

1. F	Reporter 1	Details									Initial		□Foll	ow-up
Rep	orter Nan	ne:					E-	-mail	:					
Coı	ntact add	ress:					Те	eleph	one nu	mber:				
							Fa	ax nu	mber:					
Typ	be:	☐ Physician (Spe	ecialty): _				□	Con	sumer (or other	non healthc	are p	rofessi	ional
	1	☐ Pharmacist						Oth	er (Spe	cify) _				
If re	eporter is	a consumer, have	they infor	med the	ir phys	ician	of the	expos	sure?] Yes		□ No	
Has	s the consu	ımer provided pe	rmission to	contact	t their l	healt	hcare pr	ofess	ional?] Yes		□ No	•
If y	es, please	provide healthc	are profes	ssional o	contact	t det	ails:							
Nar	me:		7	уре:						Teleph	one:			
Address:								Email:						
2. P	Patient De				T				• .			***	• •	
		Date of birth Day/Month/Year)		Age	2			Heig				Wei	_	
	(1	Day/Month/Tear)		Yrs/mo				cm	cm		kg			
					I.									
3. (Company	Drug Section	_											
		Name	Strength	Dose	Ro	ute	Indica	tion		tment	Treatme		Lot	Expiry
										date	end dat			
									(day/mo	onth/year)	(day/month/y	/ear)		
1.														
2. 3.														
3.														
4. I	Details of	Adverse Event												
	verse Eve	Start Date	Stop D		Hospi	italiz	ation		(Outcome	2	Ex	zent Ca	usality
		(day/month/year)	(day/month		Yes					d / Resolv			elated	
] No						solved With		ot Relat	ed
					yes, pr ospitaliza		dates of		uelae	ng /Resolv	vin a	□U	Inknown	1
				"	ospiiaii-zu					-	ot Resolved			
									Fatal					
									Unknowi	1				
5. I	Liver Fun	ction Tests												
				Date	,			R	esults		N	lorm	al Rang	ge
Alaı	nine transa	minase (ALT)	(day	/month/ye	ear)									
Asp	artate trans	aminase (AST)												
		ohatase (ALP)												
	umin al protein ('	ГР)												
1011	ai protein (,												



Bilirubin Gamma-glutamyltransferase			
(GGT)			
L-lactate dehydrogenase (LD)			
Prothrombin time (PT)			
()			
6. Treatment			
Treatment provided for event:			
Action taken with Company Drug	in response to event:		
a C · · · · · · · · · · · · · · · · · ·	•		
7. Concomitant Drugs & Therap	oies		
O B # 10 1 TTO /			
8. Medical History			
8. Medical History Patient's concomitant conditions, relevant med	ical history, known risk factors, rele	evant tests, laboratory data.	
	ical history, known risk factors, rele		
Patient's concomitant conditions, relevant med	ical history, known risk factors, rele	evant tests, laboratory data. ☐ Hepatitis ☐ Cholelithiasis	
Patient's concomitant conditions, relevant med. Uiral illness	ical history, known risk factors, rele	☐ Hepatitis ☐ Cholelithiasis	or bruising
Patient's concomitant conditions, relevant med Urial illness Hepatitis virus infection	ical history, known risk factors, rele	☐ Hepatitis	
Patient's concomitant conditions, relevant med Urial illness Hepatitis virus infection Autoimmune disease	ical history, known risk factors, rele	☐ Hepatitis ☐ Cholelithiasis ☐ Prone to bleeding of	
Patient's concomitant conditions, relevant med Urial illness Hepatitis virus infection Autoimmune disease Blood transfusion	ical history, known risk factors, rele	☐ Hepatitis ☐ Cholelithiasis ☐ Prone to bleeding of ☐ Intravenous drug u	
Patient's concomitant conditions, relevant med Urial illness Hepatitis virus infection Autoimmune disease Blood transfusion Drug abuse	ical history, known risk factors, rele	☐ Hepatitis ☐ Cholelithiasis ☐ Prone to bleeding of ☐ Intravenous drug uf ☐ Recent tattoos	
Patient's concomitant conditions, relevant med Viral illness Hepatitis virus infection Autoimmune disease Blood transfusion Drug abuse Recent travel	ical history, known risk factors, rele	☐ Hepatitis ☐ Cholelithiasis ☐ Prone to bleeding of ☐ Intravenous drug uf ☐ Recent tattoos ☐ Toxic exposure	se
Patient's concomitant conditions, relevant med Viral illness Hepatitis virus infection Autoimmune disease Blood transfusion Drug abuse Recent travel Anesthesia use/Surgery	ical history, known risk factors, rele	☐ Hepatitis ☐ Cholelithiasis ☐ Prone to bleeding of ☐ Intravenous drug uf ☐ Recent tattoos ☐ Toxic exposure ☐ Steroid use	se
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