



SAMI DRUG SAFETY REPORTING FORM



To be filled by SAMI Drug Safety

To be filled by Reporter

SAMI AE number	MCN number (if applicable)	Patient Registration ID (if applicable)	First Contact Date:
Report type: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up: No:	SAMI MI number (if applicable)	Does patient give consent to obtain follow-up information from HCP? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Latest contact Date:

REPORTER TYPE

Doctor (specialty: _____) Regulatory Authority
 Pharmacist Company Representative
 Nurse Consumer
 Social Media (e.g. Facebook, Twitter, Website) Literature
 Other (specify: _____)

PATIENT INFORMATION

Initials _____ Date of Birth or Age (years) or Age Group _____
 Gender Male Female Unknown Child (<18 yrs)
 Weight: lb kg Adult (≥18 yrs <65 yrs)
 Height: inch cm Elderly (≥ 65 yrs)
 Country: Pakistan Other: Please specify _____

SUSPECT DRUG (s) DETAILS – use additional sheets if required

Drug Name	Indication	Dose	Route	Frequency	Start Date	Stop Date/ongoing	Batch / lot No.	Manufacturer Name

Action taken due to the Adverse Event?
 None Dosage changed (specify _____) Discontinued Unknown

Corrective treatment?
 No Yes (specify: _____)

Did reaction abate after stopping drug/dose reduction?
 Yes No Unknown Not applicable

Was drug restarted after reaction abated?
 Yes No Unknown Not applicable

If yes, did reaction recur?
 Yes No Unknown Not applicable

ADVERSE EVENT (S) DETAILS - use additional sheets if required

Adverse Event (adverse event description, provide diagnosis if known)	Onset Date	Resolved / Improved Date	Seriousness (as per key below one or more)	Outcome
				1. Death 2. Not Resolved 3. Resolved 4. Resolved with sequelae 5. Resolving 6. Unknown
				1. <input type="checkbox"/> 2. <input type="checkbox"/> 3. <input type="checkbox"/> 4. <input type="checkbox"/> 5. <input type="checkbox"/> 6. <input type="checkbox"/>

Special Situation Report (SSR) Details – Did any of the following occur?

Lack of Efficacy Off Label Use Misuse Abuse Overdose Medication Error
 Pregnancy Report Infant with AEs following exposure from Breastfeeding
 Occupational exposure with AE Drug Interactions Unexpected Benefits
 Transmission of Infectious Agents via the Product Medical Device Incident
 Counterfeit or Falsified Medicines

In case of potential event related to Lack of Efficacy, marked expected reason:

Antimicrobial Resistance Drug Interaction Poor Treat Compliance
 Counterfeit Expired Under Dosing Improper Storage
 Other: specify: _____

In case of Medication Error (actual/potential):

ME with AE ME without AE
 Marked expected reason: Storage Prescription Dispensing
 Preparation for Admin Missed Dose Administration by HCP/Patient/Consumer
 Other: specify: _____

Key for seriousness criteria classification

1. Death: Date of Death: _____
Was autopsy performed? Yes No (If yes attach report)
2. Life Threatening (immediate risk of death due to event)
3. Initial / Prolonged Hospitalization, provide dates: _____ to _____
4. Birth defects
5. Persistent or significant disability
6. Medically significant (Important Medical events that may jeopardize the patient and may require medical / surgical intervention to prevent the other outcome)
7. Non Serious
8. No seriousness criteria provided

CAUSAL RELATIONSHIP OF ADVERSE EVENT:

Certain Probable / Likely Possible Unlikely Conditional /Unclassified Unassessable/Unclassifiable Not reported

CONCOMITANT DRUG(S) AND THERAPIES DETAILS - use additional sheets if required

Were any concomitant drugs/therapies used? Yes (specify below) No Unknown

Drug Name Indicate Form / Strength	Indication	Frequency	Route	Treatment Dates	
				Start	End (or ongoing)
					or <input type="checkbox"/> ongoing
					or <input type="checkbox"/> ongoing
					or <input type="checkbox"/> ongoing

SUMMARY OF EVENTS / RELEVANT MEDICAL HISTORY DETAILS - use additional sheets if required (Please provide a short summary of the event(s) and include any treatment given, relevant medical history, risk factors, outcome, surgeries, allergies, any intervention given and pregnancy with date of last period)

LABORATORY DATA/ INVESTIGATIONS DETAILS - use additional sheets if required

Lab test	Result	Unit	Date of test	Normal range

REPORTER DETAILS:

Name: _____ Address: _____ Signature: _____ Date: _____
 Email address: _____ Telephone number: _____ Fax number: _____

Please email / fax / mail completed form within 24 hours of being aware of event

Email: safety@samikhi.com
 Tel No (office and out of office hours): +92 21 34383400
 Fax: +92 21 34382012 SMS/WhatsApp: 0308 8367416 (24/7 Operations)



Mail: SAMI Pharmaceuticals (Pvt.) Limited
 Head Office: 34-C, Block 6, P. E. C. H. S., Karachi-75350, Pakistan