Adverse Event Report Form

(For reporting of Adverse events by Healthcare Professionals & Consumers)

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Please complete and return form to pv.india@viatris.com Note: Please fill mandatory fields (*)

REPORTER DETAILS *	
Name (First/Last)	
Healthcare Professional? ☐ Yes ☐ No	**Occupation:** (Include occupation e.g. physician, patient, etc)
Address/City/State Code/Country	
Telephone/Fax	
Email Address	
Has the report been reported to the Regulatory Authorities by the reporter? ☐ Yes ☐ No ☐ UNK	
Did the reporter give consent to contact for further follow up? ☐ Yes ☐ No	

PATIENT DETAILS*		
Initials/Patient ID	**Age**	**Age Units**
Sex ☐ Male ☐ Female	**DOB**	
Height	**Weight**	
Is the patient pregnant? ☐ Yes ☐ No ☐ UNK ☐ NA	**Date of LMP (**Last Menstrual Period)	

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SUSPECT PRODUCT(S)*								
Product Name/ Active Substance	**Batch No. / Expiry date**	**Route** (oral, etc.)	**Daily Dose**		**Treatment Dates**		**Indication**	**Action taken in response to AEs**
			Dose/ Unit	**Frequency**	**Start Date**	**End Date**		

CONCOMITANT PRODUCT(S)							
Product Name/ Active Substance	**Route** (oral, etc.)	**Daily Dose**		**Treatment Dates**		**Indication**	**Action taken in response to AEs**
		Dose/ Unit	**Frequency**	**Start Date**	**End Date**		

REPORTED ADVERSE EVENT(S) AND SPECIAL SITUATIONS *					
Event as reported	**Event dates**		**Seriousness criteria**	**Outcome**	**Reporter Causality**
	Start Date	**Stop Date**			

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OTHER RELEVANT HISTORY	
☐ None ☐ Unknown	
Condition	**Start – Stop Dates**

LAB DATA/ RELEVANT TESTS					
☐ None ☐ Unknown				Results Attached? ☐	
Lab Data Test	**Date**	**Results**	**Units**	**Normal Range**	**Notes**

ADDITIONAL INFORMATION: (Please give additional details on the adverse events, sequence of events, including hospitalisation details, treatment, relevant laboratory tests (if applicable) and to relevant information regarding processing of the case, for example follow up activities . This box can also be used to add extra information if you have run out of space in the other fields)