# 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 | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year | |
| PRIVACY | DOMINICAN REPUBLIC | | PRIVACY | | 12 Years | Female | Unk | | Unk | | |

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

where it marked the quantity, it stopped presenting the numbers on the screen [Device readings not obtained] placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working [Improper use of device]

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

A 12-year-old female patient received somatropin (GENOTROPIN PEN),

**(Continued on Additional Information Page)**

- ☐ 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 {Lot # LK3089; Exp.Dt. FEB-2027}
#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 ) 1.8 mg, daily (at night) | #1 ) Unknown |
| #2 ) | #2 ) Unknown |

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

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

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) Unknown | #1 ) Unknown |
| #2 ) 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.
**PV202500083464**

24c. DATE RECEIVED BY MANUFACTURER
27-AUG-2025

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

DATE OF THIS REPORT
01-SEP-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

## ADDITIONAL INFORMATION

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

first regimen (Lot number: LK3089, Expiration Date: Feb2027) at 1.8 mg daily (1.8 mg, daily (at night)) and second regimen (Lot number: HF4891, Expiration Date: Jan2026) at 1.8 mg daily (1.8 mg, daily (at night)), Device Lot Number: L092, Device Expiration Date: 31Jan2026. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "where it marked the quantity, it stopped presenting the numbers on the screen"; DEVICE USE ISSUE (non-serious), described as "placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working". The action taken for somatropin was unknown.

Causality for "where it marked the quantity, it stopped presenting the numbers on the screen" and "placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 27Aug2025for somatropin (device constituent): Site investigation (Puurs): Battery Died Before Expiry/Display Not Functioning The complaint for "stopped presenting the numbers on the screen" of "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of a reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot of the reported lot L092. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Improper Storage, was reported. An additional Complaint Issue of Display Not Functioning was reported. This Complaint Issue is considered a cascading event. 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 (INX# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: Caregiver reported that patient had been using Genotropin every day for over a year. Just that now the device where the injection was given, where it marked the quantity, it stopped presenting the numbers on the screen. Patient was not seeing the dose. Caregiver thought it was that the battery was running out, he tried but it did not turn on the screen. The nurse indicated that the caregivers had gone out somewhere and placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working, the numbers could no longer be seen. She noticed that there was only enough left for the dose on the same day of the consultation.
Follow-up (28Aug2025): Follow-up attempts are completed.

Follow-up(27Aug2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Investigation results added

**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 {Lot # HF4891; Exp.Dt. JAN-2026}; Regimen #2 | 1.8 mg, daily (at night); Unknown | Unknown | Unknown; Unknown |
| #2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L092}; Regimen #1 | ; Unknown | Unknown | Unknown; Unknown |