

Pharmacovigilance Department

ADVERSE EVENT REPORTING FORM

Type of Report: ☐ Initial case ☐ Follow up										
(A) Patient Details*										
Patient Initials		_____ [ex. Vishal Kumar Sharma <u>VKS</u>]				Country				
Age/ Date of Birth						Weight				
Gender		☐ Male ☐ Female ☐ Other				Pregnant		☐ Yes ☐ No ☐ Unknown		
(B) Suspected Medication(s) *										
S. No.	Product Name		Manufacturer name	Marketer 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/ formulation								
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# Select appropriate action taken: Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable										
Did event abated after drug withdrawn/ dose reduced?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 the event: <i>Recovering; Recovered; Not Recovered; Recovered with sequelae; Unknown; Fatal</i>										
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 _____ Attach the copy of discharge summary with this form.	If Death provide: Date of death DD/MM/YYYY ____ Cause of death _____ Autopsy: ☐ Yes ☐ No ☐ Unknown Autopsy result (If yes): _____
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.)	
(D) Reporter details*	
Name:	Occupation:
Email:	Phone No.
Address:	Date of this report:
Consent to contact Healthcare Professional (HCP) / Prescribing Physician: ☐ Yes ☐ No	
If yes, provide contact Healthcare Professional (HCP) / Prescribing Physician details	
Name:	Qualification:
Address:	
Email:	Phone No.

* Mandatory Fields for Adverse Event Reporting Form.

Please send the complete form to: Registered office: C.B. Healthcare SCF-266, First & Second Floor, Near Dental Clinic, Manimajra, Motor Market, Chandigarh-160101, India or email the scanned copy to: Email id hatinder@cbhealthcare.co.in
If any additional data, then please attach with this form:

This section filled by M/s C. B. Healthcare only:	
Report ID: _____	Receipt Date: _____
Name and Signature of receiving PV-personnel: _____	