SUSPECT ADVERSE REACTION REPORT

2025-12421(0)

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
Masked	GUATEMALA					Female		Apr	2025	

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

1) Lack of effect of the product when applied to the forehead (Lack of drug effect (10023610), Drug ineffective (10013709)) (/Apr/2025 -) - Not applicable
2) Dysport applied to the forehead (Off label use in unapproved indication (10084345), Off label use (10053762)) (09/Apr/2025 -) - Not applicable

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

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

1) DYSPORT (BOTULINUM TOXIN TYPE A, BOTULINUM TOXIN TYPE A) (Suspect) (Powder for solution for injection) (004458)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (165 international unit(s), in 1 Cyclical)	1) Unknown

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☐ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) forehead [10048042 - Wrinkles]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (09/Apr/2025 - 09/Apr/2025)	1) 1 Days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : IPSEN Group, Research and Development
70 Rue Balard
Paris, 75015, FRANCE
qppv@ipsen.comand49--1747365171

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-12421(0)
24c. DATE RECEIVED BY MANUFACTURER: 22/May/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 28/May/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

The initial version of this non-serious spontaneous non-AE case was reported by physician in Guatemala on 22-May-2025 and transmitted to our licensee partner Biopas (Reference number- 2025-GT-000004) and then transmitted to Ipsen GPS ICSR vendor (via mailbox) on 23-May-2025.

It concerns an unknown age female patient, who received Dysport (Botulinum toxin type A) for forehead (Off label use in unapproved indication) and experienced Lack of effect of the product when applied to the forehead (lack of drug effect). The patient height and weight were not reported.

No past disease, underlying condition, or concomitant medications were reported, the patient had previously administered the Dysport product on 03-Sep-2024 and had the expected paralysis effect, but did not report dose, route, number of therapies, site of administration.

On 09-Apr-2025, patient started treatment with single cyclical therapy with Dysport, at 165 u dose, powder for solution for injection via unknown route for forehead (Off label use in unapproved indication). The batch number was 004458 and expiration date were not reported.

On unknown date in Apr-2025, at the time of routine review 21 days later it was found that the product has had no effect.

Action taken and de challenge with Dysport in response to the events were not applicable.

At the time of this report, outcome of the events were not applicable.

The reporter did not provide the causality assessment for the events. However, as per data handling guidance, reporter causality coded as no reasonable possibility for non-AE case.

SERIOUSNESS AS PER REPORTER: Not serious (Lack of effect of the product when applied to the forehead, Dysport applied to the forehead)
SERIOUSNESS AS PER COMPANY: Not serious (Lack of effect of the product when applied to the forehead, Dysport applied to the forehead)
CAUSALITY AS PER REPORTER: No reasonable possibility (Lack of effect of the product when applied to the forehead, Dysport applied to the forehead)
CAUSALITY AS PER COMPANY: No reasonable possibility (Lack of effect of the product when applied to the forehead, Dysport applied to the forehead)
EXPECTEDNESS: Unlabelled (Lack of effect of the product when applied to the forehead, Dysport applied to the forehead)

No further information was available.

Company Remarks (Sender's Comments) :

Events off label use, drug ineffective are special situation for which causality cannot be assessed. Considering above mentioned, according to the WHO-UMC method of assessment, the causal relationship between the events and the suspect drug is assessed as unassessable by Ipsen.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	DYSPORT (BOTULINUM TOXIN TYPE A)
Active Substance	:	BOTULINUM TOXIN TYPE A
Drug Characterization	:	Suspect
Form of Admin	:	Powder for solution for injection
Lot Number	:	004458
Daily Dose	:	(165 international unit(s), in 1 Cyclical)
Route of Admin	:	Unknown
Indications	:	1) forehead [10048042 - Wrinkles] 2) off label use [10053762 - Off label use]
Therapy Dates	:	From : 09/Apr/2025 To :09/Apr/2025
Therapy Duration	:	1 Days
Action(s) Taken With Drug	:	Not applicable

Causality

1) Lack of effect of the product when applied to the forehead (Lack of drug effect - 10023610, Drug ineffective - 10013709)

Causality as per reporter	:	No reasonable possibility
Causality as per Mfr	:	No reasonable possibility
DeChallenge	:	Not applicable

2) Dysport applied to the forehead (Off label use in unapproved indication - 10084345, Off label use - 10053762)

Causality as per reporter	:	No reasonable possibility
Causality as per Mfr	:	No reasonable possibility
DeChallenge	:	Not applicable

Continuation Sheet for CIOMS report

Labeling :

1) Lack of effect of the product when applied to the forehead
   CORE UnLabeled
2) Dysport applied to the forehead
   CORE UnLabeled