# 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 | | 11 Years | Female | Unk | 25 | JUL | 2025 | |

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

the medication caused intense itching [Itching]

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

An 11-year-old female patient received somatropin (GENOTROPIN PEN), since 18Jul2025 (Batch/Lot number: unknown) at 1 mg 1x/day (1 mg, at night), Device Lot Number: LG3751, Device Expiration Date: Feb2027. The patient's relevant medical history and concomitant medications were not reported.

**(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
#2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # LG3751}

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

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) 1 mg, 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 ) 18-JUL-2025 / 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.
**PV202500091516**

24c. DATE RECEIVED BY MANUFACTURER
26-JUL-2025

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

DATE OF THIS REPORT
31-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

## ADDITIONAL INFORMATION

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

The following information was reported: PRURITUS (non-serious) with onset 25Jul2025, outcome "unknown", described as "the medication caused intense itching". The action taken for somatropin was unknown.
Additional information: The patient's caregiver stated that her daughter had started Genotropin treatment eight days ago (18Jul2025). She mentioned that since yesterday (25Jul2025), the girl had been saying the medication caused intense itching and that she couldn't stand it. The caregiver said she didn't know if this reaction was normal, as no one had informed her about such symptoms. She added that her daughter cried a lot and no longer wanted to continue with the treatment. Device lot number: LG3751. Device expiration date: Feb2027.

The information on the batch/lot number for somatropin will be requested and submitted if and when received.