JENBURKT
Delivering Excellence in Life Sciences

Jenburkt Pharmaceuticals Ltd.

Suspected Adverse Event Reporting Form

A. PATIENT INFORMATION**

1. Patient Initials ..... (first, last)

2. Age at time of event ..... years

OR

Date of Birth / / dd/mm/yyyy

3. Gender (please tick) ☐ M ☐ F ☐ Other

4. Weight ..... kg

5. Height ..... cm

6. Country .....

B. SUSPECTED ADVERSE EVENT**

7. Date when event started / / dd/mm/yyyy

8. Date when event stopped / / dd/mm/yyyy

9. Describe adverse event, and its management with details

10. Relationship of event to the suspected medication (Causality) (please tick)

☐ Certain ☐ Probable/Likely ☐ Possible ☐ Unlikely

☐ Conditional/ Unclassified ☐ Unassessable/ Unclassifiable ☐ Unknown

C. SUSPECTED MEDICATION(S)**

11. S. No.	Brand Name	Generic Name	Formulation/ Strength	Batch No./ Lot No.	Expiry Date	Daily dose	Route	Frequency	Therapy - Start Date	Therapy - Stop Date	Indication for use
i											
ii											
iii											

12. Action taken with respect to suspect medication (please tick) ☐ Unknown ☐ Not Applicable ☐ No ☐ Yes If Yes, choose one of the below (please tick)

☐ Dose decreased Date of dose decrease / / dd/mm/yyyy

☐ Temporarily discontinued* Date stopped / / dd/mm/yyyy Date re-started / / dd/mm/yyyy

☐ Permanently discontinued$ Date stopped / / dd/mm/yyyy

☐ Dose increased Date of dose increase / / dd/mm/yyyy

13. $Did the event abate after stopping the drug (De-challenge) (please tick) ☐ Unknown ☐ No ☐ Yes ☐ Not Applicable

14. *Did the event reappear after re-starting the drug (Re-challenge) (please tick) ☐ Unknown ☐ No ☐ Yes ☐ Not Applicable

15. Concomitant medical products and therapy dates including self-medication and herbal remedies (exclude those used to treat event)

S. No.	Name (Brand / generic)	Daily dose	Route	Frequency	Therapy - Start Date	Therapy - Stop Date	Indication for use
i							
ii							
iii							

16. Relevant tests/investigations/laboratory data, including dates

17. Relevant medical/medication history (e.g. allergies, pregnancy, addiction, smoking alcohol use, hepatic/renal dysfunction etc.)

18. Seriousness of the event (please tick) ☐ Not Serious ☐ Serious If Serious, then choose the relevant box (please tick)

☐ Death / / dd/mm/yyyy ☐ Hospitalization-Initial/Prolonged ☐ Congenital anomaly/Birth defect

☐ Life threatening ☐ Significant disability ☐ Other medically important event

19. Outcome of the event (please tick) ☐ Recovered/Resolved ☐ Recovered/Resolved with sequelae ☐ Recovering/Resolving (Improved) ☐ Not Recovered/Resolved

☐ Worsened ☐ Fatal ☐ Unknown

D. REPORTER DETAILS**

Are you (please tick) ☐ Healthcare Professional ☐ Consumer ☐ Other

20. Name and Address

City Pin code Country

Telephone No. Email ID

Qualifications Signature

Date of this report / / dd/mm/yyyy

E. REPORTER CONSENT**

Permission given by reporter to follow up (please tick) ☐ No ☐ Yes

If reporter is a consumer, is permission given to contact your Healthcare Professional? (please tick)

☐ No ☐ Yes If Yes, please provide the details

Healthcare Professional contact details Name

Speciality Telephone No.

FOR COMPANY OFFICE USE ONLY

Date of receipt of information / / dd/mm/yyyy Country (Name) of Incidence

Worldwide Unique No. ☐ Initial Report ☐ Follow-up Report

The identity of the patient and reporter will be kept strictly confidential and protected in accordance with the applicable laws, including accessing, processing and preserving the data submitted herein above. Submission of this report does not imply or admit that the medical personnel, manufacturer, marketer, or the product caused or contributed to the adverse event. Reporting this adverse event has no legal implications on the reporter, medical personnel, manufacturer or marketer of the product.

**Mandatory Fields

Kindly email the completed form to: **drugsafety@jenburkt.com**

Please use extra pages if space is insufficient and attach them to this form.