SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1.PATIENT INITIALS (First, Last)	1a. COUNTRY	2. DATE OF BIRTH	2a. AGE	3. SEX	4-6 REACTION ONSET
UNK	Costa Rica	UNK	UNK	Female	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	From	To	Duration
Patients had no therapeutic effect ((LLT) Lack of drug effect)	UNK	UNK	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-000002

24c. DATE RECEIVED BY MANUFACTURER

9-Jun-2025

24d. REPORT SOURCE

☐ STUDY ☐ LITERATURE
☐ HEALTH PROF ☒ NOS Other

DATE OF THIS REPORT

12-Jun-2025

25a. REPORT TYPE

☒ INITIAL ☐ FOLLOW-UP

Primary Reporter:
Y CG
Costa Rica

PV Safety Group:
Biopas
Calle 127A #53A-45
Torre 2, Oficina 1202
Bogota 111121
Colombia

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MANUFACTURER CONTROL NUMBER	2025-CR-000002

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: