# 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 | | 11 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)

was unable to administer the medication. [Drug dose omission by device]
the dose adjustment button is "running" [Device leakage]
despite marking the dose, the button does not press on the substance/device used to administer the hormone to the girl was damaged/device was indeed damage [Device mechanical jam]

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.

**(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 {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 ) 1.0 mg, daily | #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.
**PV202500049362**

24c. DATE RECEIVED BY MANUFACTURER
22-MAY-2025

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

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

## ADDITIONAL INFORMATION

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

An 11-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LK3089, Expiration Date: Feb2027) at 1 mg daily (1.0 mg, daily) and second regimen (Lot number: nk3089, Expiration Date: Feb2027) at 1 mg daily (1.0 mg, daily), Device Lot Number: A127, Device Expiration Date: 31Mar2025. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DRUG DOSE OMISSION BY DEVICE (non-serious), described as "was unable to administer the medication."; DEVICE LEAKAGE (non-serious), described as "the dose adjustment button is "running""; DEVICE MECHANICAL ISSUE (non-serious), described as "despite marking the dose, the button does not press on the substance/device used to administer the hormone to the girl was damaged/device was indeed damage". The action taken for somatropin was unknown.

Additional information: patient is afraid to apply the medication and lose the medication. She said the patient has already lost an entire cartridge because he was unable to administer the medication. Upon follow-up received on 22May2025, the patient's caregiver stated that the device used to administer the hormone to the girl was damaged. They made a video call with her, checked everything, and confirmed that the device was indeed damage, because when the cartridge was inserted, it didn't inject the dose.

Causality for "was unable to administer the medication.", "the dose adjustment button is "running"" and "despite marking the dose, the button does not press on the substance/device used to administer the hormone to the girl was damaged/device was indeed damage" was determined associated to device constituent of somatropin (malfunction).

Follow-up (22May2025): This is a follow-up report received from a Consumer or other non HCP, Program ID: 164974.
Updated information: additional details reported for the event device mechanical issue and clinical course updated.

**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 # nk3089; Exp.Dt. FEB-2027}; Regimen #2 | 1.0 mg, daily; Unknown | Unknown | Unknown; Unknown |
| #2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # A127}; Regimen #1 | ; Unknown | Unknown | Unknown; Unknown |