

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (First, Last) UNK	1a. COUNTRY Costa Rica	2. DATE OF BIRTH UNK	2a. AGE UNK	3. SEX Female	4-6 REACTION ONSET UNK	8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED INVOLVED OR PROLONGED IN-PATIENT ☐ HOSPITALISATION INVOLVED PERSISTENCE OR SIGNIFICANT ☐ DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ OTHER MEDICALLY SIGNIFICANT EVENT
7. + 13. DESCRIBE REACTION(S) (including relevant tests / lab data) [further details on Continuation Page] Events Patients had no therapeutic effect ((LLT) Lack of drug effect) From UNK To UNK Duration UNK Initial information (09-JUN-2025) City of occurrence: Not reported. Reporter reports that the physician commented that two female patients were given approximately 120 units of Dysport and had no therapeutic effect. After 15 days of the first application, the product was reapplied. The reporter sent forms to the physician for further						

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECTED DRUG(S) (include generic name) 1) DYSPORT (CLOSTRIDIUM BOTULINUM TYPE A TOXIN HEMAGGLUTININ COMPLEX); MAH Ref 4132-AEX-9635; Formulation Powder for solution for injection		20. DID REACTION ABATE AFTER STOPPING DRUG? YES ☐ NO ☐ NA ☒
15. DAILY DOSE(S) 1) 120 IU	16. ROUTE(S) OF ADMINISTRATION 1) Unknown	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? YES ☐ NO ☐ NA ☒
17. INDICATION(S) FOR USE 1) Unknown		
18. THERAPY DATES (From/To) 1) From: To:	19. THERAPY DURATION 1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)	Route	From	To
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc) Medical History: (Unknown (LLT) UNK)			

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER IPSEN LIMITED Costa Rica	24b. MFR CONTROL No. 2025-CR-000003	Primary Reporter: Y CG Costa Rica PV Safety Group: Biopas Calle 127A #53A-45 Torre 2, Oficina 1202 Bogota 111121 Colombia
24c. DATE RECEIVED BY MANUFACTURER 9-Jun-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROF ☒ NOS Other	
DATE OF THIS REPORT 17-Jun-2025	25a. REPORT TYPE ☒ INITIAL ☐ FOLLOW-UP	

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MANUFACTURER CONTROL NUMBER		2025-CR-000003													
7. + 13. DESCRIBE REACTION(S) (including relevant tests / lab data) - continued information, but no response has been obtained. The presentation of dysport is unknown. The reporter did not report the causality of the events.															
[Site Details - continued]															
26. REMARKS Clinical trial Clinical trial patient number:															