

Pancreatic effect

Targeted

1. Reporter Details		☐ Initial	☐ Follow-up
Reporter Name:		E-mail:	
Contact address:		Telephone number:	
		Fax number:	
Type:	☐ Physician (Specialty): _____ ☐ Pharmacist	☐ Nurse ☐ Other Healthcare professional (Please 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. Suspect Product Details									
	Name	Strength	Dose	Route	Indication	Treatment Start date (day/month/year)	Treatment end date (day/month/year)	Lot	Exp. date
1.									
2.									
3.									

4. Pancreatic Disorder Details	
Symptoms:	
☐ Abdominal pain	☐ Malaise
☐ Nausea	☐ Vomiting
☐ Jaundice	☐ Fever
☐ Weight loss	☐ Abdominal bleeding
☐ Diarrhoea	☐ Change in colour or consistency of stools
☐ Itching	☐ Bloating
Other relevant symptoms:	
Please provide, the diagnosis of the patient:	
Does the patient have acute pancreatitis?	
☐ Yes ☐ No	

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If yes, please specify the severity.

☐ Mild ☐ Moderate ☐ Severe.

Is the pancreatitis associated with any of the following?

☐ Interstitial edema ☐ Necrosis of pancreatic or peripancreatic tissue

Is the pancreatitis associated with any of the following organ failures?

☐ respiratory failure ☐ cardiovascular failure ☐ renal failure

Is the pancreatitis associated with any of these local complications?

☐ Peripancreatic fluid collections ☐ Pancreatic pseudocysts
☐ Acute necrotic collections ☐ Walled-off pancreatic necrosis

Other relevant details:

5. Laboratory tests

	Date (day/month/year)	Results	Normal Range
Amylase			
Lipase			
Ultrasonogram			
Endoscopic Ultrasound			
Abdominal X-Ray			
CT scan			
Magnetic Resonance Cholangiopancreatography			
Endoscopic Retrograde Cholangiopancreatography			
Liver function tests			
Other relevant test details:			

6. Medical History

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

☐ Trauma	☐ Diabetes
☐ Cholecystitis	☐ Cholelithiasis

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☐ Autoimmune disease	☐ Cystic fibrosis
☐ Pancreatitis	☐ Hepatitis
☐ Drug abuse	☐ Colitis
☐ Infections	☐ Toxic exposure
☐ Drug abuse	☐ Alcohol use: Glass/day
Other relevant medical history:	

7. Treatment for Pancreatic Disorders

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8. Details of Adverse Events

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

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8. Details of Other Adverse Events

Adverse Event	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
				☐ Fatal ☐ Unknown	

9. Concomitant Drugs & Therapies

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

10. Completed By

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