KAISHA Lifesciences

ADVERSE EVENT REPORTING FORM

Please mail this form to:

Kaisha Lifesciences Private Limited, Survey No. 342/3(77), Village Bhimpore, Nani Daman – 396210, Landline: +91 7574996300/400. Or Email at: pv@kaishalifesciences.com.

A. Patient Information

1. Name/Initials:
2. Age:
3. Sex: □ Male □ Female □ Other
4. Weight:_____ Kg
5. Country:

B. Adverse Event

6. Date when event started(dd/mm/yyyy):
7. Date of recovery (dd/mm/yyyy):
8. Describe Event, Problem or Product Use Error:
9. Seriousness of the event: □ No □Yes (if yes please tick anyone)

□ Death
□ Life-threatening
□ Hospitalization/ Prolonged
□ Others (Specify)
□ Congenital anomaly
□ Disability
□ Required intervention to prevent permanent impairment/damage

10. Relevant tests/laboratory data (attach memo, if required):
11. Other relevant history, including pre-existing medical conditions (e.g., allergy, pregnancy, smoking and alcohol use, hepatic/renal dysfunction etc.):
14. Concomitant medicinal products (name, dose, frequency, and route used), and therapy dates (dd/mm/yyyy) (exclude those used for treatment of adverse event):
15. Reaction abated after use stopped or dose reduced
□ Yes □ No □ NA
16. Reaction reappeared after reintroduction
□ Yes □ No □ NA
17. Outcomes
□ Recovered □ Not recovered
□ Recovering □ Unknown
□ Fatal □ Other

D. Reporter's Details

18. Name:
19. Address:
20. Phone No.: 21. Fax:
22. Pin Code 23. E-mail:
24. Occupation:
25. Complaint Sample Available? □ Yes □No
26. Also reported to: □ Regulatory Agencies
□ Distributor/ Sales Personnel
27. Date of this report (dd/mm/yyyy):

C. Suspected Medications/ Drugs use details

Sr. No	12. Name (Brand/Generic)	Manufacturer (if known)	Strength	Batch No	Expiry Date	Dose Used	Route Used	Frequency
1								
2								
3								
4								

Therapy Dates

Sr. No	13. Start Date	End Date	Duration	Batch No	Expiry Date	Indications
1						
2						
3						
4						

CONFIDENTIAL

Any information related to the identities of the reporter and patient will be kept confidential.

1. What is an adverse event?

An adverse event is any undesirable experience associated with the use of a medicinal product in a patient. It is commonly referred to as a "side effect".

2. What does this include?

- Undesirable symptoms and signs e.g., headache, vomiting, abnormal ECG.
- Medication errors e.g., wrong dose, intravenous administration instead of intramuscular
- Overdose
- Drug Interactions
- Drug Misuse or Abuse
- Drug exposure during pregnancy and breastfeeding
- Product technical complaints e.g., discoloured or deteriorated products, improper labelling
- Lack of drug effect

3. Why should I report an adverse event?

We don't want to miss out on important data which could help us use our medicines more effectively and safely. If you report an adverse event, It would also help us identify rare adverse effects, unexpected/unknown adverse effects, drug/food interactions with medications, unknown risk factors and long-term safety profile of the medications.

4. What to report?

a. Patient Identifier

- Who experienced the Adverse Event?
- Patient and reporter identifier is important to avoid case duplication and facilitate follow up of appropriate cases.
- The term identifiable in this context refers to the verification of the existence of a patient (e.g., you might provide sex, age etc)

b. Event Description

- Describe the nature of the adverse event, any signs and symptoms and outcome of the event.

c. Reporter Details

- Who is reporting the Event?
- Give your name, address, and phone number as you may need to be contacted for further information.
- If you are reporting on behalf of a healthcare professional (e.g., if you are a sales representative), be prepared to also give their details.

d. Drug Details

- These include name, batch number, dosage etc. of the medicinal product suspected to cause the adverse event.

5. Who can report?

Health care professionals (Doctors, Dentists, Nurses, Pharmacists) and Non-healthcare professional (Patient, relative, friend, etc).

6. Where to report?

- Just fill in the sections that apply to your report.
- Attach additional pages if needed.
- Use a separate form for each patient and event.

Please mail this form to: Kaisha Lifesciences Private Limited, Survey No. 342/3(77), Village Bhimpore, Nani Daman – 396210, Landline: +91 7574996300/400. Or Email at: pv@kaishalifesciences.com