Mylan	Global
	Form
PSRM-OPS - Adverse Event Report Form	
Effective	5.0, CURRENT

REPORTER DETAILS	
Name (First/Last) *Please adhere to local privacy laws. See note below*	
Healthcare Professional? ☐ Yes ☐ No	**Occupation:** Choose an item.
Address/City/State Code *Please mark as 'Privacy' if details have been provided, but local data privacy laws prevents cross-border exchange of personal information*	
Telephone/Fax *Please adhere to local data privacy laws. See note above*	
Email Address *Please adhere to local data privacy laws. See note above*	
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 *Please adhere to local data privacy laws. See note above*	**Age**	**Age Units** Choose an item.
Sex ☐ Male ☐ Female	**DOB** Click or tap to enter a date.	
Height	**Weight**	
Is the patient pregnant? ☐ Yes ☐ No ☐ Unk.	**Date of LMP (**Last Menstrual Period) Click or tap to enter a date.	

SUSPECT PRODUCT(S) *(Please add additional rows if required)*

Product Name/ Active Substance (Check box for Mylan products)	**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**		
☐								Choose an item.
☐								Choose an item.
☐								Choose an item.
☐								Choose an item.
☐								Choose an item.

CONCOMITANT PRODUCT(S) *(Please add additional rows if required)*

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		
							Choose an item.
							Choose an item.
							Choose an item.
							Choose an item.
							Choose an item.

REPORTED ADVERSE EVENT(S) AND SPECIAL SITUATIONS
(Please add additional rows if required)

Event as reported	Event dates		Seriousness criteria	Outcome	Reporter Causality
	Start Date	Stop Date			
			Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.
			Choose an item.	Choose an item.	Choose an item.

OTHER RELEVANT HISTORY *(Please add additional rows if required)*	
☐ None ☐ Unknown	
Condition	**Start – Stop Dates**

LAB DATA/ RELEVANT TESTS *(Please add additional rows if required)*					
☐ 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). This box can also be used to add extra information if you have run out of space in the other fields)