

ADVERSE EVENT (AE) REPORT FORM

UID number (for office use only): _____ Date of report: _____

Type of report: Initial follow up/number (Please specify) _____



Reporter Details: Reporter is HCP: physician patient nurse others (Please specify) _____

Consumer: patient relative friend others (Please specify) _____

Name: _____ Qualification/designation: _____ Address: _____

City _____ State _____ Zip code: _____ country _____ Contact number: _____

Email: _____

Permission to contact treating physician (If reporter is a consumer): Yes No Unknown (If YES, provide contact details of physician below)

Treating Physician Details:

Name: _____ Contact number: _____

Email: _____ Address: _____

city: _____ state: _____ Zip code: _____ Country: _____

Patient detail: Name/Initial: _____ Age at the time of onset of AE: _____

years DOB: _____ Sex: M F Unknown Weight: _____ kg/lbs

Hospital registration number (If any): _____

Adverse Event details						
Adverse Event(s)	Date of onset DD/MM/YY	*Causal relationship with the suspect drug	*** Outcome	Date of resolution /ongoing	Severity (Mild/Moderate/Severe)	**Seriousness (serious/nonserious)

*Select the appropriate causality term (refer page 4 for assessment criteria of below mentioned causality): **CR**; certainly related, **POR**; possibly related, **PRR**; probably related, **ULR**; Unlikely related, **UC**; unclassified, **UA**; unassessable **NR**; Not related

**If serious select seriousness criteria: Death Disability Life threatening Medically significant Congenital Anomaly/Birth Defect Hospitalization Prolongation of hospitalization

*** Select the appropriate outcome of the event term: **R**- Resolved, **I**- Improving, **P**- Persisting, **U**- Unknown, **RS**- Resolved with Sequelae

If Hospitalized provide
 Date of admission _____ Date of discharge _____
 Attach the copy of discharge summary with this form.

Suspect drug details

Prescribed by Physician Yes No

Product name with dosage form and strength. Trade name (generic)	Indication	Route/ formulation/freq uency/strength	Batch No.	Mfg. Date	Expiry date	Therapy date	
						Start date DD/MM/ YY	Stop date DD/MM/ YY

Is there any product quality complaint: Yes No (If YES please provide brief description in narrative section)

Action Taken with suspect drug (If more than one AE kindly mention in Narrative section): drug withdrawn reducing drug dose interrupting drug dose no change in drug dose drug dose increased NA
 Reaction subsided after action taken: Yes No NA
 Reaction reappeared after re-introducing drug Yes No NA

Death Information

Date of Death (DD/MM/YYYY): _____ Autopsy: Yes No Unknown
 Cause of Death: _____ Autopsy result (if yes): _____

Concomitant Medications

Product name Trade name (Generic name)	Indication	Route/ formulation/ frequency/strength	Therapy dates (DD/MM/YY)		Continued (Yes/No)
			Start date	Stop date	

Relevant Medical History Medical history (in addition to indications mentioned above): Yes No

Medical History	Start date	Stop date (Ongoing/Past history)

Any laboratory test performed: Yes No

Test name	Result	Normal range	Date performed

Brief Narrative (Description of adverse event, treatment for adverse event if any and additional information missing in the form):

Response provided to the reporter:

Note: In-Case of diagnostic test/lab test/abnormal ECG/biopsy etc. attach the copy of reports with this form.

 (PVD personnel signature with date)
 (for Office use only)

Email us at:
DrugSafety@biocon.com

*The assessment criteria of the various categories (WHO-UMC causality Categories)

CAUSALITY TERM	ASSESSMENT CRITERIA*
Certain/Definitely related	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/ Likely	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	<ul style="list-style-type: none"> • Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	<ul style="list-style-type: none"> • Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified