

Adverse Event (AE) Report Form											
Attachment of the SOP No.: PV-004.06		SOP version: 06		SOP issue date: 24 June, 2026		Doc. No.: PV/AEF/001		Page of			
To be filled by Pharmacovigilance Team of Radiant		Date of receipt of AE by PV Team:		Processed by:		Checked by:		Case ID:			
		Day Zero:		Type of Report: ☐ Initial ☐ Follow-up ☐ Final ☐ Initial & Final							
		Source: ☐ Spontaneous ☐ Patient survey ☐ Study report ☐ Literature ☐ Other:									
REGION:					COUNTRY:						
REPORTER DETAILS					PATIENT DETAILS						
Reporter name:					Initials/Name/ID:						
Designation/Title					Name of health facility (If applicable):						
Address:					Patient address:						
E-mail address:					Contact number:						
Contact number:					Age_____ (yr) Weight_____ (kg) Height_____ (cm/ft)						
Date of submission:					Gender ☐ Male ☐ Female ☐ Unknown						
Occupation ☐ Physician (Specialty)_____					Pregnant ☐ Yes ☐ No ☐ Unknown ☐ Not applicable						
☐ Pharmacist ☐ Nurse ☐ Consumer ☐ Company rep.					Breastfeeding ☐ Yes ☐ No ☐ Unknown ☐ Not applicable						
SUSPECTED DRUG DETAILS (If more than 3, please list in additional information section or use duplicate form if needed)											
Particulars		Suspected drug product 1		Suspected drug product 2		Suspected drug product 3					
Brand name											
Generic name											
Strength											
Dosage form											
Dose(unit)											
Frequency											
Indication											
Batch number											
Route											
Manufacturer											
Medication start date (Day/Mon/Yr)											
Medication stop date (Day/Mon/Yr)											
ADVERSE EVENTS (Please continue in additional information section or use duplicate form if needed)											
Symptoms		Date of onset/start (Day/Month/Year)		Was any diagnosis done for AE? (Yes/No, if yes, specify)		Was AE/symptom treated? (Yes/No, if yes, specify)		Date of resolve/stop (Day/Month/Year)			
Nature of Event (Tick where applicable)		☐ Suspected ADR ☐ Overdose ☐ Off label use ☐ Abuse ☐ Misuse ☐ Occupational exposure ☐ Medication errors ☐ Lack of efficacy ☐ Product quality problem ☐ Other_____									
Action taken after the adverse reaction		Did adverse reaction diminish after stopping/reducing dose of product?		Was product restarted after adverse reaction diminished?							
☐ Dose stopped ☐ Dose reduced ☐ Unknown ☐ No action taken/dose continued		☐ Yes ☐ Unknown ☐ No ☐ Not applicable		☐ Yes ☐ No ☐ Unknown ☐ Not applicable If yes, did adverse reaction reappear? ☐ Yes ☐ No ☐ Unknown ☐ Not applicable							
Seriousness of the adverse event (Tick where applicable) ☐ Death ☐ Required/prolongation of hospitalization ☐ Congenital anomaly/birth defect ☐ Persistent/significant disability ☐ Life threatening ☐ Non-serious ☐ Other serious (specify):_____ ☐ Other medically significant event (specify):_____											
Outcome of the adverse event (at the time of this report) ☐ Complete recovery ☐ Recovering ☐ Not recovered/On-going ☐ Unknown ☐ Fatal _____ ☐ Recovered with sequelae, specify sequelae _____											

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CONCOMITANT MEDICATION (If more than 3, please list in additional information section or use duplicate form if needed)																			
Particulars				Product 1				Product 2				Product 3							
Brand name																			
Generic name																			
Strength																			
Dosage form																			
Dose(unit)																			
Frequency																			
Indication																			
Route																			
Medication start date (Day/Mon/Yr)																			
Medication stop date (Day/Mon/Yr)																			
Other relevant medical history [Provide any other information that can help in the evaluation of the reported adverse event such as relevant medical history (diabetes, hypertension, liver/kidney problems, etc.), race, allergies, smoking and alcohol use, etc]																			
Causality relationship with drug reaction: ☐ Certain ☐ Probable ☐ Doubtful ☐ Unassessable ☐ Not assessed																			
Has the regulatory authority been notified of this report? ☐ Yes ☐ No ☐ Not applicable																			
Has the patient discussed the event with health care professional? ☐ Yes ☐ No ☐ Unknown If yes, name/initial of health care professional _____ Contact : _____																			
Case narrative including relevant tests & laboratory results (Attachment if any) (Detail description, investigation of ADR, PQC/MIQ associated with adverse event, medication error etc)																			
Additional information section (List of attachment if any)																			
Consent taken for follow-up ☐ Yes ☐ No ☐ Not given																			
Remarks (of Pharmacovigilance Team of Radiant)																			
																		_____ Signature & date	
_____ Reporter's signature										Date: ____ / ____ / ____ (Day/Month/Year)									