

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"/> Pharmacist <input type="checkbox"/> Other Healthcare professional (Please 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. 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	
<b>Symptoms:</b>	
<input type="checkbox"/> Abdominal pain	<input type="checkbox"/> Malaise
<input type="checkbox"/> Nausea	<input type="checkbox"/> Vomiting
<input type="checkbox"/> Jaundice	<input type="checkbox"/> Fever
<input type="checkbox"/> Weight loss	<input type="checkbox"/> Abdominal bleeding
<input type="checkbox"/> Diarrhoea	<input type="checkbox"/> Change in colour or consistency of stools
<input type="checkbox"/> Itching	<input type="checkbox"/> Bloating
Other relevant symptoms:	
Please provide, the diagnosis of the patient:	
Does the patient have acute pancreatitis?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	

Confidential

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.	
<input type="checkbox"/> Trauma	<input type="checkbox"/> Diabetes
<input type="checkbox"/> Cholecystitis	<input type="checkbox"/> Cholelithiasis

Confidential

<input type="checkbox"/> Autoimmune disease	<input type="checkbox"/> Cystic fibrosis
<input type="checkbox"/> Pancreatitis	<input type="checkbox"/> Hepatitis
<input type="checkbox"/> Drug abuse	<input type="checkbox"/> Colitis
<input type="checkbox"/> Infections	<input type="checkbox"/> Toxic exposure
<input type="checkbox"/> Drug abuse	<input type="checkbox"/> Alcohol use: Glass/day
Other relevant medical history:	

<b>7. Treatment for Pancreatic Disorders</b>

8. Details of Other Adverse Events					
Adverse Event	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
			<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide dates of hospitalization.	<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
			<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide dates of hospitalization.	<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
			<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide dates of hospitalization.	<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"/> Related <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown

Confidential

### 8. Details of Other Adverse Events

Adverse Event	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
				<input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	

### 9. Concomitant Drugs & Therapies

--

### 10. Completed By

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

Confidential