

Pharmacovigilance Department
Adverse Event Reporting Form

Type of Report <input type="checkbox"/> Initial case <input type="checkbox"/> Follow up case			
(A) Patient Details*			
Patient Initials _____ (write RKM for Ramesh Kumar Mishra)		Country	
Age / Date of Birth: _____	Weight (in kg): _____	Pregnant	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other		Date of LMP (Last Menstrual Period)	In case of Pregnant, mention date of LMP DD/MM/YYYY _____

(B) Suspected Medication(s) *									
S. No.	Product Name		Manufacturer name	Batch number/ Expiry Date	Dose, Route & Frequency (OD/BD etc.)	Therapy Start date <small>DD/MM/YYYY</small>	Therapy Stop date <small>DD/MM/YYYY</small>	Indication	# Action Taken
	Brand Name	Generic Name with strength							
1.									
2.									
3.									

Select appropriate action taken:
Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

Did event abated after drug withdrawn/ dose reduced? <input type="checkbox"/> Yes / <input type="checkbox"/> No / <input type="checkbox"/> Unknown / <input type="checkbox"/> Not applicable	Did event reappeared after reintroduction? <input type="checkbox"/> Yes / <input type="checkbox"/> No / <input type="checkbox"/> Unknown / <input type="checkbox"/> Not applicable
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Concomitant medications (Any other medications consumed along with our company drugs):

Drug Name	Dose & Frequency	Route	Therapy dates		Reason for use
			From	To	

(C) Adverse Event Details *			
Adverse event	Date of event Onset	Date of event stopped	## Outcome

Select outcome of adverse event: *Recovering; Recovered; Not Recovered; Recovered with sequelae; Unknown; Fatal*

Is the adverse event serious? ☐ Yes / ☐ No

If yes, please indicate why it is serious? (Check all that apply)

<input type="checkbox"/> Death	<input type="checkbox"/> Life threatening	<input type="checkbox"/> Hospitalization-Initial /Prolonged
<input type="checkbox"/> Congenital anomaly/birth defect	<input type="checkbox"/> Disability	<input type="checkbox"/> Other important medical event

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If hospitalized provide: Date of admission _____ Date of discharge _____	If Death, provide: Date of death DD/MM/YYYY _____ Cause of death _____
Description of adverse events: (including sign and symptoms with specific diagnosis, treatment): _____ _____	
Relevant Lab test Details (with dates, results and normal range) : _____ _____	
Other relevant history including pre-existing medical conditions: (e.g. allergies, smoking, alcohol use, liver/kidney problems etc.) _____ _____	
Relationship of the adverse event with drug: <input type="checkbox"/> Related <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown	

(D) Reporter details

Name:	Qualification:
Address:	Occupation:
Email:	Phone No.
Date of this report :	Signature:

*** Mandatory Fields for Adverse Event Reporting Form.**

ADVICE ABOUT REPORTING

Who can report? All healthcare professionals (Clinicians, Dentists, Pharmacists, Nurse etc.) can report adverse event.	Where to report? Please Send the complete filled form to: Registered office: M/s Prosper Channel Lifescience India Pvt. Ltd., <u>Pharmacovigilance department, Unit No-1004, Pearl Best Heights-2, Plot No-C-9, Netaji Subhash Place, Delhi-110034.</u> Or email the scanned copy to pv@prosperchannel.in
What to report? All adverse event should be reported. Report all (serious / non-serious adverse event) occurred due to medicines Imported by M/s Prosper Channel Lifescience India Pvt. Ltd.	

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of this report does not have any legal implication on the reporter.

This section filled by Prosper Channel Lifescience India Pvt. Ltd. only

Report ID: _____ Receipt Date: _____	<i>Signature and name of receiving PV-personnel at M/s Prosper Channel Lifescience India Pvt. Ltd.</i> _____
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