Adverse Event Reporting Form (For Health Care Professionals)

Type of Report ☐ Initial case ☐ Follow up case

(A) Patient Details*

Patient Initials _____ (write RKM for Ramesh Kumar Mishra)		Country	
Age / Date of Birth: _____	Weight (in kg): _____	Pregnant	☐ Yes ☐ No ☐ Unknown
Gender: ☐ Male ☐ Female ☐ 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 DD/MM/YYYY	Therapy Stop date DD/MM/YYYY	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Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

Did event abated after drug withdrawn/ dose reduced? ☐ Yes / ☐ No / ☐ Unknown / ☐ Not applicable	Did event reappeared after reintroduction? ☐ Yes / ☐ No / ☐ Unknown / ☐ 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: *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)

☐ Death ☐ Life threatening ☐ Hospitalization-Initial /Prolonged

☐ Congenital anomaly/birth defect ☐ Disability ☐ 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: ☐ Related ☐ Not Related ☐ 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.

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.

Where to report?
Please Send the complete filled form to:

Registered office:

M/s Synokem Pharmaceuticals Ltd., Pharmacovigilance department, 14/486, Sunder Vihar, Outer Ring Road, Paschim Vihar, New Delhi-110087, India.

Or email the scanned copy to
pv@synokempharma.com
ska@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* _____