USK THERAPEUTICS PVT LTD

Guidance on Adverse Event Reporting

Why to report?

- Detection of unknown safety issues associated with medicines
- Detection of increases in frequency of known safety issues associated with medicines
- Identification of risk factors
- Quantifying risks associated with medicines
- Preventing patients from being adversely affected unnecessarily after medicine intake
- Patient safety
- Compliance/Regulatory Requirements.

When to report?

Within 24 hours of noticing any safety issue/product complaint

Who can report?

Any health care professionals (such as physicians, pharmacists, nurses) and consumers (such as patients, familymembers)

How to report?

For adverse events or product feedback/complaints, please fill adverse event form and email to
info@usktpl.com or directly call on Help Line Numbers.

What to report?

If you get to know that an adverse event has occurred; collect the below minimum information:

- Details of the patient: Characterized by initials, patient identification number, date of birth, age orgender
- Details of the reporter: Characterized by qualification (e.g., physician, pharmacist, other healthcareprofessional, lawyer, consumer or other nonhealthcare professional) name, initials, or address
- A USKTPL suspect drug: One or more suspected substance/medicinal product
- Adverse Event (AE): One or more suspected adverse event (may or may not be related to USKTPL product)

Confidentiality of the events reported

The patient's and reporter's identity are handled with strict confidentiality. Company shall not disclose the reporter's or patient's identity in response to a request from the public.

To report an adverse event (Side Effect) about a USK Therapeutics product in INDIA, please contact us at:

Email:
info@usktpl.com

Phone:
+91 72079 42646 (Monday through Friday 10 AM to 5 PM)

Mail:
USK Therapeutics Private Limited
D.NO.15-28-11/1, G P RAO, ENCLAVE, ROAD NO.3, KPHB COLONY, KUKATPALLY(V), KUKATPALLY(M), MEDCHAL - MALKAJGIRI(D), TELANGANA HYDERABAD-500072.