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
KPA	Costa Rica	3-May-1985	39 Year(s)	Female	3-May-2025

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
the expected effect of temporary facial muscle paralysis was not produced ((LLT) No therapeutic response)	3-May-2025	3-Jun-2025	31 Days
At the time of reconstitution of the product the presence of the usual vacuum in the bottle is not evident since there is no suction of the physiological saline ((LLT) Product quality	2-May-2025	UNK	UNK

II. SUSPECT DRUG(S) INFORMATION

[further details on Continuation Page for 14-19]

14. SUSPECTED DRUG(S) (include generic name)

1) DYSPORT (CLOSTRIDIUM BOTULINUM TYPE A TOXIN HEMAGGLUTININ COMPLEX);MAH
Ref 4132-AEX-9635;Lot# 018421;Expiry date Nov-2026;Formulation Powder for solution for injection
1) DYSPORT (CLOSTRIDIUM BOTULINUM TYPE A TOXIN HEMAGGLUTININ COMPLEX);MAH

20. DID REACTION ABATE AFTER STOPPING DRUG? YES ☐ NO ☐ NA ☒

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) 300 IU x 1 per Once	1) intramuscular
1)	1) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? YES ☐ NO ☐ NA ☒

17. INDICATION(S) FOR USE 1) Aesthetics

18. THERAPY DATES (From/To)	19. THERAPY DURATION
1) From: 2-May-2025 To: 2-May-2025	1) 0 Days
1) From: May-2025* To:	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:
Overweight
((LLT) Overweight)
(Unknown (LLT) UNK)
Not pregnant

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

IPSEN LIMITED
Costa Rica

24b. MFR CONTROL No.

2025-CR-000004

24c. DATE RECEIVED BY MANUFACTURER

14-Jul-2025

24d. REPORT SOURCE

☐ STUDY ☐ LITERATURE
☐ HEALTH PROF ☒ * OTHER

DATE OF THIS REPORT

17-Jul-2025

25a. REPORT TYPE

☒ INITIAL ☐ FOLLOW-UP

Primary Reporter:
M CR
Costa Rica

Y C
Costa Rica

PV Safety Group:
Biopas
Calle 127A #53A-45

[further details on Continuation Page]

* Medical Physician

SUSPECT ADVERSE REACTION REPORT
Continuation Page

MANUFACTURER CONTROL NUMBER: 2025-CR-000004

7. + 13. DESCRIBE REACTION(S) (including relevant tests / lab data) - continued

issue)

Initial information (14-Jul-2025) : At the time of reconstitution of the product the presence of the usual vacuum in the bottle is not evident since there is no suction of the physiological saline, so the company is notified at the time but waits for the placement and final result. However, the expected effect of temporary facial muscle paralysis was not produced, so after two weeks the patient was placed again with a different bottle with success.

Clarification is requested to the treating physician regarding the following information, the following answers are obtained:

1. In the field of the form: “relationship of the reporter with the patient” is registered: patient, but your name is registered as the reporter. Could you confirm by this means, the relationship that you have with the patient? Or if you are the patient?
Answer: The relationship is, Physician-Patient.

2. Please confirm the dates of onset of therapeutic failure, as it reports 03/05/2025, but the date of application of Dysport is recorded as 02/05/2025
Answer: The expected date for onset of effect is 24 hours, so the following day and days after it is placed.

3. Please clarify the final date of the therapeutic failure, since in the description of the case you mention that after 2 weeks, there was a new application of the product with successful result, but in the field of final date of the adverse event you register 03/06/2025 (that is, 1 month later)
Answer: After two weeks, the patient returns completely without muscle blockage with the therapeutic failure, so another toxin with a different batch is applied, achieving the expected result two weeks later, totaling one month of seeing the patient.

4. Please clarify the date of the second application of the product, as it is registered 02/06/2025, but in the description of the case, it is mentioned that the product was applied two weeks later (date of first application registered 02/05/2025):
Answer: In summary, the treatment had to be applied again with another toxin to achieve the expected result, since the first application did not help at all

The reporter considers the causality of the events as not reported.

II. SUSPECT DRUG(S) INFORMATION (Continued)

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

15. DAILY DOSE(S)

16. ROUTE(S) OF ADMINISTRATION

1) Unknown

18. THERAPY DATES (From/To)

1) From: May-2025* To:

19. THERAPY DURATION

1) Unknown

[Site Details - continued]

Torre 2, Oficina 1202
Bogota 111121
Colombia

26. REMARKS

Clinical trial

Clinical trial patient number: