



Adverse Event Reporting Form (For Health Care Professionals)

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 & dosage form							
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# Select appropriate action taken: Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable									
Did event abated after drug withdrawn/ dose reduced?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				
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: <i>Recovering; Recovered; Not Recovered; Recovered with sequelae; Unknown; Fatal</i>			
Is the adverse event serious? <input type="checkbox"/> Yes / <input type="checkbox"/> 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 (Health Care Professional)*	
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: <u>M/s Synokem Pharmaceuticals Ltd., Pharmacovigilance department, 14/486, Sunder Vihar, Outer Ring Road, Paschim Vihar, New Delhi-110087, India.</u>
What to report? All adverse event should be reported. Report all (serious / non-serious adverse event) occurred due to medicines manufactured by M/s Synokem Pharmaceutical Ltd.	Or email the scanned copy to pv@synokempharma.com

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 Synokem only	
Report ID: _____ Receipt Date: _____	Signature and name of receiving PV-personnel at Synokem _____