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
DAC	Costa Rica	UNK	Unknown	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

Medically significant event

7. + 13. DESCRIBE REACTION(S) (including relevant tests / lab data) *[further details on Continuation Page]*

Events	From	To	Duration
decompensation on several occasions equal to syncope ((LLT) Syncope)	UNK	UNK	UNK
constant sneezing ((LLT) Sneezing)	UNK	UNK	UNK
Irritation of eyes ((LLT) Irritation of eyes)	UNK	UNK	UNK
itchy nose ((LLT) Nasal pruritus)	UNK	UNK	UNK
allergies ((LLT) Allergy)	UNK	UNK	UNK

II. SUSPECT DRUG(S) INFORMATION

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

1) DYSPORT (CLOSTRIDIUM BOTULINUM TYPE A TOXIN HEMAGGLUTININ COMPLEX);MAH Ref 4132-AHM-3882B ;Formulation Powder for solution for injection

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

15. DAILY DOSE(S)

1) unknown

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: Jun-2024 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.

2024-CR-000012

24c. DATE RECEIVED BY MANUFACTURER

2-Sep-2024

24d. REPORT SOURCE

☐ STUDY ☐ LITERATURE
☐ HEALTH PROF ☒ * OTHER

DATE OF THIS REPORT

9-May-2025

25a. REPORT TYPE

☒ INITIAL ☐ FOLLOW-UP

Primary Reporter:
L G
Costa Rica

PV Safety Group:
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* Medical Physician

SUSPECT ADVERSE REACTION REPORT
Continuation Page

MANUFACTURER CONTROL NUMBER	2024-CR-000012

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

Initial information (02-Sep-2024):

Product: Dysport 500
Application: June 2024

Reactions: allergies, itchy nose, eye irritation, constant sneezing, and most importantly decompensation on several occasions equal to syncope.
The reporter considers the causality of the events as not reported.

Biopas comment: In accordance with the findings identified in the recent IPSEN audit, a correction is sent for this case.

[Site Details - continued]

26. REMARKS

Clinical trial

Clinical trial patient number: