

Adverse Reaction Report Form for Human Medicines

IN CONFIDENCE

Please complete this form in confidence and return to Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Telephone 353-1-6764971, Fax 353-1-6762517, e-mail medsafety@hpra.ie.

Reporter name: _____

Address: _____

E-mail: _____

Telephone number: _____

If healthcare professional, state profession and area of speciality: _____

Profession: _____

Area of speciality: _____

Patient Initials/Record Number	Sex	Male <input type="checkbox"/>	Female <input type="checkbox"/>	Age:
Reason for treatment:				
Suspect Drug(s)/Vaccine(s) ¹	Daily Dose	Route	Batch No.	Dates/Duration of treatment
Suspected reaction: <i>(Brief description of the effects/side effects/interactions, including any information relevant to the circumstances of this reaction, such as in use conditions, medication error, occupational exposure etc.)</i>				
Time to onset (hours/days)	Onset of reaction (date)		Duration of reaction	
Treatment given / Action taken				
Outcome of reaction <input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Continuing <input type="checkbox"/> Fatal				

¹ Please use brand names where possible. Please note that for biological products, including vaccines, it is essential to include the brand name and batch number of the product.

<p>Drug Discontinued: Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Improvement on discontinuation Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Patient rechallenged Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, state outcome</p>	<p>Do you consider the reaction serious? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please indicate the basis for this, ticking all the criteria that apply:</p> <p><input type="checkbox"/> Fatal</p> <p><input type="checkbox"/> Life threatening (immediately)</p> <p><input type="checkbox"/> Patient hospitalised / hospitalisation prolonged</p> <p><input type="checkbox"/> Persistent or significant disability/incapacity</p> <p><input type="checkbox"/> Congenital anomaly or birth defect</p> <p><input type="checkbox"/> Medically significant - provide details:</p>
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Any other drugs used over this period? <i>(Please state below)</i>	None <input type="checkbox"/>	Unknown <input type="checkbox"/>
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Drug/Vaccine	Daily dose:	Route:	Dates/ Duration of Treatment:	Reason for treatment:

Relevant medical history *(including significant concomitant illness/previous drug reaction):*

Description	Start Date	End Date	Continuing

Additional information

Supply of report cards required Yes <input type="checkbox"/> No <input type="checkbox"/>	Manufacturer notified: Yes <input type="checkbox"/> No <input type="checkbox"/>
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Signature _____

Date:

Thank you for taking the time to complete this form