APPENDIX J: REPORTS OF SERIOUS HEPATIC ADVERSE EVENTS

Introduction

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Addendum

APPENDIX J:

POSTMARKETING SPONTANEOUS REPORTS OF ACUTE SEVERE LIVER INJURY AND ACUTE LIVER FAILURE

SERIOUS HEPATIC ADVERSE EVENTS FROM CLINICAL TRIALS

As described in sanofi-aventis's Briefing Document dated November 14, 2006, definitions were adopted for Acute Severe Liver Injury (ASLI) and Acute Liver Failure (ALF) in May 2006 (page 88). These definitions were applied to postmarketing spontaneous cases reported prior to FDA approval (Table 40) as well as those reported since approval (Table 64).

The enclosed, Appendix J, includes data from all clinical trial reports of serious hepatic AE cases, consisting of cases from the Phase III Western studies, the large usual care study (Study A3014), Japanese Phase III and postmarketing survey studies, pediatric Phase II and III studies, and adult Phase IV studies for the convenience of the current joint Advisory Committee.

In addition, the appendix includes line listings for all worldwide postmarketing spontaneous reports of ASLI and ALF. These data are provided as US reports (N=57) and ex-US reports (N=77) for a combined total of 134 case reports. Of note, it was determined that for ex-US reports there were not 79 hepatic adverse event (AE) cases as described in the Briefing Document (Table 64), but 77 cases as 2 cases were found to be duplicates (200121010DE and 200512675GDDC). Therefore, the total number of ASLI cases is also reduced from 136 to 134.

Sanofi-aventis will be prepared to discuss any questions on similar data on other Adverse Events of Special Interest (AESIs): exacerbation of Myasthenia Gravis, syncope, and visual disorders with the joint Advisory Committee at the December meeting.

Table 1 – Clinical trial reports of serious hepatic adverse events with telithromycin

Case ID	Study ID	Subject ID	MedDRA PT	Age	Sex	Comment
Phase II – III Pediatric						
200114654GDDC	2001	0010	Hepatitis acute, pyrexia, nausea, vomiting, abdominal pain, jaundice, AST increased, ALT increased, bilirubin increased	7 Y	F	25 days after last dose of TEL, ALT 981 U/L, total bilirubin 68 (3-21 µmol/L) with jaundice, fever, abdominal pain. Acute hepatitis A confirmed with positive IgM titers.
200116063GDDC	2001	14	Transaminase increased, diarrhea, pyrexia, ALT increased, AST increased	23 mo	M	23 month old with fever, diarrhea with ALT 335, AST 670 3 days after starting telithromycin. Patient recovered
200311908EU	2006	6	AST increased, platelet count decreased, ALT increased	12 mo	M	1 year old noted to have ALT 153 with total bilirubin normal 5 days after initiating telithromycin. Patient recovered.
200613626GDDC	3006	6001	Hypersensitivity, liver function test abnormal, dehydration, rash, vomiting, arthralgia, joint swelling	15 Y	F	Serum sickness with rash, joint pain, fever 5 days after starting TEL. Rash continued 3-4 weeks after discontinuing TEL, then resolved completely. Increased ALT 179 U/L, AP 186 U/L, total bilirubin 0.8, eosinophils 8.7%.
Phase 3 Adult						
199910127RUPV	3000	0502/069	Hepatitis, pyrexia, gastroenteritis, malaise, ALT increased,	54 Y	M	Baseline ALT 81. Increased to 1529 10 days after last TEL dose, bilirubin 1.5x ULN, eosinophils increased. Liver biopsy revealed centrolobular necrosis with granulomas and eosinophilic infiltration. 3 months later ALT returned to pre-treatment values, then 6 months later with no repeat exposure to telithromycin ALT 1331. ANA

Case ID	Study ID	Subject ID	MedDRA PT	Age	Sex	Comment
						negative. Second biopsy showed hepatitis withcentrolobular liver cell depletion with no frank necrosis. ALT normal 2 months later. Expert opinion- preexisting autoimmune hepatitis possibly exacerbated by TEL during first episode. Last f/u April 2005, ALT normal.
199911017HMRI	3006	0060/039	Hepatocellular damage	76 Y	F	Asymptomatic ALT elevation 418. Anti hepatitis A,B,C were nonreactive. Patient recovered in 7 days. No history of liver problems
199911578HMRI	3008	0259/005	Hepatocellular damage, diarrhea	19 Y	M	2 days after completing TEL, ALT 124. Consumed alcohol night before phlebotomy. Hepatitis A,B,C serology negative. Laboratory values returned to normal 8 days later
200011081HMRI	3010	0473/001	Pancreatitis, pancreatic mass, cholelithiasis, bile duct obstruction, small cell lung cancer, hyponatremia, abdominal pain upper, blood amylase increased, lipase increased, nausea, lymphadenopathy, jaundice	54 Y	M	History of alcohol abuse. Hospitalized for persistent abdominal pain. Amylase 4,174, lipase 35,600. CT showed gallstone, dilated common bile duct and enlarged pancreatic head. Biopsy of mediastinal lymph nodes revealed small cell carcinoma. Patient underwent ERCP with stent placement and bilirubin returned to normal and symptoms resolved.
200212006US	3012	1027/006	Transaminases increased, ALT increased, AST increased, LDH increased	19 Y	M	ALT elevated at baseline and increased initially to 160 during TEL treatment. Recent history of acetaminophen use. Peak ALT 447. ALT levels normalized on follow up 3 months later
Study 3014						
200123739US	3014	7	Diabetes mellitus non-insulin dependent, hepatic enzyme increased, fatigue, polyuria,	67 Y	F	13 days after last dose of TEL, diagnosed with DM type II at which time ALT 417 U/L. 10 days later eosinophils 6.9% (ULN 6.8%), absolute

Case ID	Study ID	Subject ID	MedDRA PT	Age	Sex	Comment
						eosinophil count 870, ALT 401.
200210473US	3014	23	Cardiac arrest, myocardial infarction, hepatorenal failure, blood creatinine increased, blood urea increased, hepatic enzyme increased	74 Y	M	On day 2 of TEL suffered sudden cardiac arrest secondary to acute myocardial infarction. In ICU, developed secondary hepatorenal failure. Died 12 days after start of TEL.
200210645US	3014	001	Hepatitis viral, pneumonia, cough, pyrexia,	39 Y	M	Patient diagnosed with hepatitis approximately 1 day after starting TEL requiring hospitalization. ALT 210, AP 157, bilirubin 0.5. The patient recovered
200210981US	3014	12	Biliary neoplasm, liver function test abnormal	53 Y	F	Patient diagnosed with gallbladder mass (adenomyoma with chronic cholecystitis) associated with transient liver enzyme elevation requiring cholecystectomy. Peak ALT 99
200211388US	3014	1	Liver function test abnormal, hepatitis, fatigue, nausea, jaundice, pyrexia, abdominal pain	75 Y	F	12 days after last dose of TEL, ALT 969, AP 285 and total bilirubin 1.8. No jaundice. Patient was hospitalized and subsequently recovered. Med history- cholecystectomy
200211928US	3014	28	Ovarian cyst, hepatic enzyme increased, abdominal pain, pyrexia, fatigue	37 Y	F	14 days after last dose of TEL, patient was noted to have ALT 344, peaking at 441. total bilirubin 1.7. Associated with fever and fatigue. Resolved
200212136US	3014	39	Liver function test abnormal, hepatitis C, liver function test abnormal	53 Y	F	20 days after last dose of TEL, ALT 521, AP 140. Patient diagnosed with hepatitis C. Patient recovered.
200212522US	3014	26	Autoimmune hepatitis	60 Y	F	ALT 347, AP 105; bilirubin 0.6. Anti-smooth muscle antibody positive, ANA positive. Eosinophils 8.7%. Patient recovered

Case ID	Study ID	Subject ID	MedDRA PT	Age	Sex	Comment
200212542US	3014	1	Liver function test abnormal, hepatitis C, fatigue, nausea	49 Y	M	After 1 day of TEL treatment ALT 124 which peaked to 181, 17 days later. Patient with history of intravenous drug use. Ongoing at last visit
200212572US	3014	26	Hepatitis C	32 Y	M	16 days after last dose of TEL, ALT 145. ALT 53 at baseline. Asymptomatic. Patient diagnosed with Hep C. Ongoing at last visit
200212789US	3014	3	Hepatitis B	34 Y	F	8 days after last dose of TEL. Reported feeling weak. ALT 2345 U/L, AP 146, total bilirubin 2.2. Work-up revealed acute hepatitis B infection. The patient recovered
Japanese Studies						
200211111JP	3104	11-1	Hepatic function abnormal	21 Y	F	History of asthma and taking OTC cold medications. Treated for cervicitis. 18 days after last dose of TEL, ALT 732 U/L, Eosinophils 12.8%, absolute eosinophil count 800, highest total bilirubin 1.1. Hospitalized for increased transaminases. Condition resolved
200211626JP	3109	79-102	Hepatocellular damage	31 Y	F	3 days after last dose, ALT 605, AST 182, Alk Phos 351,T. bili 1.2. Patient recovered. Concomitant Hepatitis B infection.
200411769JP	5012	0168-00	Hepatitis acute	68 Y	M	Subject was jaundiced when TEL started for pneumonia. Hepatic enzymes worsened for a week after TEL, then improved. AP 2060 (predominantly ALP2-hepatic parenchymal disorder), ALT 234 U/L, AST 170 U/L. Subsequently he was found to have a mass of the duodenal papilla. Viral titers negative.

Case ID	Study ID	Subject ID	MedDRA PT	Age	Sex	Comment
Phase IV						
200410845EU	4014	3	Bronchitis acute, pneumonia, agitation, atrial fibrillation, endocarditis, facial paresis, liver function test abnormal, dyspnea, cyanosis	71 Y	F	Few details. LFTs reported abnormal 10 days after last dose of study medication. No laboratory values provided. Reported as possible meropenam induced liver impaired liver function. Patient recovered

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CORPORATE DRUG SAFETY

Site Id : GDDC

Case Line Listing

Query Text :

WHERE (VW_CASE.CASE_ID IN SELECT DISTINCT A.USA FROM NANNEY_GDDC.US A WHERE (A.USA IS NOT NULL))

Printed by: CTQUERY_GDDC

Sorted according to - Drug
- Source (Division)
- Case Id

Legend :

- Patient Died
DT - Diagnosis Type
R/C - R = Reporter C = Company
UNL - Unlabeled
LOC UNL - Local Unlabeled

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200416859US Health Professional	09-SEP-2004	US	F	UNKNOWN				RC	ELEVATED LIVER FUNCTION TESTS	UNK	Y	N		COND
200417186US Health Professional	21-SEP-2004 16-NOV-2004	US	M	800 MG PO TBLS	13-SEP-2004 17-SEP-2004		17-SEP-2004	RC	CHOLESTATIC JAUNDICE - increased bilirubin 10 - AST = 343 - ALT = 597 - ALK Phos = 439	RECOVERED	Y	N	POSS	COND
200417230US Health Professional	22-SEP-2004 29-DEC-2004	US	33Y F	2 TABLETS PO	01-AUG-2004 10-AUG-2004			RC RC	EMOTIONAL TRAUMA GALL BLADDER NOT FUNCTIONING AT FULL SPEED	ONGOING RECOVERED	Y Y	Y Y		COND COND
						10 DAY(S)	16-AUG-2004	RC	HEPATIC DYSFUNCTION - fever 104'F - really tired - right upper quadrant pain - ALT = 1000 - AST = 550 - liver inflammation - jaundice - dark urine - itching - nausea - pruritis - abdominal pain	RECOVERED	Y	N	POSS	COND

CORPORATE DRUG SAFETY

Case Line Listing

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Case Division : **Spontaneous**

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Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200417856US Health Professional	14-OCT-2004 16-NOV-2004	US	53Y F	800 MG PO TBLS 400 MG PO TBLS	30-AUG-2004 08-SEP-2004 09-SEP-2004 28-SEP-2004	30 DAY(S)	28-SEP-2004	RC	ALLERGIC REACTION - nausea - abdominal pain - fever - dizziness - jaundice - elevated liver function tests - electrolyte imbalance	ONGOING	Y	N	POSS	COND
200418119US Health Professional	21-OCT-2004 03-FEB-2005	US	52Y F	800 MG PO TBLS	15-SEP-2004 16-SEP-2004		29-SEP-2004	RC	INCREASED LIVER ENZYMES - fatigue - nausea - fever - AST = 150 - ALT = 189 - Alk Phos = 203	RECOVERED	Y	N	POSS	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200419782US	23-DEC-2004	US		UNK			16-DEC-2004	RC	ACUTE RENAL FAILURE	RECOVERED	Y	Y		COND
Health Professional	09-FEB-2005		F				23-DEC-2004							
									- bloated - weight gain - elevated creatinine level					
							16-DEC-2004 23-DEC-2004	RC	SUSPECTED BACTEREMIC SEPSIS	RECOVERED	Y	Y		COND
									- fever - rash - ecoli in blood - ecoli in urine - hypotension					
							16-DEC-2004 23-DEC-2004	RC	ACUTE INTERSTITIAL NEPHRITIS	RECOVERED	Y	Y		COND
							16-DEC-2004	RC	SUSPECTED ACUTE GALLSTONES	RECOVERED	N	Y		COND
									- increased alkaline phosphatase					
							16-DEC-2004	RC	MULTIPLE ORGAN FAILURE	RECOVERED	Y	Y		COND
									- abnormal liver enzymes - fatigue - mild jaundice - pruritis - right upper quadrant pain - dark urine - increased bilirubin					
							16-DEC-2004	RC	CONFUSED WITH SLOW MENTAL PROCESS	RECOVERED	N	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200511098US	11-FEB-2005	US	27Y	800 MG	27-JAN-2005	10 DAY(S)	05-FEB-2005	RC	ELEVATED LIVER FUNCTION TESTS	ONGOING	Y	N	PROB	COND
Health Professional	03-JUN-2005		M	PO TBLS	31-JAN-2005	6 DAY(S)								
									- malaise - dark urine - jaundice - elevated bilirubin (8.7) - elevated AST (227) - elevated ALT (272) - elevated alk phos (413) - elevated direct bilirubin (7.4)					

CORPORATE DRUG SAFETY

Case Line Listing

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Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200512913US	07-APR-2005	US	47Y	800 MG	11-FEB-2005	1 DAY(S)	11-FEB-2005	RC	LIVER DAMAGE	RECOVERED	Y	N	POSS	UNREL
Health Professional	24-OCT-2006		M	PO TBLS	14-FEB-2005				- fatty liver					
						6 DAY(S)	16-FEB-2005	RC	ALLERGIC REACTION	RECOVERED	Y	N	POSS	PROB
						4 DAY(S)								
									- transient rash					
									- nausea					
									- itching					
						1 DAY(S)	11-FEB-2005	RC	DRUG INDUCED HEPATITIS	SEQUELAE	Y	N	POSS	POSS
									- malaise					
									- bilirubin in urine					
									- jaundice					
									- fatigue					
									- increased ALT (748-948 U/L)					
									- increased AST (200 U/L)					
									- increased alkaline phosphatase (291 U/L)					
									- hyperbilirubinemia (3.8-4.5)					
									- direct bilirubin increased (2.37)					
									- sleepy					
									- urine turned red					
									- flu like symptoms					
									- pruritis					
									- anorexia					
									- myalgias					
									- joint discomfort					
									- night sweats					
									- ggt increased (147)					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200512913US	07-APR-2005	US	47Y			23 DAY(S)	05-MAR-2005	RC	SUBSEGMENTAL ATELECTASIS RIGHT LUNG BASE	UNK	N	Y		COND
Health Professional	24-OCT-2006		M			21 DAY(S)								
						23 DAY(S)	05-MAR-2005	RC	CYST IN RIGHT KIDNEY	UNK	N	Y		COND
						21 DAY(S)								
						215 DAY(S)	13-SEP-2005	RC	WEIGHT GAIN	UNK	N	Y		COND
						213 DAY(S)								
						2 MTH(S)	??-APR-2005	RC	RECURRENT SINUS INFECTION	UNK	N	Y		COND
						2 MTH(S)								
							24-MAR-2005	RC	FERRITIN INCREASED (359)	UNK	N	Y		COND
											DARVOCET			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

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Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200513250US Health Professional	15-APR-2005 06-AUG-2006	US	51Y F	800 MG PO TBLS	29-MAR-2005 03-APR-2005		31-MAR-2005	RC	ESLD OF UNDETERMINED ORIGIN - jaundice - malaise - bloating - anorexia - total bilirubin increased (9.5-28.9mg/dl) - eyes had yellow tinge, icteric - platelet decreased - chest pain - feel bad - hypoalbuminemia (2.2-3.4) - dry skin - skin itched - cognitive difficulty - spelling impaired - difficulty concentrating - dizzy - swollen legs, ankles, feet, and abdomen - handwritting sloppy - direct bilirubin increased - nauseated - epigastric pain - ALT increased (68-766) - AST increased (42-1143) - alpha fetoprotein increased (4) - PT increased (11.8-34.8) - increased eosinophils 5.3%	SEQUELAE	Y	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200513250US	15-APR-2005	US	51Y				31-MAR-2005	RC	ESLD OF UNDETERMINED ORIGIN	SEQUELAE	Y	N		COND
Health Professional	06-AUG-2006		F						- fatigue					
									- sick in stomach/diarrhea					
									- edema					
									- increase IgG level (37.6)					
									- decreased ceruloplasmin 17					
									- weight gain					
									- decreased urination					
									- increased alkaline phosphatase (121-274)					
									- urine discoloration					
									- abdominal pain					
									- indigestion					
								RC	SLIGHT ANEMIA	ONGOING	N	N	POSS	COND
									- hematocrit low (30.6-38.7)					
									- hemoglobin low (8.5-13.2)					
									- increased ferritin 2667					
								RC	SMOOTH MUSCLE ANTIBODY POSITIVE 32	UNK	Y	Y		COND
							25-MAY-2005	RC	HYPONATREMIA	RECOVERED	Y	Y	POSS	COND
								RC	TINGLING IN FEET	UNK	N	N		COND
								RC	HEADACHE	UNK	N	N		COND
								RC	SENSITIVE TEETH	UNK	N	Y		COND
								RC	POST-TRANSPLANT DIABETES	UNK	Y	Y		COND
									- blood glucose increased (120-350)					
								RC	POST-TRANSPLANT HYPERTENSION	RECOVERED	N	Y		COND
								RC	CHRONIC KIDNEY	UNK	N	Y	UNREL	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
200513250US	15-APR-2005	US	51Y					RC	CHRONIC KIDNEY DISEASE, 50% FUNCTION	UNK	N	Y	UNREL	COND
Health Professional	06-AUG-2006		F						- BUN decreased (5-7)					
									- creatinine (1.6-7.2)					
							21-APR-2005	RC	CIRRHOSIS	UNK	Y	Y		COND
									- varices					
									- dyspnea					
									- ascites					
									- splenomegaly					
									- pleural effusion					
								RC	HYPOKALEMIA (3.0-3.5)	RECOVERED	N	Y		COND
								RC	CHLORIDE DECREASED (83-100)	UNK	N	Y		COND
							21-APR-2006	RC	BLOOD GLUCOSE 58	RECOVERED	N	Y		COND
							22-APR-2006							
								RC	HYPOCALCEMIA (8.1-8.8)	UNK	N	Y		COND
							09-JUN-2005	RC	TRANSPLANT REJECTION	RECOVERED	Y	Y		COND
								RC	ANXIETY	UNK	N	Y		COND
								RC	INSOMNIA	UNK	N	N		COND
								RC	COUGHING	UNK	N	Y		COND
								RC	SHRIVELED	UNK	N	Y		COND
								RC	FLU LIKE FEELING	UNK	N	Y		COND
									- fever					
									- cold sweat					
								RC	ABDOMEN NUMB	UNK	N	N		COND
								RC	AURA IN VISION	UNK	N	N		COND
								RC	HEAD FELT FULL OF WATER	UNK	N	Y		COND
								RC	CALCINEURIN INHIBITOR NEPHROTOXICITY	UNK	Y	Y	UNREL	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200513250US	15-APR-2005	US	51Y					RC	BLOOD IN STOOL	UNK	N	Y		COND
Health Professional	06-AUG-2006		F					RC	VOMITING	UNK	N	N		COND
								RC	PAINFUL URINATION	UNK	N	Y		COND
								RC	BLOOD IN URINE	UNK	N	Y		COND
							??-MAY-2005	RC	HEPATORENAL PHYSIOLOGY VOLUME OVERLOAD - pleural effusions	UNK	Y	Y		COND
							??-MAY-2005	RC	MALNUTRITION	UNK	N	Y		COND
								RC	NOCTURIA	UNK	N	Y		COND
								RC	FREQUENT URINATION	UNK	N	Y		COND
								RC	HYPOALBUMINEMIA	UNK	N	Y		COND
											CALCINEURIN INHIBITOR			
200513490US	25-APR-2005	US	58Y	UNK			24-APR-2005	RC	ACUTE HEPATIC ISCHEMIC HEMORRHAGE - liver edematous and inflamed - jaundice - elevated bilirubin - coagulopathy - right upper quadrant pain - extensive hepatic hemorrhage	ONGOING	Y	Y	PROB	COND
Health Professional			M					RC	MULTIPLE ORGAN FAILURE - renal failure	ONGOING	Y	Y		COND
								RC	SEPTIC SHOCK - hypotensive - worsened dyspnea	UNK	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200513491US	25-APR-2005	US	26Y	800 MG		10 DAY(S)		RC	FULMINANT GLOBAL HEPATIC NECROSIS C/W TOXIC HEPATITIS FATAL	DIED	Y	Y	POSS	COND
Health Professional	01-MAY-2006		M	PO TBLS					- increased bilirubin 20					
									- elevated liver enzymes					
									- jaundice					
									- hepatomegaly					
									- increased ALT					
									- increased AST					
									- elevated bilirubin					
									- PTT increased					
									- partial thromboplastin time increased					
									- INR increased					
									- ascites					
						10 DAY(S)		RC	MULTISYSTEM ORGAN FAILURE	DIED	Y	Y	POSS	COND
									- renal failure					
									- liver failure					
									- extensive abdominal extension					
							03-FEB-2005	RC	FEVER	DIED	Y	Y	POSS	COND
								RC	MELENA	DIED	Y	Y	POSS	COND
							03-FEB-2005	RC	HEMATEMESIS	DIED	Y	Y	POSS	COND
								RC	ILL	DIED	Y	Y	POSS	COND
								RC	DIAPHOERTIC	DIED	Y	Y	POSS	COND
								RC	TACHYCARDIA	DIED	Y	Y	POSS	COND
								RC	TACHYPNEA	DIED	Y	Y	POSS	COND
								RC	FIRM BDOMEN	DIED	Y	Y	POSS	COND
								RC	ABDOMEN TYMPANIC	DIED	Y	Y	POSS	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200513491US	25-APR-2005	US	26Y					RC	TENDERNESS TO PALPATION IN MID-EPIGASTRIC REGION/RUQ	DIED	Y	Y	POSS	COND
Health Professional	01-MAY-2006		M					RC	BOWEL-WALL THICKENING	DIED	Y	Y	POSS	COND
								RC	GASTRITIS	DIED	Y	Y	POSS	COND
								RC	HYPOTENSIVE	DIED	Y	N	POSS	COND
								RC	CARDIOPULMONARY FAILURE	DIED	Y	Y	POSS	COND
								RC	METABOLIC ACIDOSIS	DIED	Y	Y	POSS	COND
								RC	ASYSTOLIC	DIED	Y	Y	POSS	COND
							FULMINANT GLOBAL HEPATIC NECROSIS C/W TOXIC HEPATITIS FATAL MULTISYSTEM ORGAN FAILURE							

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200514291US	17-MAY-2005	US	57Y	UNK	20-APR-2005		23-APR-2005	RC	LIVER FAILURE	UNK	Y	Y		COND
Health Professional			M						- jaundice					
									- bleeding					
									- pt prolonged					
									- INR increased					
									- elevated transaminases					
							23-APR-2005	RC	SYSTEMIC INFLAMMATORY RESPONSE SYNDROME	UNK	Y	Y		COND
							23-APR-2005	RC	MULTIPLE ORGAN FAILURE	UNK	Y	Y		COND
							17-MAY-2005	RC	ELECTROLYTE ABNORMALITY	UNK	Y	Y		COND
									- hyperkalemia					
									- chloride decreased					
									- BUN increased					
									- hyponatremia					
							23-APR-2005	RC	REACTION NOS	UNK	Y	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200516569US	12-SEP-2005	US	56Y	800 MG	16-AUG-2005		??-???-2005	RC	HEPATITIS (INCREASED AST AND ALT) - epigastric pain - right upper quadrant tenderness with radiation to the back - cramping - bloating - nausea - chills - malaise - burping - low grade fever - poor appetite - odors bothered her	ONGOING	Y	N	PROB	COND
Health Professional	28-OCT-2005		F	PO TBLS	??-AUG-2005									

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200516593US	15-SEP-2005	US	81Y	400 MG	04-SEP-2004		25-OCT-2004	RC	CHOLESTASIS	UNK	Y	N		COND
Health Professional	18-APR-2006		F	PO TBLS 800 MG	04-NOV-2004		03-DEC-2004	RC	URINARY TRACT INFECTION	UNK	N	Y		COND
				PO TBLS	11-NOV-2004		25-OCT-2004	RC	DRUG INDUCED HEPATITIS	UNK	Y	N		COND
									- jaundice					
									- fatigue					
									- abdominal pain					
									- right upper quadrant pain					
									- dark urine					
									- right flank pain					
									- light colored stools					
									- hemoccult positive stool					
									- AST increased (60-466)					
									- ALT increased (81-575)					
									- ALK PHOS increased (372-605)					
									- LDH increased (477)					
									- poor appetite					
									- GGT increased (183-531)					
									- dbil increased (1.8-2.8)					
									- tbili increased (1.3-7)					
200517752US	17-OCT-2005	US		800 MG				RC	LIVER FAILURE	UNK	Y	Y		COND
Health Professional			U	PO TBLS										
200518509US	21-OCT-2005	US	73Y	800 MG	29-SEP-2005		12-OCT-2005	RC	LIVER FAILURE	RECOVERED	Y	Y	POSS	COND
Health Professional	23-MAR-2006		F	PO TBLS	12-OCT-2005				- jaundiced					
								RC	PRURITIS	RECOVERED	N	N		COND
								RC	FATIGUE	RECOVERED	N	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
200519100US Other	02-NOV-2005	US	32Y M	UNK PO TBLS				RC	ELEVATED LIVER ENZYMES	ONGOING	Y	N		COND
200520201US Consumer	07-DEC-2005 20-JAN-2006	US	U	UNKNOWN PO TBLS				RC	LIVER FAILURE	UNK	Y	Y	PROB	COND
200520456US Health Professional	18-OCT-2005 06-JUN-2006	US	45Y F	800 MG PO TBLS	14-OCT-2005 16-OCT-2005	3 DAY(S)	??-OCT-2005	RC	INCREASED LFT'S - ast increased (>5000) - alt increased (>5000) - bilirubin increased (4.4)	ONGOING	Y	N		COND
						3 DAY(S)	??-OCT-2005	RC	DECREASED LEVEL OF CONSCIOUSNESS	RECOVERED	N	N		COND
						0 MTH(S)	??-OCT-2005	RC	INR INCREASED (1.4)	UNK	N	N		COND
						3 DAY(S)	??-OCT-2005	RC	CREATININE INCREASED (2.4)	UNK	N	Y		COND
200520723US Health Professional	21-DEC-2005	US	M	UNKNOWN				RC	HEPATITIS	UNK	Y	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
200610032US	02-JAN-2006	US		UNKNOWN	??-NOV-2005		19-DEC-2005	RC	HEPATITIS	UNK	Y	N		COND
Health Professional	26-JAN-2006		F	PO TBLS					- increased ALT - increased AST - increased INR - increased total bilirubin - increased alk phos - right upper quadrant tenderness - asthenia - fever - jaundice					
								RC	EPSTEIN-BARR TITER POSITIVE	ONGOING	Y	Y		COND
200610411US	10-JAN-2006	US	77Y	800 MG	26-DEC-2005			RC	HEPATITIS	RECOVERED	Y	N	PROB	COND
Health Professional	28-JUN-2006		F	PO	30-DEC-2005				- ast (816) - alt (806) - alkaline phosphatase (304) - nausea - anorexia - right upper quadrant pain					
								RC	FATIGUE	RECOVERED	Y	N	PROB	COND
								RC	WEAKNESS	RECOVERED	Y	N	PROB	COND
								RC	DIARRHEA	RECOVERED	Y	N	PROB	COND
200610825US	23-JAN-2006	US	60Y	UNKNOWN				RC	CHOLESTATIC JAUNDICE	ONGOING	Y	N		COND
Health Professional	28-APR-2006		M	PO TBLS										

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200610841US	24-JAN-2006	US	41Y	800 MG	01-MAY-2006		07-JUN-2005	RC	HEPATITIS	ONGOING	Y	N	POSS	COND
Other	06-JUN-2006		F	PO TBLS					- fever 103-104 DEGREES F					
									- fatigue					
									- nausea					
									- vomiting					
									- weakness					
									- abdominal pain					
									- mild anemia					
									- enlarged liver					
									- AST (340-608)					
									- ALT (706-1078)					
									- bilirubin 1.3					
									- PT (13.3-14)					
									- elevated ESR 67					
									- body aches and pain					
							17-JUN-2005		BASILAR ATELECTASIS	UNK	Y	Y	POSS	COND
									- wheezing					
									- small right pleural effusion					
							14-JUN-2005	RC	THICKENED GALLBLADDER	UNK	N	Y		COND
									- gallbladder removed					
								RC	FIBROMYALGIA	ONGOING	Y	Y	POSS	COND
									- myalgia					
							??-JUN-2005	RC	ACUTE LIVER FAILURE	UNK	Y	Y		COND
									- flu like symptoms					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200610952US Health Professional	27-JAN-2006 12-OCT-2006	US	53Y F	800 MG	18-JAN-2006 22-JAN-2006	7 DAY(S) 3 DAY(S)	24-JAN-2006	RC	DRUG-RELATED ACUTE HEPATITIS - drug induced jaundice - nausea - malaise - elevated SGOT 2821 - elevated SGPT 1244 - insomnia due to nausea - increased total bilirubin (13.2) - increased direct bilirubin (7.2) - elevated INR - coagulopathy - dark urine	ONGOING	Y	N	POSS	COND
200611175US Health Professional	01-FEB-2006	US	F	UNKNOWN				RC	HEPATITIS - vomiting - diarrhea - jaundice	UNK	Y	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200611224US	30-JAN-2006	US	58Y	2 TABLETS	26-JAN-2006	1 DAY(S)	27-JAN-2006	RC	ELEVATED LIVER FUNCTION TESTS - elevated bilirubin - alkaline phosphatase increased - SGOT increased - SGPT increased	RECOVERED	Y	N	POSS	COND
Health Professional	19-APR-2006		F		26-JAN-2006									
							27-JAN-2006	RC	FEELS PUNY	UNK	N	Y	POSS	COND
						2 DAY(S)	27-JAN-2006	RC	JAUNDICE	UNK	N	N	POSS	COND
						2 DAY(S)	27-JAN-2006	RC	CHLORIDE INCREASED	RECOVERED	N	Y	POSS	COND
						2 DAY(S)	27-JAN-2006	RC	HIGH DENSITY LIPOPROTEIN INCREASED	UNK	N	Y	POSS	COND
						2 DAY(S)	27-JAN-2006	RC	CO2 OUT OF RANGE	ONGOING	N	Y	POSS	COND
						2 DAY(S)	29-JAN-2006	RC	CALCIUM DECREASED	RECOVERED	N	Y	POSS	COND
						4 DAY(S)	29-JAN-2006	RC	GLUCOSE INCREASED	RECOVERED	N	Y	POSS	COND
						4 DAY(S)	03-MAR-2006	RC	RED BLOOD CELLS OUT OF RANGE	UNK	N	Y	POSS	COND
						37 DAY(S)	03-MAR-2006	RC	HEMOGLOBIN INCREASED	UNK	N	Y	POSS	COND
						37 DAY(S)	03-MAR-2006	RC	HEMATOCRIT INCREASED	UNK	N	Y	POSS	COND
200611232US	03-FEB-2006	US		UNKNOWN				RC	VOMIT	RECOVERED	Y	N		COND
Health Professional			F					RC	COULD NOT BREATHE	RECOVERED	Y	Y		COND
								RC	LIVER SHOCK	RECOVERED	Y	Y		COND
								RC	UNABLE TO URINATE	RECOVERED	Y	Y		COND
											ATORVASTATIN CALCIUM NIFEDIPINE			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200611277US	03-FEB-2006	US	41Y	800 MG	31-JAN-2006	2 DAY(S)	01-FEB-2006	RC	SEVERE HEPATITIS	RECOVERED	Y	N		COND
Health Professional			F	PO TBLS	01-FEB-2006				- jaundice					
200611390US	08-FEB-2006	US	46Y	UNK	26-DEC-2005	2 MTH(S)	??-FEB-2006	RC	CHOLESTATIC JAUNDICE	UNK	Y	N		COND
Health Professional			U	PO TBLS	30-DEC-2005									
200611392US	06-FEB-2006	US	26Y	800 MG	03-FEB-2006		04-FEB-2006	RC	LIVER FAILURE	RECOVERED	Y	N	UNLIK	COND
Health Professional	13-OCT-2006		F	PO TBLS	03-FEB-2006				- ast level (3,000 which got to 24,000 at admission)					
									- hepatic encephalopathy					
									- coagulopathy					
									- edema					
								RC	BRAIN EDEMA	RECOVERED	Y	Y		COND
								RC	LEUCOCYTOSIS	RECOVERED	Y	Y		COND
								RC	SIGNS OF DIC	RECOVERED	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200611473US	13-FEB-2006	US	69Y	UNKNO	04-DEC-2005	60 DAY(S)	01-FEB-2006	RC	FATAL PERFORATED	DIED	Y	Y		COND
Health Professional	27-JUL-2006		F	WN	07-DEC-2005	57 DAY(S)			DUODENAL ULCER					
						2 MTH(S)	??-FEB-2006	RC	FATAL ACUTE RENAL	DIED	Y	Y		COND
						2 MTH(S)			FAILURE					
						2 MTH(S)	??-FEB-2006	RC	ACUTE RESPIRATORY	DIED	Y	Y		COND
						2 MTH(S)			DISTRESS SYNDROME FATAL					
						2 MTH(S)	??-FEB-2006	RC	FATAL CARDIAC	DIED	Y	Y		COND
						2 MTH(S)			FAILURE					
						41 DAY(S)	13-JAN-2006	RC	CIRRHOSIS	DIED	Y	Y		COND
						38 DAY(S)								
									- increased INR (1.9-9.6)					
									- abdominal pain					
									- jaundice					
									- fluid retention in lower extremities					
									- ALT increased (485-690)					
									- AST increased (286-552)					
									- albumin decreased (1.6)					
									- bilirubin increased(13.8-20.5)					
						2 MTH(S)	??-FEB-2006	RC	BLEEDING	DIED	Y	Y		COND
						2 MTH(S)								
							13-JAN-2006	C	HEPATITIS	DIED	Y	N		COND
							01-FEB-2006	C	HEPATIC FAILURE	DIED	Y	N		COND
									- fulminant acute hepatic insufficiency					
					11-FEB-2006		***ACUTE RENAL FAILURE***							
							ACUTE RESPIRATORY DISTRESS SYNDROME							
							CARDIO FAILURE							
							CIRRHOSIS							

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200611652US	17-FEB-2006	US	59Y	800 MG	12-JAN-2006		05-FEB-2006	RC	CHEMICALLY INDUCED HEPATITIS DUE TO KETEK - elevated liver enzymes (100 time and 20 times the normal) - increased bilirubin - increased AST (239) - increased ALT (739) - dark urine - decreased INR - fever - decreased hemoglobin - increased eosinophils (11%) - rash - nausea - weak - decreased appetite	ONGOING	Y	N		COND
Health Professional	07-JUL-2006		F	PO TBLS	01-FEB-2006									
								RC	INFECTIOUS COLITIS WITH POSSIBLE DIVERTICULOSIS EXACER - diarrhea - abdominal pain	ONGOING	N	Y		COND
							08-FEB-2006	RC	SODIUM DECREASED 134	UNK	N	Y		COND
							08-FEB-2006	RC	CALCIUM DECREASED (8-8.3)	UNK	N	Y		COND
							08-FEB-2006	RC	ALBUMIN DECREASED (2.5-3.3)	UNK	N	Y		COND
							16-FEB-2006	RC	DECREASED RBC COUNT	UNK	N	Y		COND
							16-FEB-2006	RC	DECREASED HEMOGLOBIN	UNK	N	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment: Reporter	Assessment: Company
200611652US	17-FEB-2006	US	59Y				16-FEB-2006	RC	DECREASED HEMOGLOBIN	UNK	N	Y		COND
Health Professional	07-JUL-2006		F											
							16-FEB-2006	RC	DECREASED HEMATOCRIT	UNK	N	Y		COND
							03-FEB-2006	RC	PASSED OUT	UNK	Y	N		COND
							03-FEB-2006	RC	DIZZINESS	UNK	Y	N		COND
								RC	FELT ITCHY IN GROIN AND NECK	ONGOING	N	N		COND
							15-FEB-2006	RC	MINIMAL BIBASILAR ATELECTASIS	UNK	Y	Y		COND
								RC	DIFFUSE LOW-DENSITY LIVER PARENCHYMA (CHRONIC DISEASE)	UNK	Y	Y		COND
								RC	KIDNEY FLUID ATTENUATION LESION CONSISTENT W/ A SIMPLE CYST	UNK	Y	Y		COND
								RC	3 MM LOW ATTENUATION WITHIN SUPERIOR POLE OF LEFT KIDNEY	UNK	Y	Y		COND
								RC	5 MM LOW ATTENUATION LESION WITHIN RIGHT LOBE OF LIVER	UNK	Y	Y		COND
								RC	ENLARGED LIVER	UNK	Y	Y		COND
											MONTELUKAST SODIUM			
200611864US	23-FEB-2006	US		UNK				RC	INCREASED LIVER ENZYMES	UNK	Y	N		COND
Health Professional			F											

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200612213US	08-MAR-2006	US	85Y	800 MG	24-FEB-2006	7 DAY(S)	04-MAR-2006	RC	FATAL LIVER FAILURE	DIED	Y	Y	H.PROB	COND
Health Professional	25-MAY-2006		F	PO TBLS	02-MAR-2006				- increased AST (5470 and 2731) - increased ALT (4351 and 3448) - increased bilirubin (1.2 and 1.7)					
						7 DAY(S)	02-MAR-2006	RC	EXTREME WEAKNESS	DIED	Y	Y	H.PROB	COND
						7 DAY(S)	04-MAR-2006	RC	FATAL RENAL FAILURE - increased creatinine (5.2 and 6.3) - increased BUN (51 and 65) - decreased urination	DIED	Y	Y	H.PROB	COND
						7 DAY(S)	02-MAR-2006	RC	SYNCOPE	DIED	Y	N	H.PROB	COND
						7 DAY(S)	02-MAR-2006	RC	PNEUMONIA (RIGHT LOWER LOBE INFILTRATES) (Lack of drug effect)	DIED	Y	N		COND
200612286US	10-MAR-2006	US	37Y	400 MG	24-DEC-2005		??-FEB-2006	RC	ALT ELEVATED (125-152)	ONGOING	Y	N		COND
Consumer			F	PO TBLS	??-FEB-2006		??-FEB-2006	RC	AST INCREASED (42-56)	ONGOING	N	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200612419US	13-MAR-2006	US	50Y	UNK			18-JAN-2006	RC	DRUG INDUCED HEPATITIS - hepatomegaly - ascites - sgot increased 394 - sgpt increased 560 - alkaline phosphatase 280 - bilirubin 2.2 - albumin low 3.3 - elevated blood glucose 168 - right upper quadrant pain - nausea - vomiting - weakness - dizziness/lightheadedness - fever 101, 102 source not determined - tachycardia - extrimities edema - hemoglobin increased 16.4 - hematocrit increased 51.2	RECOVERED	Y	N	PROB	COND
Health Professional	25-APR-2006		F					RC	BRONCHITIS (Lack of drug effect)	UNK	Y	N		COND
							18-JAN-2006	RC	PLEURAL EFFUSION WITH PATCHY INFILTRATES	UNK	Y	Y		COND
							18-JAN-2006	RC	POSSIBLE GASTRITIS	ONGOING	N	Y		COND
							18-JAN-2006	RC	ITCHING	ONGOING	N	N		COND
							18-JAN-2006	RC	BUDD-CHIARI SYNDROME - hepatomegaly	ONGOING	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200612419US	13-MAR-2006	US	50Y				18-JAN-2006	RC	BUDD-CHIARI SYNDROME - asictes - sgot increased 394 - sgpt increased 560 - alkaline phosphatase 280 - bilirubin 2.2 - right upper quadrant pain - nausea - vomiting - weakness - dizziness/lightheadedness - fever 101, 102 source not determined - tachycardia - hemoglobin increased 16.4 - hematocrit increased 51.2 - right hepatic vein was not seen - extrimities edema	ONGOING	Y	Y		COND
Health Professional	25-APR-2006		F											

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200612457US	09-MAR-2006	US	37Y	UNK	02-FEB-2006			RC	EXTENSIVE HEPATOTOXICITY	UNK	Y	N	UNREL	COND
Health Professional	25-APR-2006		M					RC	LIVER FAILURE	UNK	Y	Y	UNREL	COND
								RC	DRUG INDUCED HEPATITIS	ONGOING	Y	N	POSS	COND
									- fatigue					
									- ALT increased					
									- AST increased					
									- increased right upper quadrant abdominal pain					
									- fever					
									- nausea					
									- increased bilirubin (direct: 2.3 indirect: 1.4)					
								RC	IRRITABLE BOWEL SYNDROME	ONGOING	Y	Y		COND
									- constipation					
								RC	ASCITES	RECOVERED	Y	Y		COND
							07-FEB-2006	RC	ABDOMINAL BLOATING	RECOVERED	Y	N		COND
								RC	GLUCOSE INCREASED 155	RECOVERED	N	Y		COND
								RC	PLEURAL EFFUSION	RECOVERED	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200612730US Health Professional	20-MAR-2006 14-AUG-2006	US	60Y F	800 MG PO	21-JAN-2006 25-JAN-2006		27-JAN-2006	C	HEPATOCELLULAR DAMAGE - AST increased (8xuln) - ALT increased (8xuln) - alkaline phosphatase increased (505) - bilirubin increased (9.8) - acute jaundice - nausea - fatigue - dark urine - abdominal pain	RECOVERED	Y	N	POSS	COND
											NITROFURANTOIN			
200612961US Health Professional	27-MAR-2006	US	71Y F	800 MG PO TBLS	17-FEB-2006 08-MAR-2006		10-MAR-2006	RC	LIVER DISEASE - not feeling well - wbc 29000 - bilirubin 20-25 - lft's increased in the 800 range - jaundice	ONGOING	Y	N	PROB	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200612991US	24-MAR-2006	US	71Y	800 MG	17-FEB-2006		??-FEB-2006	RC	LIVER TRANSAMINASES INCREASED	RECOVERED	Y	N	PROB	COND
Health Professional	18-JUL-2006		F	PO TBLS	05-MAR-2006		??-JUL-2006		- ast increased (1126-1700) - alt increased (1615-1748)					
							??-FEB-2006	RC	BILIRUBIN INCREASED (13.4-29)	RECOVERED	Y	N	PROB	COND
							??-JUL-2006		- jaundice					
							28-MAR-2006	RC	CLOSTRIDIUM DIFFICILE ENTEROCOLITIS	RECOVERED	Y	N	PROB	COND
							??-JUN-2006		- increased WBC (19000-29,800) - diarrhea					
							28-MAR-2006	RC	EOSINOPHIL INCREASED	ONGOING	Y	N	POSS	COND
							??-MAR-2006	RC	FEVER	UNK	N	Y		COND
							??-???-2006	RC	RASH ON LEGS	UNK	N	N		COND
							??-???-2006	RC	SWOLLEN LEGS	UNK	N	Y		COND
							??-FEB-2006	RC	FELT SICK	UNK	N	Y		COND
							28-MAR-2006	RC	PNEUMONIA MRSA	ONGOING	Y	Y		COND
									- increased WBC (19000-29,800) - could not breathe - chest congestion					
							??-MAR-2006	RC	RUN DOWN	UNK	N	N		COND
							10-MAR-2006	RC	INR INCREASED (1.5)	UNK	N	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200613058US Health Professional	30-MAR-2006	US	90Y F	UNKNO WN PO TBLS	09-MAR-2006 10-MAR-2006	5 DAY(S)	13-MAR-2006	C	HEPATIC INJURY - ast increased (520) - alt increased (839) - bilirubin increased (3.2) - alkaline phosphatase increased (205) - not feeling well	ONGOING	Y	N		COND
200613235US Health Professional	05-APR-2006	US	63Y F	UNKNO WN	??-???-2006 ??-???-2006		??-MAR-2006	RC	ATRIAL FIBRILLATION	RECOVERED	Y	Y		COND
								RC	ELEVATED LFT'S - ast increased (285)	RECOVERED	Y	N		COND
								RC	ABDOMINAL PAIN	ONGOING	N	N		COND
							04-APR-2006	RC	PAPILLARY NECROSIS - flank pain - hematuria - bleeding from the right kidney	ONGOING	Y	Y		COND
200614373US Health Professional	15-MAY-2006 22-MAY-2006	US	36Y F	UNK PO TBLS	27-MAR-2006	20 DAY(S)	14-APR-2006 05-MAY-2006	RC	DRUG INDUCED HEPATITIS - AST 245 - ALT 378 - fever - diarrhea	RECOVERED	Y	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200615076US	09-JUN-2006	US	80Y	800 MG	28-MAY-2006		30-MAY-2006	RC	PERSISTANT BRONCHITIS	DIED	Y	Y	POSS	COND
Health Professional	06-SEP-2006		M	PO TBLS	30-MAY-2006				(Lack of drug effect) - fever - sweats - chills - cough					
							30-MAY-2006	RC	PROGRESSIVE HEPATIC FAILURE - alt 88-1200 - toxic hepatitis secondary to the Ketek exposure - ast 55-800 - pt 17.6 - alkaline phosphatase 550 - bilirubin 5.4	DIED	Y	N	POSS	COND
							??-JUN-2006	RC	ACUTE RENAL FAILURE - increased creatinine - azotemia - acidosis	DIED	Y	Y		COND
							??-JUN-2006	RC	RESPIRATORY FAILURE - ards - respiratory distress - decreased O2 saturation	DIED	Y	Y	POSS	COND
							05-JUN-2006	RC	ASYSTOLE WITH CARDIAC ARREST	DIED	Y	Y		COND
								RC	SEPSIS	DIED	Y	Y		COND
							??-???-2006	RC	ACUTE MYOCARDIAL INJURY - spike in troponin - diffuse global hypokinesis on echocardiogram	DIED	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
#200615076US	09-JUN-2006	US	80Y				??-???-2006	RC	ACUTE MYOCARDIAL INJURY - tachycardic - hypotensive	DIED	Y	Y		COND
Health Professional	06-SEP-2006		M											
							??-???-2006	RC	THROMBOCYTOPENIA	UNK	Y	Y		COND
							??-???-2006	RC	VENTRICULAR TACHYCARDIA	UNK	Y	Y		COND
							??-???-2006	RC	SUPRAVENTRICULAR TACHYCARDIA	UNK	Y	Y		COND
								RC	ACUTE THROMBUS IN RIGHT ATRIUM - elevated D-dimer	UNK	Y	Y		COND
					05-JUN-2006		*ASYSTOLE WITH CARDIAC ARREST*							
200615079US	08-JUN-2006	US	30Y	800 MG	10-MAY-2006		17-MAY-2006		ELEVATED LIVER ENZYMES - alkaline phosphatase increased (122) - alt increased (129) - ast increased (65) - nausea - vomiting	RECOVERED	Y	N		COND
Health Professional			M	PO TBLS	15-MAY-2006									
							17-MAY-2006	RC	SEVERE POLYARTHRALGIAS	RECOVERED	Y	Y		COND
							17-MAY-2006	RC	MYALGIA - couldn't walk	RECOVERED	Y	Y		COND
							17-MAY-2006	RC	MILDLY ANEMIC	UNK	N	Y		COND
							17-MAY-2006	RC	SYMPTOMS STILL PRESENT (Lack of drug effect)	RECOVERED	N	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
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Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200615085US	07-JUN-2006	US	31Y	800 MG	10-MAY-2006		04-JUN-2006	RC	ANGIOEDEMA	RECOVERED	Y	N		COND
Health Professional	12-OCT-2006		M	PO TBLS			08-JUN-2006							
									- rash					
							??-MAY-2006	RC	ACUTE FEBRILE ILLNESS	RECOVERED	Y	Y		COND
							??-MAY-2006	RC	ELEVATED LFT'S	ONGOING	Y	N		COND
									- direct bilirubin increased					
									- AST increased (500)					
									- ALT increased (700-900)					
									- total bilirubin increased (2-2.5)					
									- indirect bilirubin increased					
									- jaundice					
							??-MAY-2006	RC	ABDOMINAL PAIN	RECOVERED	N	N		COND
							01-JUN-2006	RC	RIGHT PLEURAL EFFUSION W/ MILD RIGHT BASILAR ATELECTASIS	UNK	N	Y		COND
							01-JUN-2006	RC	PELVIC FLUID	UNK	N	Y		COND
									- red blood cell decreased					
									- hemoglobin decreased					
									- iron decreased					
									- total ibc decreased					
									- hematocrit decreased					
							01-JUN-2006	RC	GALLBLADDER SLUDGE	UNK	N	Y		COND
							??-MAY-2006	RC	NAUSEA	RECOVERED	Y	N		COND
							??-MAY-2006	RC	VOMITING	RECOVERED	Y	N		COND
							01-JUN-2006	RC	MILD ANEMIA	UNK	N	Y		COND
							??-MAY-2006	RC	BRIEF PERIOD OF LEFT EYE BLINDNESS	RECOVERED	Y	Y		COND
							??-JUN-2006	RC	NONINFECTIOUS	UNK	Y	Y	POSS	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
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Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200615085US	07-JUN-2006	US	31Y				??-JUN-2006	RC	NONINFECTIOUS VASCULITIC SYNDROME - sed rate increased	UNK	Y	Y	POSS	COND
Health Professional	12-OCT-2006		M											
							??-JUN-2006	RC	SLIGHT COUGH	UNK	N	Y		COND
								RC	ACUTE INTRAHEPATIC CHOLESTASIS (PROBABLY DRUG RELATED) - fatty liver - possible liver injury due to Ketek	UNK	Y	N	POSS	COND
							01-JUN-2006	RC	EOSINOPHILIA	RECOVERED	N	N		COND
							01-JUN-2006	RC	POTASSIUM DECREASED	UNK	N	Y		COND
							02-JUN-2006	RC	ALBUMIN DECREASED	UNK	N	Y		COND
							05-JUN-2006	RC	RIGHT HAND RASH - red spots on palm of hand	RECOVERED	N	N		COND
							01-JUN-2006	RC	URTICARIA - flushing of face - pruritus	RECOVERED	N	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
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Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200615086US	06-JUN-2006	US	49Y	800 MG	02-FEB-2006			RC	FULMINANT LIVER FAILURE (FATAL) - increased alanine aminotransferase 1399, 2489, 1980,1328 - aspartate aminotransferase increased 3510, 9112, 3792,1225 - alkaline phosphatase increased 115, 131,139, 110 - total bilirubin increased 1.5, 3.1, 2.9, 2.9 - platelet count decreased 72,000 - thrombocytopenia - international normalized ratio increased 1.9 - creatinine increased - nausea - vomiting	DIED	Y	Y		COND
Reg. Authority	21-JUN-2006		F	PO TBLS	03-FEB-2006									
								RC	RESPIRATORY FAILURE (FATAL) (Lack of drug effect)	DIED	Y	Y		COND
								RC	DIC (FATAL) - partial thromboplastin time prolonged 55.8 - fibrinogen decreased 161	DIED	Y	Y		COND
							07-FEB-2006	RC	LEUKOPENIA - decreased white blood cell count	UNK	N	Y		COND
								RC	CPK INCREASED 10,934	UNK	N	Y		COND
								RC	ANTIMITOCHONDRIAL	DIED	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
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Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200615086US	06-JUN-2006	US	49Y					RC	MAGNESIUM INCREASED 2.2	UNK	N	Y		COND
Reg. Authority	21-JUN-2006		F					RC	ALBUMIN DECREASED 2.4	UNK	N	Y		COND
								RC	INCREASED BLOOD GLUCOSE 124	UNK	N	Y		COND
								RC	DIRECT COOMBS TEST POSITIVE	UNK	Y	Y		COND
								RC	LIVER CYST	UNK	N	Y		COND
								RC	NEUROLOGIC DETERIORATION	UNK	N	Y		COND
								RC	BRAIN NATRIURETIC PEPTIDE INCREASED (BNP) 118	UNK	Y	Y		COND
								RC	HEMOGLOBIN DECREASED 10.8	UNK	N	Y		COND
								RC	HEMATOCRIT DECREASED 31.5	UNK	N	Y		COND
								RC	DECREASED SODIUM	DIED	N	Y		COND
								RC	INCREASED TROPONIN-1		Y	Y		COND
											CEFTRIAXONE			
200615276US	14-JUN-2006	US		UNK				RC	LIVER TOXICITY	RECOVERED	Y	N	POSS	COND
Health Professional	30-AUG-2006		F						- abnormally high liver enzyme levels					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200615319US Health Professional	20-JUN-2006 19-JUL-2006	US	87Y F	UNK PO TBLS	??-JUN-2006	1 DAY(S)	13-JUN-2006	RC	DRUG INDUCED HEPATITIS - increased alt (401, 213, 154) - increased ast (745, 153, 71) - increased alkaline phosphatase (158, 130, 118) - nausea - vomiting - upper abdominal pain	RECOVERED	Y	N	POSS	COND
200615425US Health Professional	22-JUN-2006 10-JUL-2006	US	35Y F	UNK TBLS	05-JUN-2006 07-JUN-2006	3 DAY(S)	07-JUN-2006	RC	DRUG INDUCED HEPATITIS - elevated liver function tests (12 times upper limits) - abdominal pain	RECOVERED	Y	N		COND
								RC	PANCREATIC ENZYMES ABOVE NORMAL	ONGOING	N	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200615919US	14-JUL-2006	US	42Y	800 MG	14-JAN-2006		18-JAN-2006	RC	MILD TO MODERATE ACTIVE CHRONIC HEPATITIS WITH CHOLANGITIS	RECOVERED	Y	N	H.PROB	COND
Health Professional	08-AUG-2006		M	TBLS	19-JAN-2006									
							16-JAN-2006	RC	PIECEMEAL NECROSIS & FIBROSIS CONSISTENT W/ DRUG INDUCED INJ - jaundice - increased alkaline phosphatase - increased AST - increased ALT - increased bilirubin - flu like symptoms (fever, chills, back pain, tiredness) - increased ferritin level - nausea - dark urine - light clay to green colored stools - decreased stool - decreased intake - abdominal pain	ONGOING	Y	N		COND
								RC	URINARY URGENCY	UNK	N	Y		COND
								RC	ROUND OPACITY IN PARATRACHEAL REGION REPRESENTING TORTUOUS	UNK	N	Y		COND
								RC	RIGHT RENAL CYST	UNK	N	Y		COND
								RC	FATTY INFILTRATION LIVER	UNK	N	Y		COND
								RC	DECREASED INR	ONGOING	N	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	DT	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200615919US	14-JUL-2006	US	42Y					RC	INCREASED GLUCOSE	UNK	N	Y		COND
Health Professional	08-AUG-2006		M					RC	DECREASED BUN	ONGOING	N	Y		COND
								RC	DECREASED ALBUMIN	ONGOING	N	Y		COND
								RC	DECREASED CHLORIDE	UNK	N	Y		COND
								RC	CONTRACTED GALLBLADDER	UNK	N	Y		COND
200616091US	19-JUL-2006	US	41Y	UNKNOWN	31-JAN-2006		??-???-2006	RC	FULMINANT LIVER FAILURE - ascites - hepatosplenomegaly - albumin decreased - total bilirubin increased - alkaline phosphatase increased - AST increased - ALT increased - abdominal pain - abdominal distension - weight gain - vomiting - icteric - pruritis - nausea	ONGOING	Y	N		COND
Health Professional	31-OCT-2006		F		04-FEB-2006									
							03-AUG-2006	RC	CIRRHOSIS - esophageal varices - anemia - upper GI bleed - prothrombin time increased - international normalized ratio increased	ONGOING	Y	Y		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	DT	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200616174US	21-JUL-2006	US	79Y	800 MG	11-APR-2006		??-JUN-2006	RC	ACUTE RENAL FAILURE-FATAL	DIED	Y	Y		COND
Health Professional	17-NOV-2006		M	TBLS										
				800 MG TBLS	21-MAR-2006		??-JUN-2006	RC	RESPIRATORY FAILURE-FATAL	DIED	Y	Y		COND
							??-MAY-2006	RC	HEPATIC FAILURE - FATAL - jaundice - elevated liver enzymes	DIED	Y	N		COND
							??-???-2006	RC	BLURRED VISION	UNK	N	N		COND
#200616195US	25-JUL-2006	US	70Y	UNKNOWN	??-???-2006		??-???-2006	RC	FATAL LIVER FAILURE - liver issue nos	DIED	Y	N		COND
Health Professional	13-NOV-2006		M				??-???-2006	RC	FATAL DIC	DIED	Y	Y	INSU	COND
							FATAL DIC ***FATAL LIVER FAILURE***							
200616365US	31-JUL-2006	US		800 MG	??-APR-2006			RC	VIRAL SYNDROME - respiratory arrest	RECOVERED	Y	Y	UNREL	COND
Health Professional	16-NOV-2006		M	PO TBLS				RC	RENAL FAILURE	RECOVERED	Y	Y	UNREL	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200617796US	14-SEP-2006	US	19Y	UNK	??-MAR-2006		??-???-2006	RC	SHORTNESS OF BREATH	DIED	N	Y		COND
Health Professional			M				??-???-2006	RC	FATIGUE	DIED	N	Y		COND
							??-MAY-2006	RC	NAUSEA	DIED	N	N		COND
							??-MAY-2006	RC	VOMITING	DIED	N	N		COND
							??-MAY-2006	RC	RIGHT UPPER QUADRANT PAIN	DIED	N	N		COND
							??-???-2006	RC	PLEURAL EFFUSION	DIED	Y	Y		COND
							??-???-2006	RC	PERICARDIAL EFFUSION	DIED	Y	Y		COND
							??-???-2006	RC	LOWER LEG EDEMA	DIED	Y	Y		COND
							??-???-2006	RC	FULMINANT HEPATIC FAILURE - elevated liver enzymes (AST, ALT, AMMONIA, TOTAL BILIRUBIN)	DIED	Y	N		COND
							??-???-2006	RC	ACUTE RENAL FAILURE - elevated serum creatinine (1.2mg/dL to 3.3mg/dL)	DIED	Y	Y		COND
							12-JUN-2006	RC	VENTRICULAR FIBRILLATION	DIED	Y	Y		COND
											AZITHROMYCIN			

Number of Distinct Cases per Source : Spontaneous **57**

Number of Distinct Cases per Drug : TELITHROMYCIN **57**

CORPORATE DRUG SAFETY

Case Line Listing

Total Number of Cases Selected by Query	**57**
Total Number of Cases Detailed	**57**
Total Number of Incomplete Cases	**0**

			Number of Distinct Cases per Source per Drug	Number of Distinct Cases per Drug
HMR3647	**TELITHROMYCIN**	Spontaneous	57	**57**

Notes :
As a case can have multiple suspect drugs, it can appear under more than one drug category. Hence, it will be counted for each drug.
The sum of the distinct cases over all drugs can be greater than the **Total Number of Cases Detailed**.
Cases having more than one suspect drug record for the same drug will appear more than once within one drug category. However they will only be counted once within a drug category.

Printed : 24-NOV-2006 14:03

Version 1.3.5 NT

CORPORATE DRUG SAFETY

Site Id : GDDC

Case Line Listing

Query Text :

WHERE (VW_CASE.CASE_ID IN SELECT DISTINCT A.NON_USA FROM NANNEY_GDDC.NON_US A WHERE (A.NON_USA IS NOT NULL))

Printed by: CTQUERY_GDDC

Sorted according to - Drug
- Source (Division)
- Case Id

Legend :

- Patient Died
DT - Diagnosis Type
R/C - R = Reporter C = Company
UNL - Unlabeled
LOC UNL - Local Unlabeled

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment: Reporter	Assessment: Company
200121010DE Health Professional	09-NOV-2001 12-NOV-2001	DE	20Y M	800 MG PO FTAB	25-OCT-2001		31-OCT-2001	RC	HEPATITIS - increase in bilirubin to 7.7 - jaundice	ONGOING	Y	N		UNLIK
200211440DE Health Professional	01-FEB-2002 21-MAR-2002	DE	61Y F	 PO FTAB	13-DEC-2001 ??-DEC-2001			RC	INCREASE IN LIVER VALUES	UNK	Y	N	UNREL	COND
200213783EU Reg. Authority	20-NOV-2002 12-FEB-2003	IT	26Y M	800 MG PO FTAB	12-OCT-2002 16-OCT-2002	5 DAY(S)	16-OCT-2002 24-OCT-2002	RC	CHOLESTATIC SYNDROME	RECOVERED	Y	N	POSS	COND
						5 DAY(S)	16-OCT-2002 24-OCT-2002	RC	HEPATIC CYTOLYSIS - hypertransaminasemia	RECOVERED	Y	N	POSS	COND
200213996DE Other	28-MAY-2002 10-JUN-2002	DE	58Y F	 PO FTAB	??-MAY-2002 ??-MAY-2002		17-MAY-2002 29-MAY-2002	RC	HEPATITIS - fatigue - nausea - constipation - open oral mucous membrane - tiredness - headache	RECOVERED	Y	N		COND
200214071EU Reg. Authority	12-DEC-2002 10-JAN-2003	BE	26Y M	800 MG PO	22-NOV-2002 25-NOV-2002		??-NOV-2002	RC	HEPATITIS	NOT_RESOLVED	Y	N		COND
200214202DE Health Professional	12-JUN-2002 28-JUN-2002	DE	70Y M					RC	CHOLESTATIC HEPATITIS - icterus (max bilirubine 24.9) - light stool - dark coloured urine - collapse	UNK	Y	N	POSS	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200215044FR	17-DEC-2002	FR	75Y	800 MG	27-NOV-2002	7 DAY(S)	03-DEC-2002	RC	FATAL HEPATITIS FULMINANT - Cytolytic hepatitis - Jaundice (conjugated bilirubin at 215) - Coagulation factor V decreased (36 %) - Coma	DIED	Y	Y		UNREL
Health Professional	23-DEC-2002		M	PO CTAB	01-DEC-2002	3 DAY(S)								
						7 DAY(S) 3 DAY(S)	03-DEC-2002	RC	ACUTE CHOLECYSTITIS SUSPECTED	DIED	Y	Y		UNREL
						8 DAY(S) 3 DAY(S)	04-DEC-2002	RC	NODULAR LIVER	DIED	Y	Y		UNREL
						8 DAY(S) 3 DAY(S)	04-DEC-2002	RC	MULTIVISCERAL FAILURE (Aggravation reaction) - Acute renal insufficiency - Disseminated Intravascular coagulation	DIED	Y	Y		UNREL
					08-DEC-2002		***FATAL HEPATITIS FULMINANT***				DI-ANTALVIC PREDNISOLONE			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200215530DE	11-SEP-2002	DE	75Y	800 MG	03-AUG-2002	17 DAY(S)	19-AUG-2002	RC	TOXIC LIVER DAMAGE	RECOVERED	Y	N		COND
Health Professional	02-DEC-2002		F	PO FTAB	17-AUG-2002	3 DAY(S)	25-NOV-2002							
									- nausea - vomiting - inappetence - abdominal tension - dark urine - yellowish color of skin - increase in liver values - malaise, tiredness					
200216069DE	25-OCT-2002	DE	56Y	800 MG	15-MAY-2002	18 DAY(S)	01-JUN-2002	RC	INCREASED TRANSAMINASES OF UNKNOWN ORIGIN	SEQUELAE	Y	N		COND
Reg. Authority	05-MAR-2003		F	PO FTAB	25-MAY-2002	8 DAY(S)								
						18 DAY(S)	01-JUN-2002	RC	STEATOSIS HEPATIS	SEQUELAE	Y	Y		COND
						8 DAY(S)								
200310276FR	17-JAN-2003	FR	55Y		??-OCT-2002		??-OCT-2002	RC	INFECTIOUS SYNDROME AGGRAVATED	RECOVERED	Y	Y		INSU
Health Professional			F	PO CTAB										
						4 DAY(S)	??-OCT-2002	RC	HEPATIC CYTOLYSIS (5 N)	ONGOING	Y	N		COND
						9 DAY(S)	05-NOV-2002	RC	LEFT HEMIPLEGIA DUE TO CEREBROVASCULAR ACCIDENT (Aggravation reaction)	ONGOING	Y	Y		INSU
						9 DAY(S)	05-NOV-2002	RC	AURICULAR FIBRILLATION	UNK	Y	N		INSU

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200310305DE	03-FEB-2003	DE	50Y	800 MG	14-OCT-2002	22 DAY(S)	04-NOV-2002	RC	DRUG TOXIC LIVER CELL DAMAGE	SEQUELAE	Y	N		COND
Reg. Authority	17-FEB-2006		F	PO FTAB	31-OCT-2002	5 DAY(S)			- ascites - abdominal pain - asthenia - tiredness - centrolobular parenchymal necrosis					
200311612FR	07-APR-2003	FR	40Y					RC	FATIGUE	ONGOING	Y	Y		COND
Health Professional			M			3 DAY(S)								
								RC	ABDOMINAL PAIN	ONGOING	Y	N		COND
						3 DAY(S)								
								RC	NAUSEA	ONGOING	Y	N		COND
						3 DAY(S)								
								RC	PANCYTOPENIA SUSPECTED	ONGOING	Y	Y		COND
						3 DAY(S)								
								RC	TRANSAMINASE INCREASED	ONGOING	Y	N		COND
						3 DAY(S)								
								RC	MODERATE DECREASE OF PROTHROMBIN RATE	ONGOING	Y	Y		COND
						3 DAY(S)								
											PREDNISOLONE			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200311931DE	24-JUL-2003	DE	36Y	800 MG	11-MAR-2003	3 DAY(S)	13-MAR-2003	RC	HEPATITIS	UNK	Y	N		COND
Reg. Authority	18-NOV-2003		M	PO FTAB	13-MAR-2003				- asthenia - nausea - pruritus - abdominal pain - upper abdominal pain right side - fair stool - dark urine - icterus - fever - increased liver values					
											IBUPROFEN			
200312978DE	20-NOV-2003	DE	40Y		??-NOV-2003		??-NOV-2003	RC	ICTERUS	UNK	Y	N		COND
Health Professional	09-FEB-2004		M	PO FTAB	??-NOV-2003		??-NOV-2003	RC	HEPATOPATHY	UNK	Y	N		COND
									- severe pruritus - decrease in appetite - retching - stool light colored - dark urine - loss of weight (4 kg) - increase in liver values					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200313257EU	31-OCT-2003	BE	66Y	800 MG	13-OCT-2003	5 DAY(S)	17-OCT-2003	RC	LIVER TEST ABNORMAL	ONGOING	Y	N	POSS	COND
Health Professional			F	PO	17-OCT-2003				- increased alkaline phosphatase - increased gamma GT					
						5 DAY(S)	17-OCT-2003	RC	ACUTE RENAL FAILURE	ONGOING	Y	Y	POSS	COND
						5 DAY(S)	17-OCT-2003	RC	INFLAMMATORY SYNDROME	ONGOING	Y	Y	POSS	COND
200313860FR	14-OCT-2003	FR	64Y	800 MG	13-OCT-2003		??-???-2003	RC	PULMONARY INTERSTITIAL LESIONS ON CHEST X.RAY	UNK	Y	Y		UNREL
Health Professional	08-DEC-2003		M	PO CTAB	14-OCT-2003									
							??-???-2003	RC	BIOLOGICAL SIGNS OF INFLAMMATION (CRP:80)	UNK	Y	Y		UNREL
							??-???-2003	RC	CPK INCREASE (2N)	UNK	Y	Y		UNREL
							??-???-2003	RC	ALAT INCREASED (1.5N)	UNK	Y	N		UNREL
							??-???-2003	RC	ACUTE RENAL INSUFFICIENCY (PLASM CREAT : 1200 micro ml/l) - Anuria - Hematuria - Hyperkalemia (6.9) - Acute pulmonary edema - Cardiomegaly - Anemia (Hb: 10 g/100ml)	ONGOING	Y	Y		UNREL

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200410080FR	08-JAN-2004	FR	73Y	800 MG	02-DEC-2003	3 DAY(S)	05-DEC-2003	RC	ACUTE PANCREATITIS (SERUM LIPASE12.500)	RECOVERED	Y	Y	POSS	UNLIK
Health Professional	18-MAR-2004		M	PO CTAB	05-DEC-2003				- Abdominal pain					
						3 DAY(S)	05-DEC-2003	R	ACUTE HEPATITIS	RECOVERED	Y	N	POSS	UNLIK
									- Asthenia					
									- Arthralgia					
									- Transaminases increased (ALAT: 10N, ASAT: 23N)					
									- Bilirubin increased (2N)					
200410220JP	30-JAN-2004	JP	59Y	600 MG	22-JAN-2004	3 DAY(S)	24-JAN-2004	RC	GENERALIZED DRUG ERUPTION	RECOVERED	N	N	PROB	COND
Licence Partner	07-DEC-2005		M	PO TBLS	26-JAN-2004		06-FEB-2004							
						5 DAY(S)	26-JAN-2004	RC	DRUG-INDUCED HEPATIC DISORDER	RECOVERED	Y	N	PROB	COND
						1 DAY(S)	06-FEB-2004							
						5 DAY(S)	26-JAN-2004	RC	HYPERGLYCAEMIA	RECOVERED	Y	Y	POSS	COND
						1 DAY(S)	06-FEB-2004							
200410258FR	22-JAN-2004	FR	36Y		15-NOV-2003	26 DAY(S)	10-DEC-2003	R	TOXIC CHOLESTATIC HEPATITIS	RECOVERED	Y	N	POSS	COND
Reg. Authority	29-MAR-2004		F	PO	21-NOV-2003	20 DAY(S)								
									- Pruritus					
									- Icterus					
						26 DAY(S)	10-DEC-2003	C	CHOLESTATIC LIVER INJURY	RECOVERED	Y	N		COND
						20 DAY(S)								
									- Pruritus					
									- Icterus					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200410825DE	15-APR-2004	DE	45Y	800 MG	16-FEB-2004	2 DAY(S)	??-FEB-2004	RC	TOXIC REACTIVE HEPATITIS	RECOVERED	Y	N	POSS	COND
Health Professional	09-AUG-2004		F	PO FTAB	20-FEB-2004		07-JUN-2004		- loss of weight - vomiting - increase in liver values - increasing tiredness - asthenia - collapse tendency - nausea - pain in right upper abdomen					
200410918JP	16-MAR-2004	JP	34Y		??-FEB-2004	1 MTH(S)	08-MAR-2004	RC	DRUG-INDUCED CHOLECYSTITIS	RECOVERED	Y	Y	POSS	COND
Licence Partner	02-JUL-2004		F	PO TBLS			20-MAR-2004							
						1 MTH(S)	08-MAR-2004 23-MAR-2004	RC	DRUG-INDUCED LIVER DISORDER	RECOVERED	Y	N	POSS	COND
											CEFALEXIN LYSOZYME MEQUITAZINE			
200411145JP	02-APR-2004	JP	73Y	600 MG	27-MAR-2004	3 DAY(S)	29-MAR-2004	RC	HEPATIC DISORDER	ONGOING	Y	N	POSS	COND
Licence Partner	14-JUN-2004		F	PO TBLS	29-MAR-2004	1 DAY(S)								
											HYDROCORTISONE SODIUM SUCCINATE			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200411160FR	18-MAR-2004	FR	35Y	800 MG	17-FEB-2004	1 DAY(S)	21-FEB-2004	RC	CHOLESTATIC LIVER INJURY - Abdominal pain - Nausea - Vomiting - Icterus - Transaminases increased (ALAT = 5.6N) - Alkaline phosphatase increased (5.6N) - Bilirubin conjugated increased (3N)	RECOVERED	Y	N	UNLIK	UNLIK
Health Professional	06-JUL-2004		F	PO CTAB	21-FEB-2004									
						1 DAY(S)	17-FEB-2004	RC	FATIGUE	RECOVERED	N	Y	UNLIK	UNLIK
						1 DAY(S)	17-FEB-2004	RC	FEVER	RECOVERED	N	Y	UNLIK	UNLIK
200411193EU	14-APR-2004	IT	32Y	800 MG	01-APR-2004	7 DAY(S)	07-APR-2004	RC	ACUTE HEPATITIS	RECOVERED	Y	N		COND
Reg. Authority	19-MAY-2004		F	PO	02-APR-2004	6 DAY(S)								
200411473JP	23-APR-2004	JP	48Y	600 MG	06-APR-2004	3 DAY(S)	08-APR-2004	RC	HEPATIC FUNCTION DISORDER	RECOVERED	Y	N	H.PROB	COND
Licence Partner	01-JUN-2004		M	PO TBLS	07-APR-2004	2 DAY(S)	26-APR-2004							
						2 DAY(S)	07-APR-2004	RC	DRUG ERUPTION	NOT_RESOLVED	Y	N	H.PROB	COND
						1 DAY(S)	12-APR-2004							
											SULPYRINE			
200412160JP	25-JUN-2004	JP	31Y	600 MG	??-APR-2004	2 MTH(S)	01-JUN-2004	RC	ACUTE HEPATITIS	RECOVERED	Y	N	POSS	COND
Licence Partner	13-JUL-2004		F	PO TBLS	??-APR-2004	1 MTH(S)	28-JUN-2004							
				600 MG	??-MAY-2004									
				PO TBLS	??-MAY-2004									

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200412163JP	24-JUN-2004	JP	23Y	600 MG	14-JUN-2004	3 DAY(S)	16-JUN-2004	RC	HEPATIC FUNCTION DISORDER	RECOVERED	Y	N	PROB	COND
Licence Partner	22-JUL-2004		M	PO TBLS	16-JUN-2004	1 DAY(S)	02-JUL-2004							
											FOSFOMYCIN CALCIUM			
200412363JP	15-JUL-2004	JP	26Y	600 MG	23-FEB-2004	17 DAY(S)	10-MAR-2004	RC	HEPATIC FUNCTION DISORDER	RECOVERED	Y	N	PROB	PROB
Licence Partner	03-AUG-2004		M	PO TBLS	27-FEB-2004	13 DAY(S)	30-MAR-2004							
200412461JP	28-JUL-2004	JP	31Y	600 MG	04-JUN-2004	19 DAY(S)	22-JUN-2004	RC	LIVER DISORDER	RECOVERED	Y	N	PROB	COND
Licence Partner	07-SEP-2004		F	PO TBLS	09-JUN-2004	14 DAY(S)	24-JUL-2004							
200412473JP	22-JUL-2004	JP	70Y	600 MG	06-JUL-2004	7 DAY(S)	12-JUL-2004	RC	MALAISE OF ENTIRE BODY	ONGOING	Y	Y	UNREL	UNREL
Licence Partner	10-AUG-2004		M	PO TBLS	11-JUL-2004	2 DAY(S)								
						7 DAY(S)	12-JUL-2004	RC	PRURITUS	ONGOING	Y	N	UNREL	UNREL
						2 DAY(S)								
						7 DAY(S)	12-JUL-2004	RC	JAUNDICE	ONGOING	Y	N	UNREL	UNREL
						2 DAY(S)								
						7 DAY(S)	12-JUL-2004	RC	HEPATITIS	ONGOING	Y	N	UNREL	UNREL
						2 DAY(S)								
											BEZAFIBRATE GLICLAZIDE NIFEDIPINE VOGLIBOSE			
200412541JP	03-AUG-2004	JP	62Y	600 MG	16-JUL-2004	15 DAY(S)	30-JUL-2004	RC	ACUTE HEPATITIS CHOLESTATIC	RECOVERED	Y	N	POSS	COND
Licence Partner	30-SEP-2004		M	PO TBLS	20-JUL-2004	11 DAY(S)	31-AUG-2004							
200412586JP	10-AUG-2004	JP	27Y	2 TABLETS PO TBLS	11-JUN-2004	14 DAY(S)	24-JUN-2004	RC	HEPATITIS ACUTE	ONGOING	Y	N		COND
Licence Partner	23-AUG-2004		F		15-JUN-2004	10 DAY(S)								

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200413028JP Health Professional	28-SEP-2004 07-JUL-2005	JP	38Y F	2 TABLETS PO TBLS 2 TABLETS PO TBLS	26-AUG-2004 31-AUG-2004 07-SEP-2004 09-SEP-2004	15 DAY(S) 1 DAY(S)	09-SEP-2004 15-OCT-2004	RC	LIVER DISORDER	RECOVERED	Y	N	PROB	COND
200413189EU Reg. Authority	22-OCT-2004	ES	45Y F	800 MG PO FTAB	15-AUG-2004 16-AUG-2004	2 DAY(S)	16-AUG-2004 28-AUG-2004	RC	HEPATITIS CHOLESTATIC	RECOVERED	Y	N		COND
											IBUPROFEN *PARACETAMOL*			
200413213JP Licence Partner	15-OCT-2004 03-APR-2006	JP	57Y M	300 MG PO TBLS	30-JUL-2003			RC	GENERALIZED DRUG ERUPTION	UNK	Y	N		COND
								RC	DRUG-INDUCED LIVER DISORDER	UNK	Y	N		COND
								RC	RENAL FUNCTION ABNORMAL	UNK	Y	Y		COND
200413214JP Licence Partner	15-OCT-2004 11-DEC-2004	JP	48Y M	600 MG PO TBLS	09-OCT-2004 11-OCT-2004	2 DAY(S)	10-OCT-2004 ??-OCT-2004	RC	DRUG INDUCED LIVER DISORDER	RECOVERED	Y	N	PROB	COND
						2 DAY(S)	10-OCT-2004 ??-OCT-2004	RC	DRUG ERUPTION	RECOVERED	Y	N	PROB	COND
											CARBAMAZEPINE *LOXOPROFEN* *PA*			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
#200413245JP	19-OCT-2004	JP	78Y	300 MG	28-SEP-2004			RC	GENERALIZED CIRCULATORY FAILURE	UNK	Y	Y	UNREL	UNREL
Licence Partner	12-JAN-2005		F	PO TBLS	16-OCT-2004	20 DAY(S)	17-OCT-2004	RC	HEPATIC SHOCK FATAL	DIED	Y	Y	COND	COND
						2 DAY(S)	18-OCT-2004							
					18-OCT-2004		***CARDIAC FAILURE HEPATIC FAILURE***							
200413376FR	09-SEP-2004	FR	21Y	800 MG	27-AUG-2004	6 DAY(S)	01-SEP-2004	C	ACUTE RENAL INSUFFICIENCY (rise in creat of more than 50%) (Aggravation reaction)	UNK	Y	Y		COND
Health Professional	28-OCT-2004		F	PO CTAB	01-SEP-2004	6 DAY(S)	01-SEP-2004	RC	LOSS OF CONSCIOUSNESS (Aggravation reaction)	UNK	Y	N	PROB	COND
						6 DAY(S)	01-SEP-2004	RC	HEPATOCELLULAR INJURY (ALAT : 49N) - Vomiting - Asthenia - Abdominal pain	UNK	Y	N	PROB	COND
200413435JP	09-NOV-2004	JP	28Y	600 MG	28-OCT-2004	3 DAY(S)	30-OCT-2004	RC	HEPATITIS ACUTE	SEQUELAE	Y	N	PROB	COND
Licence Partner	18-NOV-2004		M	PO TBLS	30-OCT-2004	1 DAY(S)	16-NOV-2004							
200413475JP	11-NOV-2004	JP	29Y	600 MG	01-NOV-2004	2 DAY(S)	02-NOV-2004	RC	LIVER DISORDER	RECOVERED	Y	N	PROB	COND
Licence Partner	18-JAN-2005		F	PO TBLS	04-NOV-2004		24-NOV-2004							
200413505JP	16-NOV-2004	JP	82Y	600 MG	13-NOV-2004	3 DAY(S)	15-NOV-2004	RC	HEPATITIS FULMINANT	RECOVERED	Y	Y	H.PROB	COND
Licence Partner	03-DEC-2004		M	PO TBLS	15-NOV-2004	1 DAY(S)								

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200413544JP	11-NOV-2004	JP	40Y	300 MG	04-NOV-2004	5 DAY(S)	08-NOV-2004	RC	TOXICODERMA	UNK	Y	N	PROB	COND
Licence Partner	28-DEC-2004		F	PO TBLS	08-NOV-2004	1 DAY(S)								
						5 DAY(S)	08-NOV-2004	RC	HEPATIC FUNCTION DISORDER	UNK	Y	N	PROB	COND
						1 DAY(S)								
200413572JP	22-NOV-2004	JP	49Y	600 MG	25-SEP-2004	41 DAY(S)	10-NOV-2004	RC	HEPATIC FUNCTION DISORDER	RECOVERED	Y	N	POSS	COND
Licence Partner	28-DEC-2004		M	PO TBLS	29-SEP-2004	41 DAY(S)	20-DEC-2004							
											AUGMENTIN CEFTERAM PIVOXIL LORATADINE PL			
200413683JP	01-DEC-2004	JP	58Y	600 MG	22-NOV-2004	2 DAY(S)	23-NOV-2004	RC	HEPATIC FUNCTION ABNORMAL	RECOVERED	Y	N	POSS	POSS
Health Professional	24-JAN-2005		F	PO TBLS	23-NOV-2004	1 DAY(S)	17-DEC-2004							
						2 DAY(S)	23-NOV-2004	RC	RASH	RECOVERED	Y	N	POSS	POSS
						1 DAY(S)	17-DEC-2004							
200413810JP	08-DEC-2004	JP	48Y	600 MG	18-NOV-2004	5 DAY(S)	22-NOV-2004	RC	HEPATIC FUNCTION DISORDER	RECOVERED	Y	N		COND
Licence Partner	28-DEC-2004		M	PO TBLS	22-NOV-2004	1 DAY(S)	04-DEC-2004							
											AMOXAPINE			
200414038JP	27-DEC-2004	JP	56Y	600 MG	12-OCT-2004	23 DAY(S)	03-NOV-2004	RC	HEPATIC FUNCTION DISORDER	ONGOING	Y	N	PROB	COND
Health Professional	20-JAN-2005		F	PO TBLS	19-OCT-2004	16 DAY(S)								

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200414426FR Health Professional	20-NOV-2004 08-MAR-2005	FR	36Y M	800 MG PO CTAB	03-NOV-2004	3 DAY(S)	05-NOV-2004	RC	ICTERUS (Free bilirubin increased)	UNK	N	Y	UNLIK	COND
						3 DAY(S)	05-NOV-2004	RC	LIVER INJURY (ALAT 2.5N) - Hepatic pain at palpation - Fever NOS - asthenia - arthralgia - abdominal pain - vomiting	UNK	N	N	UNLIK	COND
200420029GDDC Health Professional	07-OCT-2004 06-JUN-2005	CA	70Y F	800 MG PO	07-SEP-2004	8 DAY(S)	14-SEP-2004	RC	ELEVATED LIVER ENZYMES - jaundice - dark urine - shortness of breath - anorexia - nausea	ONGOING	Y	N	POSS	COND
200422188GDDC Health Professional	14-DEC-2004 21-FEB-2005	CA	31Y F	800 MG PO	??-SEP-2004	1 MTH(S) 2 WK(S)	12-OCT-2004 08-DEC-2004	RC	HEPATOCELLULAR NECROSIS - abdominal pain - right upper quadrant pain - fatigue	RECOVERED	Y	N	H.PROB	POSS
200510106JP Health Professional	07-JAN-2005 23-MAR-2005	JP	40Y M	600 MG PO TBLS	22-NOV-2004 26-NOV-2004	24 DAY(S) 20 DAY(S)	13-DEC-2004 12-JAN-2005	RC	DRUG INDUCED LIVER DISORDER - anorexia - pyrexia	RECOVERED	Y	N	PROB	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
200510355FR	21-JAN-2005	FR	40Y	800 MG	??-DEC-2004		25-DEC-2004	R	HEPATITIS SUSPECTED NOT CONFIRMED	UNK	Y	N		INSU
Health Professional			M	PO CTAB					- Transaminases increased (ALAT 207)					
							25-DEC-2004	RC	FEVER (38°4)	UNK	Y	Y		INSU
							25-DEC-2004	RC	DRY COUGH	UNK	Y	Y		INSU
							25-DEC-2004	RC	DYSPNEA	UNK	Y	Y		INSU
									- polypnea (32/MIN)					
							25-DEC-2004	RC	SINUS TACHYCARDIA	UNK	Y	Y		INSU
							25-DEC-2004	C	LIVER INJURY	UNK	Y	N		INSU
									- Transaminases increased (ALAT 207)					
#200510416FR	02-FEB-2005	FR	46Y	800 MG	21-DEC-2004		08-JAN-2005	C	HEPATOCELLULAR INJURY	DIED	Y	Y		COND
Reg. Authority	20-MAY-2005		M	PO	05-JAN-2005	19 DAY(S)	08-JAN-2005	R	HEPATITIS (FATAL OUTCOME)	DIED	Y	Y		COND
						3 DAY(S)								
					21-JAN-2005		***FATAL HEPATITIS***				*GEMCITABINE* *OMEPRAZOLE* *ONDANSETRON* CISPLATIN ENOXAPARIN			
200510894JP	22-MAR-2005	JP	18Y	600 MG	11-MAR-2005	12 DAY(S)	18-MAR-2005	RC	HEPATIC FUNCTION DISORDER	ONGOING	Y	N	PROB	COND
Health Professional	26-JUL-2006		M	PO TBLS	15-MAR-2005	8 DAY(S)								
200511892JP	24-JUN-2005	JP	19Y	300 MG	27-MAY-2005	2 DAY(S)	28-MAY-2005	RC	DRUG ERUPTION	RECOVERED	Y	N	PROB	COND
Health Professional	19-OCT-2006		M	PO	27-MAY-2005	2 DAY(S)	07-JUN-2005							
						2 DAY(S)	29-MAY-2005	RC	HEPATIC FUNCTION DISORDER	RECOVERED	Y	N	H.PROB	COND
						2 DAY(S)	16-JUN-2005							
											FOSFOMYCIN CALCIUM			

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200512255FR Health Professional	05-JUL-2005 20-MAR-2006	FR	85Y M	800 MG PO CTAB	07-JUN-2005 14-JUN-2005		??-JUN-2005	RC	CHOLESTATIC LIVER INJURY (Drug misuse) - General status impairing - Fatigue - Gamma GT increased at 10 N - Phosphatase alkaline increased at 5N	ONGOING	Y	N		COND
200512666DE Health Professional	18-NOV-2005 15-DEC-2005	DE	69Y F	800 MG PO FTAB	23-NOV-2004 14-DEC-2004		??-???-2004 30-DEC-2004	RC	DRUG INDUCED HEPATITIS - loss of appetite - increasing drive disorder - loss of weight - slowing - asthenia - nausea - coordination disorder	RECOVERED	Y	N	H.PROB	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
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Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200512675GDDC	23-MAR-2005	PR	52Y	800 MG	02-FEB-2005	22 DAY(S)	23-FEB-2005	RC	ACUTE HEPATITIS	RECOVERED	Y	N	PROB	COND
Health Professional	08-JUN-2005		M	PO	06-FEB-2005	18 DAY(S)								
									- fatigue - jaundice - abdominal tenderness - fever - icteric sclera - abdomen distended					
						22 DAY(S) 18 DAY(S)	23-FEB-2005 08-MAR-2005	RC	RIGHT SIDED PLEURAL EFFUSION	RECOVERED	Y	Y	PROB	COND
									- stomach was inflamed					
						22 DAY(S) 18 DAY(S)	23-FEB-2005	C	EOSINOPHILIA	RECOVERED	Y	N	PROB	COND
									- eosinophil count 2,059					
						22 DAY(S) 18 DAY(S)	23-FEB-2005	C	PERICARDIAL EFFUSION	RECOVERED	Y	Y		COND
200512876GDDC	22-MAR-2005	CA		400 MG	11-MAR-2005		15-MAR-2005	RC	SEVERE GENERALIZED PAPULAR RASH	RECOVERED	Y	N	H.PROB	COND
Health Professional	03-AUG-2005		F	PO	15-MAR-2005				- pruritis - urticaria					
							15-MAR-2005	RC	ELEVATED LIVER ENZYMES	RECOVERED	Y	N	H.PROB	COND
									- jaundice					
							15-MAR-2005 04-MAY-2005	RC	ACUTE INTERSTITIAL NEPHRITIS	RECOVERED	Y	Y	H.PROB	COND
									- fever					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
200516388GDDC Health Professional	14-JUL-2005	AT	F	400 MG PO				RC	INCREASED LIVER ENZYMES	RECOVERED	Y	N		COND
200610544FR Health Professional	09-FEB-2006	FR	M	800 MG PO CTAB				RC	SUSPECTED HEPATITIS NOT CONFIRMED	UNK	Y	N		INSU
200610558FR Reg. Authority	10-FEB-2006 03-AUG-2006	FR	24Y F	PO	10-FEB-2005 13-FEB-2005	4 DAY(S)		RC	DRESS SYNDROME SUSPECTED NOT CONFIRMED - Acute cholestatic hepatitis - Urticaria - Cheilitis - Facial edema	RECOVERED	Y	Y		UNLIK
						4 DAY(S)	13-FEB-2005	R	HEPATITIS DUE TO HYPERSENSITIVITY - Pruritus - Asthenia	RECOVERED	Y	N	COND	COND
						4 DAY(S)	13-FEB-2005	C	HEPATOCELLULAR LIVER INJURY (ALAT: 30N) - Pruritus - Asthenia	RECOVERED	Y	N		COND
200610812FR Health Professional	27-FEB-2006	FR	83Y M	800 MG PO CTAB	06-FEB-2006 10-FEB-2006		??-FEB-2006	R	HEPATIC CYTOLYSIS (Transaminases: 200)	RECOVERED	Y	N		INSU
							??-FEB-2006	C	LIVER INJURY NOS	RECOVERED	Y	N		INSU
							??-FEB-2006	RC	INR INCREASED AT 17	RECOVERED	Y	N		INSU

CORPORATE DRUG SAFETY

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Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200610872FR	02-MAR-2006	FR	67Y	800 MG	28-DEC-2005	23 DAY(S)	19-JAN-2006	RC	LIVER INJURY NOS (ALAT 1800)	ONGOING	Y	N		COND
Health Professional			F	PO CTAB	06-JAN-2006				(Drug misuse)					
				800 MG	11-JAN-2006				- dark urines					
				PO CTAB	20-JAN-2006				- fatigue					
						27 DAY(S)	23-JAN-2006	RC	FEVER	RECOVERED	N	Y		COND
						27 DAY(S)	23-JAN-2006	RC	CHILLS	RECOVERED	N	Y		COND
						27 DAY(S)	23-JAN-2006	RC	CONSTIPATION	UNK	N	N		COND
200610892GDDC	26-JAN-2006	IT	32Y	800 MG	28-DEC-2005		25-JAN-2006	RC	HEPATITIS	ONGOING	Y	N	H.PROB	COND
Reg. Authority	14-APR-2006		F	PO	18-JAN-2006				- transaminase nos increased					
									- gamma-gt value increased					
200611192FR	30-MAR-2006	FR	39Y		16-DEC-2005		03-JAN-2006	R	HEPATITIS	ONGOING	Y	N		COND
Reg. Authority			M	PO TBLS	21-DEC-2005				- abdominal pain					
							03-JAN-2006	C	CYTOLITIC LIVER INJURY	ONGOING	Y	N		COND
											PARACETAMOL *IBUPROFEN*			
200611354GDDC	11-FEB-2006	MX	22Y	800 MG	06-FEB-2006		08-FEB-2006	RC	HEPATITIS A	ONGOING	Y	Y	PROB	COND
Health Professional	15-FEB-2006		F	PO	10-FEB-2006				- transaminases increased					
									- tiredness					
									- choluria					
									- fever					
									- vomit					
									- food intolerance					

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200611800GDDC	27-FEB-2006	MX	37Y	800 MG	22-FEB-2006	3 DAY(S)		RC	HEPATITIS PROBABLY INDUCED BY DRUGS - choluria - cephalea - sclerotic jaundice - mild generalized jaundice - upset stomach - bloating - nausea - vomiting - fever (between 37-38 C) - hepatic enzyme increase - bilirubin increase - transaminase increase - malaise	ONGOING	Y	N	H.PROB	COND
Health Professional	13-MAR-2006		M	PO	22-FEB-2006									
											CIPROFLOXACIN *FEBRAX* *TRIMETHOPRIM/SULFAMETHOXAZOLE*			
200611944FR	30-MAY-2006	FR	55Y	800 MG	15-MAR-2006	17 DAY(S)	31-MAR-2006	R	SGOT INCREASED AT 51	RECOVERED	Y	N	COND	COND
Reg. Authority	18-JUL-2006		M	PO TBLS	20-MAR-2006	12 DAY(S)								
						17 DAY(S) 12 DAY(S)	31-MAR-2006	C	LIVER INJURY NOS (ALAT: 129)	RECOVERED	Y	N		COND
											AMOXICILLIN			
200612028FR	31-MAY-2006	FR	39Y		13-APR-2006	8 DAY(S)	20-APR-2006	R	HEPATITIS - Fever - Asthenia	RECOVERED	Y	N	POSS	COND
Health Professional	05-JUL-2006		M	PO TBLS	20-APR-2006									
						8 DAY(S)	20-APR-2006	C	CYTOLYTIC LIVER INJURY (ALAT: 46N, Alk Ph: 1.5N)	RECOVERED	Y	N		COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id / Reporter Type / French Assoc (C)	First Contact / Last Contact / (S)	Ctry / (I)	Age / Sex	Daily Dose / Route / Form .	Dose Start / Dose Stop / *Date of Death*	First Dose to Onset / Last Dose to Onset	Event Onset / Event Stop / *Cause of Death*	D T	Event as Reported / (Nature of Event)	Outcome	Ser. / *Other Suspect Drugs*	Unl / loc. Unl	Assessment Reporter	Assessment Company
200612521GDDC Reg. Authority	15-MAR-2006 30-MAY-2006	IT	45Y F	800 MG PO	13-JAN-2006 13-JAN-2006	1 DAY(S) 1 DAY(S)	13-JAN-2006	RC	HEPATITIS	ONGOING	Y	N	PROB	COND
						1 DAY(S) 1 DAY(S)	13-JAN-2006	RC	JAUNDICE	ONGOING	Y	N	PROB	COND
						1 DAY(S) 1 DAY(S)	13-JAN-2006	RC	CHOLECYSTITIS	ONGOING	Y	Y	PROB	COND
200612628GDDC Health Professional	16-MAR-2006 03-APR-2006	GR	66Y F	800 MG PO	28-JAN-2006		??-JAN-2006 10-FEB-2006	RC	HEPATIC LESIONS OF PHARMACEUTICAL CAUSE - jaundice - fatigue - dark urine	RECOVERED	Y	N		COND
200612779FR Reg. Authority	07-AUG-2006	FR	36Y M	800 MG PO TBLS	29-MAR-2006 04-APR-2006		22-MAR-2006 02-MAY-2006	RC	SGOT INCREASED (Aggravation reaction)	RECOVERED	Y	N		COND
							22-MAR-2006	RC	SGPT INCREASED (Aggravation reaction)	RECOVERED	Y	N		COND
							20-APR-2006 02-MAY-2006	RC	PHOSPHATASE ALKALINE INCREASED (Aggravation reaction)	RECOVERED	Y	N		COND
							22-MAR-2006	RC	GAMMA-GT INCREASED (Aggravation reaction)	RECOVERED	Y	N		COND
											LEVOFLOXACIN *AUGMENTIN*			
200613417GDDC Reg. Authority	31-MAR-2006 03-AUG-2006	IT	39Y M	800 MG PO	10-FEB-2006 01-MAR-2006	2 DAY(S)	11-FEB-2006	RC	DRUG INDUCED HEPATITIS	ONGOING	Y	N	H.PROB	COND
200613502GDDC Health Professional	03-APR-2006 28-APR-2006	IT	F	UNK				RC	TRANSAMINASES INCREASE	ONGOING	Y	N	UNREL	COND

CORPORATE DRUG SAFETY

Case Line Listing

Drug **HMR3647** **TELITHROMYCIN**
Case Division : **Spontaneous**

Case Id	First Contact	Ctry	Age	Daily Dose	Dose Start	First Dose to Onset	Event Onset	D T	Event as Reported	Outcome	Ser.	Unl	Assessment Reporter	Assessment Company
Reporter Type	**Last Contact**		**Sex**	**Route / Form .**	**Dose Stop**	**Last Dose to Onset**	**Event Stop**		**(Nature of Event)**			**loc. Unl**		
French Assoc (C)	**(S)**	**(I)**			***Date of Death***		***Cause of Death***				***Other Suspect Drugs***			
200615777GDDC	31-MAY-2006	BE	76Y	2				RC	HEPATITIS	RECOVERED	Y	N	H.PROB	COND
Health Professional	19-SEP-2006		F	PO TBLS										
200617801GDDC	26-JUL-2006	TR	22Y	UNK	10-AUG-2005	2 DAY(S)	11-AUG-2005	RC	TOXIC HEPATITIS	RECOVERED	Y	N		COND
Reg. Authority	16-NOV-2006		F	PO	11-AUG-2005	1 DAY(S)								
											TRIAMCINOLONE ACETONIDE			
200619508GDDC	12-SEP-2006	ES	68Y	400 MG	07-JUN-2006	35 DAY(S)	11-JUL-2006	RC	FATTY LIVER	ONGOING	Y	Y		COND
Reg. Authority			M	PO CTAB	11-JUN-2006	31 DAY(S)	19-JUL-2006							

Number of Distinct Cases per Source : Spontaneous **77**

Number of Distinct Cases per Drug : TELITHROMYCIN **77**

CORPORATE DRUG SAFETY

Case Line Listing

Total Number of Cases Selected by Query	**77**
Total Number of Cases Detailed	**77**
Total Number of Incomplete Cases	**0**

			Number of Distinct Cases per Source per Drug	Number of Distinct Cases per Drug
HMR3647	**TELITHROMYCIN**	Spontaneous	77	**77**

Notes :
As a case can have multiple suspect drugs, it can appear under more than one drug category. Hence, it will be counted for each drug.
The sum of the distinct cases over all drugs can be greater than the **Total Number of Cases Detailed**.
Cases having more than one suspect drug record for the same drug will appear more than once within one drug category. However they will only be counted once within a drug category.