CENTURY NOVA DRUGS

Pharmacovigilance Department
ADVERSE EVENT REPORTING FORM

Type of Report: ☐ Initial case ☐ Follow up

(A) Patient Details*

Patient Initials	_____(ex. Vishal Kumar Sharma VKS]	Country	
Age/ Date of Birth		Weight	
Gender		Pregnant	☐ Yes ☐ No ☐ Unknown

(B) Suspected Medication (s) *

S. No.	Product Name		Manufacturer Name	Marketer Name	Batch no./ Expiry Date	Dose, Route & Frequency (OD/BD etc	Therapy Start Date	Therapy Stop Date	Indication	# Action taken
	Brand Name	Generic Name with strength /Formula								
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Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

Did event abated after drug withdrawn/dose reduced?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	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: Recovering; Recovered; Not Recovered; Recovered with sequelde; 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_____ Attach the copy of discharge summary with this form.	If Death provide: Date of death _____ 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 ID;	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 ID;	Phone No.

* Mandatory Fields for Adverse Event Reporting Form.

Please send the complete form to:
Registered office: # Plot No.85, 86 Phase II, A.K.V.N Industrial Area, Umaria-Dungaria, Distt. Jabalpur 482003 (M.P.) or email the scanned copy to: Email id: centurynova123@gmail.com

If any additional data, then please attach with this form:

This section filled by M/s Century Nova Drugs Pvt. Ltd. only:

Report ID:_____	Receipt Date:_____
Name and Signature of receiving PV-personnel:	