# Alkem Laboratories Limited

## Adverse Drug Reaction Reporting Form

### A. Patient Details

| | | | |
|---|---|---|---|
| Patient Initials: __ __ __<br><br>Sex: [ ]F [ ]M | Age: _____ yrs or _____ months<br><br>Date of Birth: (DD/MM/YYYY) | Weight: ____ Kg or _____ Lb<br><br>Pregnant: [ ] Yes [ ] No | [ ] Adverse Event<br>[ ] 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)<br>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)<br>[ ] Life Threatening<br>[ ] Hospitalization- Initial/ Prolonged<br>[ ] Disability<br>[ ] Congenital Anomaly<br>[ ] Required intervention to prevent permanent impairment/ damage<br>[ ] 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 :<br><br>Pin code: E-mail: Tel. No. (with STD code):<br><br>Occupation Signature: Date of reporting: (DD/MM/YYYY) | Causality Assessment<br>[ ] Certainly<br>[ ] Probably<br>[ ] Possibly<br>[ ] Unlikely<br>[ ] Conditional<br>[ ] Unassessable |

| **Send this report to:** | **To be filled by Alkem:** |
|---|---|
| Pharmacovigilance Team, Medical Department,<br>Alkem Laboratories Ltd., Office No G/4, Empire Complex,<br>414,Senapati Bapat Marg, Lower Parel, Mumbai - 400013.<br>Toll Free: 1800-22-9910; E-mail: pvglobal@alkem.com<br>Website: https://www.alkemlabs.com/adverse-event-reporting.php | Date received by receiver: (DD/MM/YYYY)<br>Name and sign of receiver:<br>Report Type: [ ] Initial [ ] Follow up, number: ..... |

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