SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

PLASMAGEN BIOSCIENCES Chamarajpet, Bangalore-560018, Karnataka, India	**To be filled by Plasmagen PV Department:** ADR Report No.:
Report Type Initial ☐ Follow up ☐ _____	

A. PATIENT INFORMATION

1.Patient Initials _____	2. Age at time of Event or Date of Birth _____	3. M ☐ F ☐ Other ☐ 4. Weight_____Kgs

13. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy)

6. Event/Reaction stop date (dd/mm/yyyy)

7. Date of recovery (dd/mm/yyyy) or ongoing:

8. Describe Event/Reaction with treatment details, if any

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

15. Seriousness of the reaction: No ☐ If yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization/Prolonged ☐ Other Medically Important

16. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S. No	9. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											

iii											
iv											

S. No as per C	10. Action Taken (please tick)						11. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

12. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii.							

Additional Information:

D. REPORTER DETAILS

17. Name and Professional Address:

_____

_____

_____Pin:_____

E- mail_____

Tel. No. (with STD code) _____

Occupation:_____Signature:_____

18. Date of this report (dd/mm/yyyy):

<u>Confidentiality</u>: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

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www.plasmagen.in

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ADVICE ABOUT REPORTING

A. What to report

a. Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
   i. Death
   ii. Life-threatening
   iii. Hospitalization (initial or prolonged)
   iv. Disability (significant, persistent, or permanent)
   v. Congenital anomaly
   vi. Required intervention to prevent permanent impairment or damage.

b. Report non-serious, known, or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report?

a. All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions.

C. Where to report

a. Duly filled Suspected Adverse Drug Reaction Reporting Form can be sent to the Plasmagen Biosciences Pvt. Ltd.

b. Or can directly mail this filled form to pv@plasmagen.in

c. For more info regarding ADR reporting: www.plasmagen.in

D. What happens to the submitted information?

a. Information provided in this form is handled in strict confidence. The analyzed forms are forwarded to the NCC through ADR database.

b. The reports are periodically reviewed by the NCC-PvPI. The information generated based on these reports helps in continuous assessment of the benefit-risk ratio of medicines.

c. The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on:

+918197761799

(24/7, All Days)