Alkem Laboratories Limited

ALKEM

Adverse Drug Reaction Reporting Form

A. Patient Details

Patient Initials: __ __ __ Sex: [ ]F [ ]M	Age: _____ yrs or _____ months Date of Birth: (DD/MM/YYYY)	Weight: ____ Kg or _____ Lb Pregnant: [ ] Yes [ ] No	[ ] Adverse Event [ ] Product Problem (e.g., defects/malfunctions)

Other relevant history including pre-existing medical conditions (e.g. allergies, smoking, alcohol use, hepatic/ renal dysfunction etc.):

B. ADR Details

ADR term(s):	Date reaction(s) started: (DD/MM/YYYY) Date reaction(s) Stopped: (DD/MM/YYYY)
Description of adverse events: (including sign and symptoms with specific diagnosis, treatment and action taken):	[ ] Death ______________(DD/MM/YYYY) [ ] Life Threatening [ ] Hospitalization- Initial/ Prolonged [ ] Disability [ ] Congenital Anomaly [ ] Required intervention to prevent permanent impairment/ damage [ ] Other (specify)

Outcome of the event: [ ] Fatal [ ] Continuing [ ] Recovering [ ] Recovered [ ] Unknown [ ] Other(specify)

Lab test Details (with dates, results and normal range)

C. Drug details

Sr. No.	Name (brand and/or generic name)	Manufacturer (if known)	Batch no. / Lot no. (if known)	Exp. date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										

	Reaction abated after drug stopped or dose reduced					**Reaction reappeared after re-introduction**				
	Yes	No	Unknown	NA	If reduced, specify dose	Yes	No	Unknown	NA	If reduced, specify dose
i										
ii										
iii										

Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. Reporter Details

Name and Address : Pin code: E-mail: Occupation Signature:	 Tel. No. (with STD code): Date of reporting: (DD/MM/YYYY)	Causality Assessment [ ] Certainly [ ] Probably [ ] Possibly [ ] Unlikely [ ] Conditional [ ] Unassessable

Send the report to the below address	**To be filled by Alkem:**
Alkem Laboratories Ltd. Global Pharmacovigilance Cell, aŜŘƛŎŀƭ 5ŜǇŀǊǘƳŜƴǘΣ Unit No. 301, wing B, 3rd Floor, Marathon Innovo, Ganpatrao Kadam Marg, hǇǇΦ Peninsula Park Lower Parel (W) Mumbai- 400013 India.	Date received by receiver: (DD/MM/YYYY) Name and sign of receiver: Report Type: [ ] Initial [ ] Follow up, number: ………..

Toll-Free Number: 1800-22-99-10 Email: pvglobal@alkem.com

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.