	EXPEDITED (15-DAY)		LT,OT	DE-GILEAD-2015-0138413	59 YR	Male	DEU

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary fibrosis	HARVONI		S	ORAL	1 DF, QD		GILEAD
Condition aggravated	ACC	/00082801/	C	ORAL	600 mg, TID		
Respiratory failure	THYRONAJOD		C	ORAL	50 µg, QD		
	PREDNISOLON 00016201/	/	C	ORAL	UNK		
	TORASEMID		C	ORAL	5 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847665	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137143		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Unevaluable event	HARVONI	S	UNKNOWN			GILEAD
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847696	EXPEDITED (15-DAY)			US-GILEAD-2015-0137977		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatine phosphokinase increased	HARVONI	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10847706	EXPEDITED (15-DAY)			US-GILEAD-2015-0138026	40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Feb-2015	10868470	DIRECT				63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL	90-400 mg		GILEAD
	FLUTICASONE	C				
	LEVITRA	C				
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10855487	EXPEDITED (15-DAY)			US-GILEAD-2015-0136972		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	UNKNOWN	2 DF, UNK		GILEAD
	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856268	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0138007		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bladder cancer	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856385	EXPEDITED (15-DAY)		HO,OT	GB-GILEAD-2015-0137748		Male	GBR

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic cirrhosis	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856443	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0138540		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cryoglobulinaemia	HARVONI	S	UNKNOWN			GILEAD
Burning sensation						
Erythema						
Pruritus						
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856496	EXPEDITED (15-DAY)			US-GILEAD-2015-0137478	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856512	EXPEDITED (15-DAY)			US-GILEAD-2015-0137877	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling cold	HARVONI	S	ORAL	1 DF, QD		GILEAD
Peripheral coldness	LEVOTHYROXINE	C		100 µg, QD		
	TRAZODONE	C		100 mg, UNK		
	BUPROPION	C		100 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856575	EXPEDITED (15-DAY)			US-GILEAD-2015-0138048	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856603	EXPEDITED (15-DAY)			US-GILEAD-2015-0138120	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sinusitis	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856662	EXPEDITED (15-DAY)			US-GILEAD-2015-0138130	43 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856686	EXPEDITED (15-DAY)			US-GILEAD-2015-0138444		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Negative thoughts	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856691	EXPEDITED (15-DAY)			US-GILEAD-2015-0138537		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856709	EXPEDITED (15-DAY)			US-GILEAD-2015-0138532		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache Dizziness	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856718	EXPEDITED (15-DAY)			US-GILEAD-2015-0138582		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Metabolic acidosis	HARVONI	S	UNKNOWN			GILEAD
Hyperkalaemia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10856773	EXPEDITED (15-DAY)			US-GILEAD-2015-0138639		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain upper	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10863418	EXPEDITED (15-DAY)			US-GILEAD-2015-0138545		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Feb-2015	10871523	DIRECT		OT		59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug dose omission	HARVONI 90/400MG GILEAD	S	ORAL			GILEAD
	METOPROLOL	C				
	LISINOPRIL	C				
	HYDROCODONE/APAP	C				
	ASA	C				
	ACCU-CHEK AVIVA PLUS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10739296	EXPEDITED (15-DAY)			US-GILEAD-2015-0133446	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10752207	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0134070	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diverticulitis	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash generalised	PRAVASTATIN	C		20 mg, UNK		
	COUMADIN / 00014802/	C				
	GLIPIZIDE	C				
	LEVEMIR	C				
	LISINOPRIL	C				
	GABAPENTIN	C				
	AMBIEN	C				
	AMITRIPTYLINE	C				
	NORCO	C		UNK, prn		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10798483	EXPEDITED (15-DAY)		DE,HO,OT	AT-GILEAD-2015-0137032	54 YR	Male	AUT

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Septic shock	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Enterocolitis	SPIRONOLACTONE	C	ORAL	50 mg, UNK		
Abdominal pain						
General physical health deterioration						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10863535	EXPEDITED (15-DAY)			US-GILEAD-2015-0137962	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood creatinine increased	HARVONI	S	UNKNOWN	UNK		GILEAD
	LEVOTHYROXINE	C				
	BUPROPION	C				
	INDOMETHACIN / 00003801/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10863593	EXPEDITED (15-DAY)			US-GILEAD-2015-0138067		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S	UNKNOWN			GILEAD
Nausea	RIBAVIRIN	S	UNKNOWN			
Diarrhoea	FIORICET	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10863603	EXPEDITED (15-DAY)			US-GILEAD-2015-0137844	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	UNKNOWN			GILEAD
Amnesia						
Malaise						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10863605	EXPEDITED (15-DAY)			US-GILEAD-2015-0137983		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vertigo	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10863630	EXPEDITED (15-DAY)			US-GILEAD-2015-0138055		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Enzyme level decreased	HARVONI	S	UNKNOWN			GILEAD
Platelet disorder	RIBAVIRIN	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10863660	EXPEDITED (15-DAY)			US-GILEAD-2015-0138138		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Thermal burn	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10864251	EXPEDITED (15-DAY)			US-GILEAD-2015-0139019	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10864253	EXPEDITED (15-DAY)			US-GILEAD-2015-0139018	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10879531	DIRECT		OT		65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL	1 tablet Daily Oral		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10879854	DIRECT				53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Menstrual disorder	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
	NYSTATIN	C				
	GAVILYTE-G	C				
	METFORMIN	C				
	VIT C	C				
	CORRECTOL	C				
	MULTIVITAL	C				
	ENALAPRIL	C				
	HCTZ/TRAIMT	C				
	LORAZEPAM	C				

Menstrual disorder

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2015	10879939	DIRECT				63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
Diarrhoea	WARFRAIN	C				
Rash	PATANOL	C				
Rash	FENOFIBRATE	C				
	CEREFOLIN	C				
	RISPERDAL	C				

Migraine

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10777354	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0135806	45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Throat tightness	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash generalised	SYNTHROID	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10867007	NON-EXPEDITED			US-PFIZER INC-2015070354	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	Chantix	S		UNK		PFIZER
	HARVONI	S	ORAL	1 DF, 1x/day		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10867579	EXPEDITED (15-DAY)			US-GILEAD-2015-0138553	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10868079	EXPEDITED (15-DAY)			US-GILEAD-2015-0138155	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza like illness	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						
Insomnia						
Myalgia						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10868601	EXPEDITED (15-DAY)			US-GILEAD-2015-0139153	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain	HARVONI	S	ORAL	1 Unknown, QD		GILEAD
Fatigue						
Headache						
Myalgia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10868801	EXPEDITED (15-DAY)			US-GILEAD-2015-0139146	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pruritus	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abdominal discomfort						
Diarrhoea						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10877709	DIRECT				61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pain in extremity	HARVONI	S	ORAL			GILEAD
Hypoaesthesia	OMEPRAZOLE	C				
	CYCLOSPORINE	C				
	AMLODIPINE	C				
	MAGNESIUM	C				
Pain in extremity						
Sensory disturbance						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10877973	DIRECT		OT		58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Decreased appetite	RIBAVIRIN	S	ORAL			ZYDUS PHARM
Nausea	METHADONE	C				
Insomnia	HUMALOG INSULIN	C				
	SYNTHROID	C				
	CEPHALEXIN	C				
	LISINOPRIL	C				
	ATENOLOL	C				
	AMLODIPINE	C				
	LEVOTHYROXINE	C				
	FUROSEMIDE	C				
	POTASSIUM	C				
	A & D	C				
	RIBAVIRIN	C				
	CLONIDINE	C				
	MAGNESIUM	C				
	VIT D	C				
Abdominal pain upper						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10880894	DIRECT				64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain upper	HARVONI 90/400 MG GILEAD	S	ORAL			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10881494	DIRECT	Y			59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI 90/400 MG GILEAD	S	ORAL	one tablet		GILEAD
Flatulence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Feb-2015	10882614	DIRECT		HO,DS		61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cluster headache	HARVONI	S		1 pill am mouth		GILEAD
Diplopia						
Migraine						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10714690	EXPEDITED (15-DAY)		DE,OT	CA-GILEAD-2015-0131927	60 YR	Male	CAN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemorrhage	HARVONI	S	ORAL	1 DF, UNK		GILEAD
	RIBAVIRIN	C	ORAL	400 mg, UNK		
	PANGRAF	C	ORAL	1 mg, UNK		
	RANITIDINE	C	ORAL	150 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10870213	EXPEDITED (15-DAY)		HO	FR-SA-2015SA022121	14 YR	Male	FRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Epilepsy	DEPAKINE	S	ORAL			
	DEPAKINE	S	ORAL			
	LASILIX	S	ORAL			
	IMOVANE	S	ORAL			
	PANTOPRAZOLE	S	ORAL			
	HARVONI	S	ORAL			
	XEROQUEL	S	ORAL			
	ATARAX	S	ORAL	strenght: 25 mg		
	ADCIRCA	S	ORAL			
	COVERSYL	S	ORAL			
	ALDACTONE	S	ORAL			
	NICOBION	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10870716	EXPEDITED (15-DAY)			US-GILEAD-2015-0139185	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10870725	EXPEDITED (15-DAY)			US-GILEAD-2015-0139299		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Peripheral swelling	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10870752	EXPEDITED (15-DAY)			US-GILEAD-2015-0139205	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL	1 DF, QD		GILEAD
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872112	EXPEDITED (15-DAY)			US-GILEAD-2015-0138122		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872210	EXPEDITED (15-DAY)			US-GILEAD-2015-0138580	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abdominal discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872222	EXPEDITED (15-DAY)			US-GILEAD-2015-0139411	63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872229	EXPEDITED (15-DAY)			US-GILEAD-2015-0139393	62 YR	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Psychomotor hyperactivity	HARVONI	S	UNKNOWN	UNK		GILEAD
Cyst drainage						
Pain in extremity						
Pruritus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872241	EXPEDITED (15-DAY)			US-GILEAD-2015-0138742	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872260	EXPEDITED (15-DAY)			US-GILEAD-2015-0138745		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic pain	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872280	EXPEDITED (15-DAY)			US-GILEAD-2015-0138609	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872281	EXPEDITED (15-DAY)			US-GILEAD-2015-0138610	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lethargy	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Feeling abnormal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Feb-2015	10872282	EXPEDITED (15-DAY)			US-GILEAD-2015-0138641		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia universalis	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10735713	EXPEDITED (15-DAY)		HO	IE-ROCHE-1525375	61 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemoglobin decreased	Copegus	S	UNKNOWN	400mg mane and 600mg tarde		
Blood phosphorus decreased	HARVONI	S	ORAL	400mg/ 90mg Most recent therapy prior to the event was received on 09/Jan/2015		
Blood potassium decreased	TRUVADA	C	UNKNOWN	245mg/200mg		
	PREZISTA	C	UNKNOWN			
	NORVIR	C	UNKNOWN			
	LANSOPRAZOLE	C	UNKNOWN			
	SEPTRIN FORTE	C	UNKNOWN	160mg/800mg Tablets		
	METHADONE	C	UNKNOWN			
	LAXOSE	C	UNKNOWN			
	FUROSEMIDE	C	UNKNOWN	Mane		
	Diazepam	C	UNKNOWN			
	THIAMINE	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10746444	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0133704		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C	HARVONI	S	ORAL	1 DF, QD		GILEAD
Drug ineffective	NORVASC	C				
	AMARYL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10783648	EXPEDITED (15-DAY)		HO,OT	IE-GILEAD-2015-0136051	51 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Syncope	RIBAVIRIN	S	ORAL	UNK		
Body temperature decreased	ALDACTONE / 00006201/	C				
	THIAMINE	C				
	PARACETAMOL	C				
	RIFAXIMIN	C				
	OMEPRAZOLE	C				
	PROPRANOLOL	C				
	LACTULOSE	C				
	MOVICOL / 01749801/	C				
	CIPROFLOXACIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10872038	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0138727	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alanine aminotransferase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Aspartate aminotransferase increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10873696	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0138602		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastric bypass	HARVONI	S	UNKNOWN	UNK		GILEAD
Hepatitis C virus test positive						
Wrong technique in drug usage process						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874140	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0138604		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lipase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal pain						
Amylase increased						
Dyspnoea						
Malaise						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874158	EXPEDITED (15-DAY)			US-GILEAD-2015-0138606	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritability	HARVONI	S	ORAL	1 DF, QD		GILEAD
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874166	EXPEDITED (15-DAY)			US-GILEAD-2015-0138904		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling hot	HARVONI	S	UNKNOWN			GILEAD
Rash						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874168	EXPEDITED (15-DAY)			US-GILEAD-2015-0138608	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874169	EXPEDITED (15-DAY)			US-GILEAD-2015-0138936	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874180	EXPEDITED (15-DAY)			US-GILEAD-2015-0139170	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Pyrexia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874189	EXPEDITED (15-DAY)			US-GILEAD-2015-0139216	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874222	EXPEDITED (15-DAY)		HO	FR-ABBVIE-15P-056-1353278-00	14 YR	Male	FRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Epilepsy	DEPAKINE	S	ORAL			
Brain death	LASILIX	S	ORAL			
	IMOVANE	S	ORAL			
	PANTOPRAZOLE	S	ORAL			
	HARVONI (LEDIPASVIR/ SOFOSBUVIR)	S	ORAL			
	XEROQUEL	S	ORAL			
	ATARAX	S	ORAL			
	ADCIRCA	S	ORAL			
	COVERSYL	S	ORAL			
	ALDACTONE	S	ORAL			
	NICOTINAMIDE	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874237	EXPEDITED (15-DAY)			US-GILEAD-2015-0139440	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874264	EXPEDITED (15-DAY)			US-GILEAD-2015-0139803	30 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash pruritic	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash	RAMIPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10874283	EXPEDITED (15-DAY)			US-GILEAD-2015-0139681	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10875065	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0138711	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C	HARVONI	S	UNKNOWN	UNK		GILEAD
Drug ineffective						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10875372	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139346		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Crohn's disease	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10881925	DIRECT				55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	90mg/400mg 1qd po		GILEAD
Nausea	VICTOZA	C				
Insomnia	LISINOPRIL	C				
Vision blurred	PERCOCET	C				
	ATIVAN	C				
Diarrhoea						
Diplopia						
Headache						
Lymphadenopathy						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10884742	DIRECT					Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90MG-400MG	S	ORAL			GILEAD
	MORPHINE SULFATE	C				
	CYCLOBENZAPRINE	C				
	FLUVIRIN	C				
	CITALOPRAM	C				
	GLUCOS/CHOND	C				
	MORPHINE SULF	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2015	10886566	DIRECT					Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL			GILEAD
	MORPHINE SULFATE	C				
	CYCLOBENZAPRINE	C				
	FLUVIRIN	C				
	CITALOPRAM	C				
	GLUCOS/CHOND D/S	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10691719	EXPEDITED (15-DAY)			US-GILEAD-2014-0129934	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abdominal discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10722362	EXPEDITED (15-DAY)			US-GILEAD-2015-0131890	23 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pregnancy	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10727419	EXPEDITED (15-DAY)		HO	IE-GILEAD-2015-0132636	38 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemoglobin decreased	HARVONI	S	ORAL	1 DF, QD		GILEAD
	COPEGUS	S	ORAL	1000 mg, QD		
	COPEGUS	S	ORAL	400 mg, BID		
	TRUVADA	C		1 DF, UNK		GILEAD
	DAPSONE	C		100 mg, QD		
	LANSOPRAZOLE	C		15 mg, UNK		
	ZITHROMAX	C		1.25 g, Q1Wk		
	PREZISTA	C		800 mg, QD		
	LAXOSE	C		15 ml, TID		
	INDERAL	C		10 mg, BID		
	NORVIR	C		100 mg, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10739119	EXPEDITED (15-DAY)			US-GILEAD-2015-0132783	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Flatulence	HARVONI	S	UNKNOWN	UNK		GILEAD
Abdominal distension						
Abdominal pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10739308	EXPEDITED (15-DAY)			US-GILEAD-2015-0133814	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10746259	EXPEDITED (15-DAY)		HO	IE-GILEAD-2015-0133931	61 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemoglobin decreased	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Blood phosphorus decreased	COPEGUS	S	UNKNOWN	400 mg in the morning and 600 mg in the evening, UNK		
Blood potassium decreased	TRUVADA	C		1 DF, UNK		GILEAD
	TRUVADA	C				GILEAD
	PREZISTA	C		800 mg, QD		
	NORVIR	C		100 mg, QD		
	LANSOPRAZOLE	C		15 mg, QD		
	SEPTRIN	C		960 mg, QD		
	METHADONE	C		40 mg, QD		
	LAXOSE	C		15 ml, BID		
	FUROSEMIDE	C		40 mg, QD		
	DIAZEPAM	C		2 mg, QD		
	THIAMINE	C		300 mg, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10749337	EXPEDITED (15-DAY)		OT	IE-GILEAD-2015-0133933	58 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal impairment	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	S	ORAL	200 mg, BID		
	PROGRAF	S	ORAL	1 mg, BID		
	PROGRAF	S	ORAL	1 mg, QD		
	COVERSYL ARGININE	S	ORAL	2.5 mg, QD		
	CO-TRIMOXAZOLE	C				
	URSOFALK	C		250 mg, UNK		
	HALCION	C				
	OMEPRAZOLE	C				
	RIFAXIMIN	C				
	TRANEXAMIC ACID	C				
	CARVEDILOL	C				
	VENLAFAXINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10749348	EXPEDITED (15-DAY)		OT	IE-GILEAD-2015-0133934	51 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lower respiratory tract infection	HARVONI	S	ORAL	400mg/90mg		GILEAD
	RIBAVIRIN	S	ORAL	UNK		
	SPIRONOLACTONE	C				
	THIAMINE	C				
	RIFAXIMIN	C				
	OMEPRAZOLE	C				
	PROPANOLOL / 00030001/	C				
	CIPROFLOXACIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10879614	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139306		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Liver transplant	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10880004	EXPEDITED (15-DAY)			US-GILEAD-2015-0139186		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10880005	EXPEDITED (15-DAY)			US-GILEAD-2015-0139194	34 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritability	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10880305	EXPEDITED (15-DAY)		DE	US-GILEAD-2015-0140087		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bleeding varicose vein	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10897211	DIRECT	Y			54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	HARVONI	S	ORAL	1 pill QD		GILEAD
Nervous system disorder	SYNTHROID	S				
	KYLETRA	C				
	INVIRASE	C				
	ISENTRESS	C				
	VALTREX	C				
Drug interaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10897574	DIRECT				63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90-400MG TAB GILEAD SCIENCES	S	ORAL			GILEAD
	ZOLPIDEM	C				
	LOSARTAN	C				
	AMLODIPINE	C				
	LIDOCAIN	C				
	OXYCONTIN	C				
	CRESTOR	C				
	CLONIDINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10897841	DIRECT	Y			56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	one tablet		GILEAD
Fatigue						
Fungal infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Mar-2015	10898169	DIRECT	Y			56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal discomfort	HARVONI	S	ORAL			GILEAD
Insomnia						
Irritability						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10741222	EXPEDITED (15-DAY)			US-GILEAD-2015-0133671		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysphagia	HARVONI	S	ORAL	UNK		GILEAD
Intentional product misuse						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10756417	EXPEDITED (15-DAY)		OT	IE-GILEAD-2015-0134406	57 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalopathy	HARVONI	S	ORAL	1 DF, QD		GILEAD
Peritonitis bacterial	RIBAVIRIN	S	ORAL	600 mg, BID		
	OMEPRAZOLE	C				
	PROPANOLOL / 00030001/	C				
	CIPROFLOXACIN	C				
	SPIRONOLACTONE	C				
	RIFAXIMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10847525	EXPEDITED (15-DAY)			US-GILEAD-2015-0137883		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pyrexia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10856664	EXPEDITED (15-DAY)			US-GILEAD-2015-0138125	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vision blurred	HARVONI	S	ORAL	1 UNK, UNK		GILEAD
Anxiety						
Headache						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10861413	EXPEDITED (15-DAY)		DE,HO	DE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-08361BP	66 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebral haemorrhage	AGGRENOX	S	ORAL	2 anz		BOEHRINGER INGELHEIM
	HARVONI	S	ORAL	1 anz		
	PREDNISOLONE	C	UNKNOWN			
	SANDIMMUN	C	UNKNOWN			
	AZATHIOPRINE	C	UNKNOWN			
	DOCITON	C	UNKNOWN			
	PANTOZOL	C	UNKNOWN			
	SPIRONOLACTONE A L	C	UNKNOWN			
	TORASEMID	C	UNKNOWN			
	TAMSULOSIN	C	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10875360	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139065		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10882131	EXPEDITED (15-DAY)			US-GILEAD-2015-0139116		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malaise	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10882246	EXPEDITED (15-DAY)			US-GILEAD-2015-0139931	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Constipation	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10882274	EXPEDITED (15-DAY)			US-GILEAD-2015-0139975	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Sleep disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10882434	EXPEDITED (15-DAY)			US-GILEAD-2015-0139987	67 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	ORAL	UNK Unknown, BID		GILEAD
	HARVONI	S	ORAL	UNK Unknown, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10882748	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139174		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumonia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883115	EXPEDITED (15-DAY)			US-GILEAD-2015-0138985	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea Vomiting	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883124	EXPEDITED (15-DAY)			US-GILEAD-2015-0138975	68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Labyrinthitis Ear disorder	HARVONI	S	ORAL	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883444	EXPEDITED (15-DAY)			US-GILEAD-2015-0140241	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883474	EXPEDITED (15-DAY)			US-GILEAD-2015-0140323	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883506	EXPEDITED (15-DAY)			US-GILEAD-2015-0138581		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug interaction	HARVONI	S	UNKNOWN			GILEAD
Feeling abnormal	RITONAVIR	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883589	EXPEDITED (15-DAY)			US-GILEAD-2015-0139295		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10883618	EXPEDITED (15-DAY)			US-GILEAD-2015-0139479		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10900528	DIRECT		OT		63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL			GILEAD
Constipation	STOOL SOFTNER CAP	C				
	LISINOPRIL	C				
	HYDROCHLOROT	C				
	OMEPRAZOLE	C				
	PROZAC	C				
	MULTI VITAMIN	C				
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10900551	DIRECT				62 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
Weight decreased	NORTIPTYLINE	C				
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10900616	DIRECT	Y			59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 tablet		GILEAD
Myalgia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10900617	DIRECT	Y			56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
International normalised ratio decreased	HARVONI	S	ORAL	1 tablet, daily, po		GILEAD
Product substitution issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10900910	DIRECT	Y	LT		68 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oropharyngeal cancer	HARVONI 90/400 MG GILEAD	S	ORAL	1 dose		GILEAD
	WARFARIN	C				
	CALCIUM	C				
	CHOLECALCIFEROL	C				
	HYDROCODONE	C				
	SUMATRIPTONE	C				
	DILTIAZEM	C				
	TESTOSTERONE	C				
	SIROLIMUS	C				
	TEMAZEPAM	C				
	MAGNESIUM	C				
Recurrent cancer						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Mar-2015	10901069	DIRECT				69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Confusional state	HARVONI	S	ORAL	one tablet qd oral		
Dysgraphia						
Feeling jittery						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10627293	EXPEDITED (15-DAY)			US-GILEAD-2014-0125062	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	90 mg, UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10752225	EXPEDITED (15-DAY)		HO	IE-GILEAD-2015-0134164	56 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bleeding varicose vein	HARVONI	S	ORAL	1 DF, UNK		GILEAD
	COPEGUS	S	UNKNOWN	600 mg, BID		
	TRUVADA	C				GILEAD
	ISENTRESS	C		400 mg, BID		
	OMEPRAZOLE	C		20 mg, QD		
	FUROSEMIDE	C		40 mg, QD		
	ALDACTONE / 00006201/	C		100 mg, QD		
	INDERAL	C		10 mg, BID		
	DIAZEPAM	C		5 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10771921	EXPEDITED (15-DAY)		DE,HO	US-GILEAD-2015-0135884		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	UNKNOWN	1 DF, UNK		GILEAD
	VICODIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10861433	EXPEDITED (15-DAY)		DE,HO,OT	DE-B.I. PHARMACEUTICALS,INC./RIDGEFIELD-2015-BI-08148DE	66 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebral haemorrhage	AGGRENOX	S	ORAL	2 anz		BOEHRINGER INGELHEIM
	HARVONI	S	ORAL	1 anz		
	PREDNISOLON	C	ORAL	5 mg		
	SANDIMMUN	C	ORAL	125 mg		
	AZATHIOPRIN	C	UNKNOWN	50 mg		
	DOCITON	C	ORAL	30 mg		
	PANTOZOL	C	ORAL	20 mg		
	SPIRONOLACTON AL	C	ORAL	0.5 anz		
	TORASEMID	C	ORAL	10 mg		
	TAMSULOSIN	C	ORAL	0.4 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10883428	EXPEDITED (15-DAY)			US-GILEAD-2015-0140065	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Back pain	HARVONI	S	UNKNOWN			GILEAD
Fatigue						
Nausea						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10886829	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0140012		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10886837	EXPEDITED (15-DAY)		HO,OT	DE-GILEAD-2015-0139463		Female	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain upper	HARVONI	S	UNKNOWN			GILEAD
Aphagia						
Cholelithiasis						
Gamma-glutamyltransferase increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10886883	NON-EXPEDITED			US-PFIZER INC-2015070343		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aspartate aminotransferase increased	Lipitor	S		UNK		PFIZER
Alanine aminotransferase increased	HARVONI	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887139	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139947	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure congestive	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887140	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0139948	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure congestive	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887471	EXPEDITED (15-DAY)			US-GILEAD-2015-0140540		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	UNKNOWN	UNK		GILEAD
Dizziness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887472	EXPEDITED (15-DAY)			US-GILEAD-2015-0140365	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Accidental overdose	HARVONI	S	ORAL	1 DF, BID		GILEAD
	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887506	EXPEDITED (15-DAY)			US-GILEAD-2015-0140328		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	UNK		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887508	EXPEDITED (15-DAY)			US-GILEAD-2015-0140511	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887552	EXPEDITED (15-DAY)			US-GILEAD-2015-0140503	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887670	EXPEDITED (15-DAY)			US-GILEAD-2015-0140296		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Allergic sinusitis	HARVONI	S	UNKNOWN	UNK		GILEAD
	LORATADINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887677	EXPEDITED (15-DAY)			US-GILEAD-2015-0140292	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Confusional state	HARVONI	S	UNKNOWN			GILEAD
Memory impairment						
Sleep disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887680	EXPEDITED (15-DAY)			US-GILEAD-2015-0140212	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10887732	EXPEDITED (15-DAY)			US-GILEAD-2015-0139353	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD
Local swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10903354	DIRECT				54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
Upper respiratory tract infection	LYRICA	C				
Bronchitis						
Influenza like illness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10903779	DIRECT	Y	OT		52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Breast pain	HARVONI 90/400MG GILEAD	S	ORAL	one tablet QD		GILEAD
	PRILOSEC	C				
	CENTRUM	C				
	SPIRIVA INHALER	C				
Breast swelling						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10904068	DIRECT				60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anxiety	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
Abnormal dreams						
Fatigue						
Mood altered						
Sleep disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2015	10904586	DIRECT		OT		56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
Headache	STRIBILD	C				
Fatigue	LORAZEPAM	C				
Irritability	TEMAZEPAM	C				
	CIALIS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10792590	EXPEDITED (15-DAY)		DE,OT	US-GILEAD-2015-0136997	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Death	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Abdominal pain	ZIAGEN	C	ORAL	300 mg, UNK		
Vomiting	NORVIR	C	ORAL	100 mg, UNK		
Malaise	REYATAZ	C	ORAL	300 mg, UNK		
Fatigue	LYRICA	C	ORAL	100 mg, UNK		
	VITAMIN D3	C	ORAL	1000 IU, UNK		
	NEUROTIN / 01003001/	C	ORAL	600 mg, UNK		
	TIVICAY	C	ORAL	50 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10871423	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015067195	54 YR	Male	FRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Epilepsy	Aldactone	S	ORAL	75 mg, 1x/day		PFIZER
Amnesia	HARVONI	S	ORAL	82 mg, 1x/day		
Confusional state	XEROQUEL	S	ORAL	500 mg, 1x/day		
Disorientation	ATARAX	S	ORAL	25 mg, as needed		
Aphasia	ADCIRCA	S	ORAL	40 mg, 1x/day		
Agitation	DEPAKINE	S	ORAL	400 mg, 2x/day		
	DEPAKINE	S	ORAL	500 mg, 2x/day		
	COVERSYL	S	ORAL	2.5 mg, 1x/day		
	LASILIX SPECIAL /00032601/	S	ORAL	125 mg, 1x/day		
	IMOVANE	S	ORAL	7.5 mg, 1x/day		
	NICOBION	S	ORAL	1 g, 1x/day		
	PANTOPRAZOLE	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10882269	EXPEDITED (15-DAY)			US-GILEAD-2015-0139974		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Confusional state	HARVONI	S	UNKNOWN			GILEAD
Dizziness						
Gait disturbance						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10888407	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0139999		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure	HARVONI	S	UNKNOWN			GILEAD
Alanine aminotransferase decreased	VIREAD	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889094	EXPEDITED (15-DAY)			US-GILEAD-2015-0140023		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Agitation	HARVONI	S	UNKNOWN	UNK		GILEAD
Lip swelling	WELLBUTRIN	C				
Blood pressure increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889098	EXPEDITED (15-DAY)			US-GILEAD-2015-0139643	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889414	EXPEDITED (15-DAY)			US-GILEAD-2015-0139622	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889415	EXPEDITED (15-DAY)			US-GILEAD-2015-0139591	73 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abdominal distension						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889434	EXPEDITED (15-DAY)			US-GILEAD-2015-0140202		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889435	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0140287	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diabetes mellitus	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Hyperglycaemia	AMLODIPINE	S	ORAL	2.5 mg, UNK		
	OMEPRAZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889436	EXPEDITED (15-DAY)			US-GILEAD-2015-0140430	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889445	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0140530	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chest pain	HARVONI	S	UNKNOWN	UNK		GILEAD
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2015	10889447	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0140531	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10866173	EXPEDITED (15-DAY)	Y	OT	DE2015GSK004348	50 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood HIV RNA increased	TRIUMEQ	S				
Drug interaction	HARVONI	S				
Viraemia	RIBAVIRIN (RIBAVIRIN)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10891241	EXPEDITED (15-DAY)		HO	GB-009507513-1503GB R002183	47 YR	Unknown	GBR

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrotic syndrome	RIBAVIRIN	S				MERCK
	HARVONI	S				
	SOFOSBUVIR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10892340	EXPEDITED (15-DAY)			US-GILEAD-2015-0139756	72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10892864	EXPEDITED (15-DAY)		OT	IE-GILEAD-2015-0139958	69 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urinary tract infection	HARVONI	S	ORAL	1 DF, QD		GILEAD
	RIBAVIRIN	S	ORAL	1000 mg, UNK		
	SALBUTAMOL	C				
	OMEPRAZOLE	C				
	FLUOXETINE	C				
	SERETIDE	C				
	IBANDRONIC ACID	C				
	CEFUROXIME	C				
	ALDACTONE / 00006201/	C				
	TEMAZEPAM	C				
	FRUSEMIDE / 00032601/	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10892869	EXPEDITED (15-DAY)			US-GILEAD-2015-0139635	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10892872	EXPEDITED (15-DAY)			US-GILEAD-2015-0139797		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Inappropriate schedule of drug administration	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10893487	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0140039	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aggression	HARVONI	S	UNKNOWN			GILEAD
Agitation						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10893778	EXPEDITED (15-DAY)			US-GILEAD-2015-0139932		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urticaria	HARVONI	S	UNKNOWN	UNK		GILEAD
Hypersensitivity						
Periorbital oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10893783	EXPEDITED (15-DAY)			US-GILEAD-2015-0139867	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10894973	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0140462		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	HARVONI	S	UNKNOWN			GILEAD
Nausea	DIGOXIN	S	UNKNOWN			
Drug interaction						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10894983	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0140528	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood bilirubin increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Jaundice						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Mar-2015	10895717	EXPEDITED (15-DAY)			US-GILEAD-2015-0140038	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Depression	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10763137	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0135073	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalopathy	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10777845	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0136092	69 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mental impairment	HARVONI	S	ORAL	1 DF, QD		GILEAD
Confusional state						
Disorientation						
Feeling jittery						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10883454	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0140268		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neutrophil count decreased	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10887414	EXPEDITED (15-DAY)		HO,OT	CA-GILEAD-2015-0140120	71 YR	Female	CAN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bradycardia	HARVONI	S	UNKNOWN	UNK		GILEAD
Atrioventricular block complete	AMIODARONE	S	UNKNOWN	UNK		
Hypotension	BISOPROLOL	S	UNKNOWN	UNK		
Syncope	FUROSEMIDE	C				
	LACTULOSE	C				
	ASPIRIN / 00002701/	C				
	SYMBICORT	C				
	L THYROXIN	C				
	TELMASURGE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10896693	EXPEDITED (15-DAY)		HO	GB-ROCHE-1548658	47 YR	Unknown	GBR

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrotic syndrome	Ribavirin	S	UNKNOWN			
	HARVONI	S	UNKNOWN			
	SOFOSBUVIR	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10898170	EXPEDITED (15-DAY)			US-GILEAD-2015-0140545		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash generalised	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10898870	EXPEDITED (15-DAY)			US-GILEAD-2015-0140781		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain Headache Insomnia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10898875	EXPEDITED (15-DAY)			US-GILEAD-2015-0140904	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10898879	EXPEDITED (15-DAY)			US-GILEAD-2015-0140797	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10898887	EXPEDITED (15-DAY)			US-GILEAD-2015-0141002		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tinnitus	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899309	EXPEDITED (15-DAY)			US-GILEAD-2015-0139158	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899380	EXPEDITED (15-DAY)			US-GILEAD-2015-0140140		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Overdose	HARVONI	S	UNKNOWN	2 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899381	EXPEDITED (15-DAY)			US-GILEAD-2015-0139595	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nasopharyngitis	HARVONI	S	ORAL	1 DF, QD		GILEAD
Oropharyngeal pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899384	EXPEDITED (15-DAY)			US-GILEAD-2015-0140162		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899395	EXPEDITED (15-DAY)			US-GILEAD-2015-0140127	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza like illness	HARVONI	S	UNKNOWN			GILEAD
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899398	EXPEDITED (15-DAY)			US-GILEAD-2015-0140461	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Eye swelling	HARVONI	S	UNKNOWN	UNK		GILEAD
Rash generalised	KEPPRA	S	UNKNOWN			
Drug interaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899401	EXPEDITED (15-DAY)			US-GILEAD-2015-0140416	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899402	EXPEDITED (15-DAY)			US-GILEAD-2015-0140247	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Flatulence	HARVONI	S	ORAL	1 DF, QD		GILEAD
Diarrhoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899403	EXPEDITED (15-DAY)			US-GILEAD-2015-0140388		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899404	EXPEDITED (15-DAY)			US-GILEAD-2015-0140477	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sleep disorder	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899405	EXPEDITED (15-DAY)			US-GILEAD-2015-0140446		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899406	EXPEDITED (15-DAY)			US-GILEAD-2015-0140401		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspepsia	HARVONI	S				GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899409	EXPEDITED (15-DAY)			US-GILEAD-2015-0140488	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Middle insomnia Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899410	EXPEDITED (15-DAY)			US-GILEAD-2015-0140734		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899412	EXPEDITED (15-DAY)			US-GILEAD-2015-0140809		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899414	EXPEDITED (15-DAY)			US-GILEAD-2015-0140493	62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache Fatigue	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899416	EXPEDITED (15-DAY)			US-GILEAD-2015-0140739		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899417	EXPEDITED (15-DAY)			US-GILEAD-2015-0140799	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899422	EXPEDITED (15-DAY)			US-GILEAD-2015-0141219	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899423	EXPEDITED (15-DAY)			US-GILEAD-2015-0141206	56 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pyrexia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Constipation						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899424	EXPEDITED (15-DAY)			US-GILEAD-2015-0141224		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sinusitis	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899425	EXPEDITED (15-DAY)			US-GILEAD-2015-0141192		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Respiratory tract infection	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899426	EXPEDITED (15-DAY)			US-GILEAD-2015-0141213	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrointestinal disorder	HARVONI	S	ORAL	1 DF, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899428	EXPEDITED (15-DAY)			US-GILEAD-2015-0140803		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Rash generalised	HARVONI	S	ORAL	1 DF, UNK		GILEAD
Pruritus	HCTZ	C				
	LEVOXYL	C				
	PROZAC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899429	EXPEDITED (15-DAY)			US-GILEAD-2015-0141202		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	HARVONI	S	UNKNOWN			GILEAD
Blood pressure fluctuation						
Visual impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899431	EXPEDITED (15-DAY)			US-GILEAD-2015-0141246	52 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10899432	EXPEDITED (15-DAY)			US-GILEAD-2015-0141287		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C virus test positive	HARVONI	S	UNKNOWN	UNK		GILEAD

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10905042	DIRECT		OT		60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle spasms	HARVONI	S	ORAL			
Energy increased	VITAMIN D 1000 MG	C				
Indifference	POLICOSANOL	C				
	VICODIN	C				
	SCIALICA	C				
	ALPHA LIPOIC ACID	C				
Fatigue						
Muscle tightness						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10905188	DIRECT	Y			62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI 90-400MG GILEAD SCIENCES	S	ORAL			GILEAD
	ALPRAZOLAM	C				
	ATENOLOL	C				
	METHADINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10905258	DIRECT	Y	HO,LT		45 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Suicide attempt	HARVONI	S	ORAL		1 MTH	GILEAD

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10905631	DIRECT		DS,LT,OT,RI		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	HARVONI	S				
Nervous system disorder	LYICA	C				
Abasia	HYTROCLORITHY TRAMDOL	C				
Malaise	LEXPRO	C				
Muscular weakness	PROLOSEC	C				
Mental disorder	ZANAFLEX	C				
	XLEXDTIL	C				
	EQUATE	C				
Abnormal behaviour						
Diarrhoea						
Fall						
Impaired driving ability						
Pain						
Tremor						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10906907	DIRECT	Y			60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	HARVONI 90-400MG TAB GILEAD SCIENCES	S	ORAL			
Abdominal pain						
Fatigue						
Flatulence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10906970	DIRECT	Y			51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 tablet		GILEAD
Mood swings						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10907403	DIRECT	Y	HO		67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	HARVONI 90-400 MG	S	ORAL			GILEAD
Pulmonary thrombosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Mar-2015	10911597	DIRECT	Y	HO		74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Transfusion	HARVONI 90/400 MG GILEAD	S	ORAL			GILEAD

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10711467	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0130084	61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal impairment	HARVONI	S	ORAL	1 DF, UNK		GILEAD
	ASPIRIN (E.C.)	C	ORAL	325 mg, UNK		
	FLOMAX / 01280302/	C		0.4 mg, UNK		
	ATARAX / 00058402/	C		50 mg, UNK		
	LINZESS	C		145 µg, UNK		
	ATIVAN	C		1 mg, UNK		
	MEVACOR	C		40 mg, UNK		
	METHADONE HCL	C		5 mg/5 ml		
	MULTIPLE VITAMINS WITH MINERALS	C				
	METAMUCIL / 00091301/	C		0.52 g, UNK		
	ZANTAC	C		150 mg, UNK		

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10731168	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0131733	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Migraine	FUROSEMIDE	C		40 mg, BID		
Hypertension	LISINOPRIL	C		20 mg, BID		
Headache	METOPROLOL	C		12.5 mg, UNK		
	BABY ASPIRIN	C				
	CETIRIZINE	C				
	LORAZEPAM	C				
	ALBUTEROL / 00139501/	C				
	METOCARBAMOL	C				
	HYDROCODONE W/ PARACETAMOL	C				
	RANITIDINE	C				
	FORMOTEROL W/MOMETASONE	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10899972	EXPEDITED (15-DAY)		HO	IE-ROCHE-1549227	61 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	Copegus	S	ORAL			
Asthenia	HARVONI	S	ORAL	400mg/90mg		
Encephalopathy	KIVEXA	S	UNKNOWN	600mg/300mg		
Lower respiratory tract infection	PREZISTA	S	ORAL			
Fluid retention	NORVIR	S	ORAL			
	SEPTRIN	S	UNKNOWN			
	METHADONE	C	UNKNOWN			
	LAXOSE	C	UNKNOWN			
	FUROSEMIDE	C	UNKNOWN			
	Diazepam	C	UNKNOWN	Nocte		
	CALCICHEW D3 FORTE	C	UNKNOWN	544mg/400 units		
	THIAMINE	C	UNKNOWN			
	GALFER	C	UNKNOWN			
	LANSOPRAZOLE	C	UNKNOWN			
	NeoRecormon	C	SUBCUTANEOUS			
	VERSATIS	C	UNKNOWN	1 patch applied daily for 12 hours		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10901586	EXPEDITED (15-DAY)		OT	IE-GILEAD-2015-0140052	49 YR	Female	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalopathy	HARVONI	S	ORAL	OD		GILEAD
	RIBAVIRIN	S	ORAL	600 mg, BID		
	CITALOPRAM / 00582602/	C		20 mg, QD		
	CITALOPRAM / 00582602/	C		40mg OD		
	THIAMINE / 00056102/	C		UNK		
	OMEPRAZOLE	C		UNK		
	FRUSEMIDE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10901723	EXPEDITED (15-DAY)			US-GILEAD-2015-0140496	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Fatigue						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10901728	EXPEDITED (15-DAY)			US-GILEAD-2015-0140999		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tinnitus	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10901816	EXPEDITED (15-DAY)			US-GILEAD-2015-0141000	50 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tinnitus	HARVONI	S	UNKNOWN			GILEAD
	GABAPENTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10902176	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0140786		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic failure	HARVONI	S	UNKNOWN			GILEAD
Blood bilirubin increased	RIBAVIRIN	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10902872	EXPEDITED (15-DAY)			US-GILEAD-2015-0140455		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C RNA positive	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10902927	EXPEDITED (15-DAY)		OT	CA-GILEAD-2015-0140763	49 YR	Male	CAN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dermatitis bullous	HARVONI	S	UNKNOWN			GILEAD
Rash pruritic						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10912771	DIRECT	Y			33 YR	Male	

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hot flush	HARVONI	S	ORAL	one tablet		
Body temperature increased						
Hyperhidrosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2015	10912916	DIRECT	Y			62 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI 90-400 MG	S	ORAL	1 pill	8 WEEK	
Headache						
Pruritus						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2015	10905782	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0141103		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis C	HARVONI	S	UNKNOWN	UNK		GILEAD
Drug ineffective						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2015	10905834	EXPEDITED (15-DAY)		HO	US-GILEAD-2015-0140893	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
White blood cell count increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Blood alkaline phosphatase increased						
Blood bilirubin increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2015	10905845	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0140892		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood alkaline phosphatase increased	HARVONI	S	UNKNOWN	UNK		GILEAD
Hepatic enzyme increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2015	10906027	EXPEDITED (15-DAY)		OT	DE-GILEAD-2015-0141449		Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Liver transplant	HARVONI	S	UNKNOWN			GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2015	10906395	EXPEDITED (15-DAY)			US-GILEAD-2015-0137572	49 YR	Female	USA

Preferred Term	Product		Role	Route	Dosage Text	Duration	Manufacturer
Vision blurred	HARVONI		S	ORAL	1 UNK, UNK		GILEAD
Hyperkalaemia	ALBUTEROL 00139501/	/	C				
Sinusitis	ATIVAN		C				
	PAROXETINE		C				
	ALLOPURINOL		C				
	ROPINIROLE		C				
	IRON		C				
	LASIX	/00032601/	C				
	RANITIDINE		C				
	LACTULOSE		C				
	BIAXIN		C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2015	10908819	EXPEDITED (15-DAY)		DE,OT	AT-GILEAD-2015-0141490		Male	AUT

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	HARVONI	S	UNKNOWN			GILEAD
Multi-organ failure						
Nephropathy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2015	10911211	EXPEDITED (15-DAY)		HO,OT	GB-GILEAD-2015-0140638	47 YR	Unknown	GBR

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nephrotic syndrome	HARVONI	S	UNKNOWN	UNK		GILEAD
	RIBAVIRIN	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2015	10763783	EXPEDITED (15-DAY)			US-GILEAD-2015-0134909		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Erectile dysfunction	HARVONI	S	UNKNOWN	UNK DF, UNK		GILEAD
Diarrhoea						
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2015	10914621	EXPEDITED (15-DAY)			US-GILEAD-2015-0140908	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2015	10914625	EXPEDITED (15-DAY)		HO,OT	IE-GLAXOSMITHKLINE-IE2015030209	61 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Somnolence	Kivexa	S		600mg/300mg		VIIV
Asthenia	Septrin	S				GLAXOSMITHKLINE
Encephalopathy	HARVONI	S	ORAL	400mg/90mg		
Asterixis	COPEGUS	S				
Lower respiratory tract infection	PREZISTA	S				
Fluid retention	NORVIR	S				
	METHADONE	C				
	LAXOSE	C				
	FUROSEMIDE	C				
	DIAZEPAM	C		Nocte		
	CENTRUM	C				
	CALCICHEW-D3 FORTE	C		544mg/400 units		
	THIAMINE	C				
	GALFER	C				
	LANSOPRAZOLE	C				
	NEORECORMON	C	SUBCUTANEOUS			
	VERSATIS	C		1 patch applied daily for 12 hours		
	MOVICOL	C				
	LACRI-LUBE EYE OINTMENT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2015	10914660	EXPEDITED (15-DAY)			US-GILEAD-2015-0140995		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysphagia	HARVONI	S	ORAL			GILEAD
Product size issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2015	10914663	EXPEDITED (15-DAY)			US-GILEAD-2015-0140787	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	HARVONI	S	ORAL	1 DF, QD		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2015	10914783	EXPEDITED (15-DAY)		HO,LT,OT	IE-GILEAD-2015-0141025	51 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Meningitis tuberculous	HARVONI	S	ORAL	1 DF, QD		GILEAD
Meningitis cryptococcal	RIBAVIRIN	S	ORAL	1 DF, UNK		
	ALDACTONE / 00006201/	C				
	FRUSEMIDE / 00032601/	C				
	THIAMINE	C				
	PARACETAMOL	C				
	RIFAXIMIN	C				
	PROPANOLOL / 00030001/	C				
	OMEPRAZOLE	C				
	LACTULOSE	C				
	MOVICOL / 01749801/	C				
	CIPROFLOXACIN	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Mar-2015	10907893	EXPEDITED (15-DAY)		HO	IE-ABBVIE-15P-229-1357955-00	61 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalopathy	NORVIR	S	UNKNOWN			
Lower respiratory tract infection	HARVONI	S	ORAL	400mg/90mg		
Asterixis	COPEGUS	S	UNKNOWN			
Somnolence	KIVEXA	S	UNKNOWN	600mg/300mg		
Fluid retention	PREZISTA	S	UNKNOWN			
Asthenia	SEPTRIN	S	UNKNOWN			
	METHADONE	C				
	LAXOSE	C				
	FUROSEMIDE	C				
	DIAZEPAM	C		Nocte		
	CENTRUM	C		1 dosage forms		
	CALCICHEW-D3 FORTE	C		544mg/400units		
	THIAMINE	C				
	GALFER	C				
	LANSOPRAZOLE	C				
	NEORECORMON	C	SUBCUTANEOUS			
	VERSATIS	C		1 patch applied daily for 12 hours		
	MOVICOL	C		2 dosage forms		
	LACRI-LUBE	C	OPHTHALMIC			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2015	10789736	EXPEDITED (15-DAY)		HO	IE-GILEAD-2015-0136307	60 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Confusional state	HARVONI	S	ORAL	1 DF, QD		GILEAD
Asterixis	COPEGUS	C		UNK		
	TARGAXAN	C		UNK		
	LAXOSE	C		UNK		
	PINADONE	C		UNK		
	DIAZEPAM	C				
	DALMANE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2015	10790970	EXPEDITED (15-DAY)		HO,OT	IE-GILEAD-2015-0136292	55 YR	Male	IRL

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatic encephalopathy	HARVONI	S	ORAL	1 DF, QD		GILEAD
Coma scale abnormal	COPEGUS	C		400 mg, QD		
	COPEGUS	C		600 mg, QD		
	TARGAXAN	C		550 mg, BID		
	LAXOSE	C		30 ml, TID		
	BENERVA	C		100 mg, TID		
	LANSOPRAZOLE	C		15 mg, QD		
	PINADONE	C		25 mg, UNK		
	HEPA MERZ	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2015	10844763	EXPEDITED (15-DAY)		DE,OT	US-GILEAD-2015-0138415	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ischaemic enteritis	HARVONI	S	UNKNOWN	1 DF, QD		GILEAD
Mesenteric artery thrombosis	COCAINE	S	UNKNOWN			
Hepatic infarction						
Pneumonia aspiration						
Renal failure acute						
Splenic infarction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2015	10856402	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0137910	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Transient ischaemic attack	HARVONI	S	ORAL	400 mg, QD		GILEAD
Contusion						
Convulsion						
Dizziness						
Fall						
Memory impairment						
Syncope						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2015	10872265	EXPEDITED (15-DAY)		HO,OT	DE-GILEAD-2015-0138879	59 YR	Female	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Upper gastrointestinal haemorrhage	HARVONI	S	ORAL	1 DF, QD		GILEAD
Haemorrhagic anaemia	TOREM / 01036501/	C	ORAL	200 mg, UNK		
Anaemia	SPIRONOLACTONE	C	ORAL	25 mg, UNK		
Varices oesophageal	PANTOZOL / 01263204/	C	ORAL	40 mg, UNK		
Oesophageal ulcer						
Pneumonia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Mar-2015	10911199	EXPEDITED (15-DAY)		OT	DE-GILEAD-2015-0140932	39 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aspartate aminotransferase increased	HARVONI	S	ORAL	1 DF, QD		GILEAD
Gamma-glutamyltransferase increased	TRUVADA	S	ORAL	1 DF, QD		GILEAD
	TRUVADA	S				GILEAD
	PREZISTA	C	ORAL	800 mg, QD		
	NORVIR	C	ORAL	100 mg, QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Mar-2015	10781563	EXPEDITED (15-DAY)			US-GILEAD-2015-0136015	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Flatulence	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abdominal pain						
Asthenia						
Diarrhoea						
Fatigue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Mar-2015	10836030	EXPEDITED (15-DAY)			US-GILEAD-2015-0137117	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	HARVONI	S	ORAL	1 DF, QD		GILEAD
Abdominal pain upper						
Diarrhoea						
Dyspepsia						
Fatigue						
Headache						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Mar-2015	10911202	EXPEDITED (15-DAY)		HO	FR-GILEAD-2015-0135832	75 YR	Female	FRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neutropenia	HARVONI	S	UNKNOWN	UNK		GILEAD
	COAPROVEL	C	ORAL	300 mg, UNK		
	EZETROL	C	ORAL	10 mg, UNK		
	INEXIUM / 01479302/	C	ORAL	20 mg, UNK		
	LEVOTHYROX	C	ORAL	100 µg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2015	10746501	EXPEDITED (15-DAY)			US-GILEAD-2015-0134076	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tinnitus	HARVONI	S	UNKNOWN	UNK		GILEAD

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2015	10865932	EXPEDITED (15-DAY)			US-GILEAD-2015-0138668		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	HARVONI	S	ORAL	1 DF, QD		GILEAD
Feeling abnormal	PANTOPRAZOLE	C				
Oedema peripheral	FUROSEMIDE	C				
Speech disorder	TAMSULOSIN	C				
Dysphonia	VALSARTAN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2015	10911198	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0141197		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Seizure like phenomena	HARVONI	S	UNKNOWN	UNK, QD		GILEAD
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Mar-2015	10902612	EXPEDITED (15-DAY)		HO,OT	US-GILEAD-2015-0140712	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Syncope	HARVONI	S	ORAL	1 DF, QD		GILEAD
Sinus bradycardia	PROPAFENONE	S	ORAL	425 mg, UNK		
Trifascicular block	METOPROLOL SUCCINATE	S	ORAL	50 mg, QD		
	VERAPAMIL	S	ORAL	200 mg, QD		
	ASPIRIN 81	C	ORAL	81 mg, QD		

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

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2015	10717623	EXPEDITED (15-DAY)			US-GILEAD-2015-0130998	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	HARVONI	S	ORAL	1 DF, QD		GILEAD
Anxiety						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2015	10759652	EXPEDITED (15-DAY)			US-GILEAD-2015-0134395	53 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysphagia	HARVONI	S	UNKNOWN	UNK		GILEAD
Oropharyngeal pain						
Wrong technique in drug usage process						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2015	10836048	EXPEDITED (15-DAY)			US-GILEAD-2015-0137151	57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Chromaturia	HARVONI	S	UNKNOWN			GILEAD
Dysuria	CURAMIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Mar-2015	10856494	EXPEDITED (15-DAY)		OT	US-GILEAD-2015-0137532		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aspartate aminotransferase increased	HARVONI	S	ORAL	1 DF, QD		GILEAD
Alanine aminotransferase increased						