

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	<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) Suspected Medication(s) *

S. No.	Product Name		Manufacturer name	Marketer Name	Batch number/ Expiry Date	Dose, Route & Frequency (OD/BD etc.)	Therapy	Therapy	Indication	# Action Taken
	Brand Name	Generic Name with strength/ formulation					DD/MM/YYYY	DD/MM/YYYY		
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Drug Withdrawn; Dose reduced; Dose increased; Does not changed; Unknown; Not applicable

Did event abated after drug withdrawn/ dose reduced?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
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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: *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)

<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 DD/MM/YYYY _____ Cause of death _____ Autopsy: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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: <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, provide contact Healthcare Professional (HCP) / Prescribing Physician details	
Name:	Qualification:
Address:	
Email:	Phone No.

* Mandatory Fields for Adverse Event Reporting Form.

<p>Please send the complete form to:</p> <p>Registered office: 220-221, Phase III, Ind. Area, Sansarpur Terrace, Distt. Kangra (H.P.), 176501 or email the scanned copy to: Email id info@emmwelpharma.com</p>
If any additional data, then please attach with this form:

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