

Case Safety Report Form

Page 1 of 4

Report version	Dates	Report source / type
<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____	Date 1st study received (dd/mm/yyyy): _____ Date new information (PIU) received (dd/mm/yyyy): _____ Country of Event: _____	<input type="checkbox"/> Spontaneous <input type="checkbox"/> Consumer <input type="checkbox"/> Non-interventional study (Study ID: _____) <input type="checkbox"/> Pregnancy (please complete Pregnancy Report Form) <input type="checkbox"/> Misuse/abuse/overdose <input type="checkbox"/> Off-label use <input type="checkbox"/> Other: _____

1. REPORTER

Reporter	Company reporter
Name: _____ Institution: _____ Address: _____ Telephone: _____ Fax: _____ Email: _____ <input type="checkbox"/> Physician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other: _____	Name: _____ Institution: _____ Address: _____ Telephone: _____ Fax: _____ Email: _____ <input type="checkbox"/> Drug Safety <input type="checkbox"/> Sales Representative <input type="checkbox"/> Other: _____

2. PATIENT INFORMATION

Include: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Pregnant weeks of gestation: _____	Date of Birth (dd/mm/yyyy): _____ Age: _____ Age Group: _____	Height (cm): _____ Weight (kg): _____	Current: _____ Monogamous Polygamous Married Other: _____
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3. SUSPECT PRODUCT(S) *

Product (Generic name and Batch No)	Conc. of solution	Route	Treatment dosage/Infusion rate	Start/End	Duration	Indication

Overall treatment regimen with suspect drug(s) (incl. start, frequency, dates): _____

4. ADVERSE REACTION *

Adverse Event/ Diagnosis	Severity	Date (start/end)	Dosed on (incl Units)	Latency * (incl Units)	Outcome
	<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe				<input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Pending <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown
	<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe				<input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Pending <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown
	<input type="checkbox"/> mild <input type="checkbox"/> moderate <input type="checkbox"/> severe				<input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Fatal <input type="checkbox"/> Pending <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown
Did reaction(s) stop after stopping suspect product? *		<input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Not		

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M Mark



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