

1. Reporter Details		<input type="checkbox"/> Initial	<input type="checkbox"/> Follow-up
Reporter Name:		E-mail:	
Contact address:		Telephone number:	
		Fax number:	
Type:	<input type="checkbox"/> Physician (Specialty): _____	<input type="checkbox"/> Consumer or other non healthcare professional	
	<input type="checkbox"/> Pharmacist	<input type="checkbox"/> Other (Specify) _____	
If reporter is a consumer, have they informed their physician of the exposure?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has the consumer provided permission to contact their healthcare professional?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>If yes, please provide healthcare professional contact details:</b>			
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
			<input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, provide dates of hospitalization.</i>	<input type="checkbox"/> Recovered / Resolved <input type="checkbox"/> Recovered / Resolved With Sequelae <input type="checkbox"/> Recovering /Resolving <input type="checkbox"/> Not Recovered /Not Resolved <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Not Related <input type="checkbox"/> 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.

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

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

## 10. Completed By

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