

1. Reporter Details		☐ Initial	☐ Follow-up
Reporter Name:		E-mail:	
Contact address:		Telephone number:	
		Fax number:	
Type:	☐ Physician (Specialty): _____	☐ Consumer or other non healthcare professional	
	☐ Pharmacist	☐ Other (Specify) _____	
If reporter is a consumer, have they informed their physician of the exposure?		☐ Yes	☐ No
Has the consumer provided permission to contact their healthcare professional?		☐ Yes	☐ No
If yes, please provide healthcare professional contact details:			
Name:		Type:	Telephone:
Address:		Email:	

2. Patient Details			
Date of birth (Day/Month/Year)	Age Yrs/mo.	Height cm	Weight kg

3. Company Drug Section									
	Name	Strength	Dose	Route	Indication	Treatment start date (day/month/year)	Treatment end date (day/month/year)	Lot	Expiry
1.									
2.									
3.									

4. Details of Adverse Event					
Adverse Event(s)	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
			☐ Yes ☐ No <i>If yes, provide dates of hospitalization.</i>	☐ Recovered / Resolved ☐ Recovered / Resolved With Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown	☐ Related ☐ Not Related ☐ Unknown

5. Liver Function Tests			
	Date (day/month/year)	Results	Normal Range
Alanine transaminase (ALT)			
Aspartate transaminase (AST)			
Alkaline phosphatase (ALP)			
Albumin			
Total protein (TP)			

Bilirubin			
Gamma-glutamyltransferase (GGT)			
L-lactate dehydrogenase (LD)			
Prothrombin time (PT)			

6. Imaging, Biopsy results & other investigations

	Result	Date (day/month/year)
Ultrasound		
Computer tomography		
Magnetic Resonance Imaging (MRI)		
Liver Biopsy		
HBs Ag		
Anti-HCV Ab		
PCR-C		
Anti nuclear AB		

7. Treatment

Treatment provided for event:

Action taken with Company Drug in response to event:

8. Concomitant Drugs & Therapies

Name	Dose	Indication	Treatment start date (day/month/year)	Treatment end date (day/month/year)

9. Medical History/Concurrent Condition

Patient's concomitant conditions, relevant medical history, known risk factors, relevant tests, laboratory data.

☐ Viral illness	☐ Hepatitis
☐ Hepatitis virus infection	☐ Cholelithiasis
☐ Autoimmune disease	☐ Prone to bleeding or bruising
☐ Blood transfusion	☐ Intravenous drug use
☐ Drug abuse	☐ Recent tattoos
☐ Recent travel to Africa or Asia	☐ Toxic exposure
☐ Anesthesia use/Surgery/ Acupuncture	☐ Steroid use
☐ Cardiovascular disease	☐ Respiratory Disease
☐ Use of herbal supplements or teas	☐ Alcohol use: Glass/day
☐ Cancer(s)	

Other relevant medical history (e.g. pregnancy status, allergies):

10. Completed By

Name:	Signature:	Date (day/month/year):
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