

v												
S · N o a s p e r C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)					
	Drug withdra wn	Dose increased	Dose reduced	Dose not chang ed	Not applicab le	U n k n o w n	Yes	No	Effect unknown	Dose (if reintroduced)		
	i											
	ii											
	iii											
iv												
11. Any other medical product including self-medication and herbal remedies used (Exclude those used to treat reaction):												
Additional Information:						D. REPORTER DETAILS						
						16. Name and Professional Address: _____ _____ _____ Pin: _____ E- mail _____ Tel. No. (with STD code) _____ Occupation: _____ Signature: _____						
						17. 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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pv@plasmagen.in
www.plasmagen.in

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. www.plasmagen.in (for more info regarding ADR reporting: <http://www.ipc.gov.in>, A list of nationwide AMCs is available at: http://www.ipc.gov.in/PvPI/pv_home.html)

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)