# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year |
| PRIVACY | DOMINICAN REPUBLIC | | PRIVACY | | 7 Years | Male | Unk | 21 | OCT | 2024 |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

it was leaking/it leaked when it was injected to the patient [Device leakage]

Case Description: This is a spontaneous report received from a Consumer or other non HCP and a Physician from product quality group, Program ID: 164974.

A 7-year-old male patient received somatropin (GENOTROPIN PEN), first regimen since 24Jul2017 (Batch/Lot number: unknown) at 1 mg daily and second regimen (Batch/Lot number: unknown) at 0.1 mg daily for growth

**(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 ) Genotropin Pen (SOMATROPIN) Solution for injection
#2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution **(Continued on Additional Information Page)**

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

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) 1 mg, daily | #1 ) Unknown |
| #2 ) | #2 ) Unknown |

17. INDICATION(S) FOR USE
#1 ) Growth hormone deficiency (Growth hormone deficiency)
#2 ) Unknown

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 24-JUL-2017 / Unknown | #1 ) Unknown |
| #2 ) 24-JUL-2017 / Unknown | #2 ) Unknown |

## III. CONCOMITANT DRUG(S) AND HISTORY

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

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

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | | |

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
**202400288734**

24c. DATE RECEIVED BY MANUFACTURER
04-JUN-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
06-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202400288734

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

hormone deficiency, Device Expiration Date: Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious) with onset 21Oct2024, outcome "unknown", described as "it was leaking/it leaked when it was injected to the patient". The action taken for somatropin was unknown.

The reporter considered "it was leaking/it leaked when it was injected to the patient" not related to somatropin. Causality for "it was leaking/it leaked when it was injected to the patient" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 08Nov2024 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Leaking During Prep/Use, was reported. The Risk Management File was reviewed to confirm that the Hazard(s) and Hazardous Situation(s) associated with the Complaint Issue are documented in the Hazard Analysis (INX100281795), Version (9.0). All complaint investigations are trended. There is not a current trend alert documented.

Product Quality Group provided investigational results on 19Dec2024 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: This complaint is for reporter had doubts about whether user was correctly applying the treatment since it was leaking since Monday. Reporter stated the medication was bad because it leaked when it was injected to the patient with GENOTROPIN PEN was investigated by the manufacturing site. No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. This complaint was also investigated by Device Engineering. The Risk Management File was reviewed to confirm that the Hazard(s) and Hazardous Situation(s) associated with the Complaint Issue are documented in the Hazard Analysis (INX100281795), Version (9.0). All complaint investigations are trended. There is not a current trend alert documented.

Additional information: the patient's mother had doubts about whether she was correctly applying the treatment since it was leaking. She had been applying the medication unsafely since Monday. The reporter stated the medication was bad because it leaked when it was injected to the patient. As of 19Mar2025, the medication did not go down, the line that should mark did not mark, the device doesn't seem to be marking.

Follow-up (08Nov2024): This is a follow-up report from product quality group providing investigation results.

Follow-up (19Dec2024): This is a follow-up report from product quality group providing investigational results.

Follow-up (19Mar2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: (164974). Updated information includes: new dosage regimen, new event of device delivery system issue, device image display issue, additional information.

Follow-up (01May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (04Jun2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Events Poor quality device used, tDevice delivery system issue & Device image display issue deleted.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to); 19. THERAPY DURATION |
|---|---|---|---|
| #1 ) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2 | 0.1 mg, daily; Unknown | Growth hormone deficiency (Growth hormone deficiency) | Unknown; Unknown |
| #2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection; Regimen #1 | ; Unknown | Unknown | 24-JUL-2017 / Unknown; Unknown |