



## Pharmacovigilance Department

# ADVERSE EVENT REPORTING FORM

<b>Type of Report:</b> <input type="checkbox"/> Initial case <input type="checkbox"/> Follow up										
<b>(A) Patient Details*</b>										
Patient Initials		_____ [ex. Vishal Kumar Sharma <u>VKS</u> ]				Country				
Age/ Date of Birth						Weight				
Gender		<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other				Pregnant		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
<b>(B) Suspected Medication(s) *</b>										
S. No.	Product Name		Manufacturer name	Marketer 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/ formulation								
1.										
2.										
3.										
<b># Select appropriate action taken:</b> Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable										
Did event abated after drug withdrawn/ dose reduced?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						
<b>(C) Adverse Event Details *</b>										
Adverse event		Date of event Onset		Date of event stopped		##Outcome				
<b>## Select outcome of the event:</b> <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 _____ Attach the copy of discharge summary with this form.	If Death provide: Date of death <small>DD/MM/YYYY</small> _____ Cause of death _____ Autopsy: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Autopsy result (If yes): _____
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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: #463, Director House, Opposite Hanuman Mandir, Near Krishna Gaushala, VPO-Saketri, Panchkula, Haryana-134109 or email the scanned copy to: Email id [Pharmacovigilance@ultradrugs.co.in](mailto:Pharmacovigilance@ultradrugs.co.in)

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

**This section filled by M/s Ultra Drugs Pvt. Ltd. only:**

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