

ADVERSE EVENT REPORT

Physician's name, institution, address, tel., fax:			Report type: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up		Report date (dd/mmm/yyyy):		Batch/Lot no.:				
			Name drug/biologic product:		Indication:		Route of administration:				
			Dose and frequency:		Date of first administration (dd/mmm/yyyy):		Date of last administration (dd/mmm/yyyy):				
Patient Initials:		Patient no (if applicable):		Sex: <input type="checkbox"/> M <input type="checkbox"/> F		Did the event occur during the administration: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		Did the event abate after stopping administration: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		Did the event reappear after reintroduction: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	
Age (y):	Date of birth (dd/mmm/yyyy):		Height (cm):	Weight (kg):	Pregnant: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Any other comment:		Adverse event onset date (dd/mmm/yyyy):		Adverse event resolution date (dd/mmm/yyyy):	
or: <input type="checkbox"/> ongoing											

ADVERSE EVENT (PLEASE ENTER DIAGNOSIS):

In this box, please describe signs/symptoms, severity, time course, diagnostic procedure, relevant laboratory data and relevant medical history. Indicate any medication required to treat the event (use additional paper if necessary):

Case serious: <input type="checkbox"/> Yes <input type="checkbox"/> No Indicator for seriousness: <input type="checkbox"/> Death, date (dd/mmm/yyyy): ___/___/___ Autopsy: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Life-threatening <input type="checkbox"/> Required or prolonged hospitalisation <input type="checkbox"/> Persistent or significant disability/incapacity <input type="checkbox"/> Congenital anomaly <input type="checkbox"/> Important medical event that may jeopardise the patient and may require medical or surgical intervention to prevent one of the other outcomes		Outcome of event: <input type="checkbox"/> Recovered without sequelae <input type="checkbox"/> Recovered with sequelae: _____ <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Other: _____	
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Relationship with drug/biologic: <input type="checkbox"/> None <input type="checkbox"/> Unlikely / remote <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Definite <input type="checkbox"/> Assessment pending		Action taken regarding drug/biologic: <input type="checkbox"/> None <input type="checkbox"/> Dose Reduced <input type="checkbox"/> Temporarily interrupted Date stopped (dd/mmm/yyyy): ___/___/___ Date restarted (dd/mmm/yyyy): ___/___/___ <input type="checkbox"/> Stopped permanently		Severity: <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	
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CONCOMITANT THERAPY (exclude treatment for adverse event, use additional paper if necessary)

Treatment:	Total daily dose (units):	Date(s) of treatment (dd/mmm/yyyy):		Indication:	Suspect*:
		Start date	Stop date		
				<input type="checkbox"/> ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No

*Is there any indication that the concomitant medication could have contributed to the AE?

Reporter's name (Please print) _____	Date (dd/mmm/yyyy) _____	Signature _____	FRM-1402B
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