# 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 | Male | Unk | | Unk | | |

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

when the dose was set the device administered more than the quantity set [Incorrect dose administered by device]
medication continued to come out and it came out of the patient's skin. [Accidental exposure to product related to device use]
medication continued to come out and it came out of the patient's skin.

**(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 # LR7824; Exp.Dt. JUN-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 mg, 1x/day (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.
**PV202500057328**

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 4

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**

[Exposure via skin contact]
when the dose was set the device administered more than the quantity set [Device delivery system issue]
the case was leaking the medication [Device leakage]
the brown gummy that indicates the doses administered did not go down and continued to stay with the air [Device failure to prime]

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

An 11-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LR7824, Expiration Date: Jun2027) at 1 mg 1x/day (at night) and second regimen (Lot number: LK3089, Expiration Date: Feb2027), Device Lot Number: LD7551, Device Expiration Date: Jan2027. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious), DEVICE DELIVERY SYSTEM ISSUE (non-serious) and all described as "when the dose was set the device administered more than the quantity set"; ACCIDENTAL EXPOSURE TO PRODUCT (non-serious), EXPOSURE VIA SKIN CONTACT (non-serious) and all described as "medication continued to come out and it came out of the patient's skin."; DEVICE LEAKAGE (non-serious), described as "the case was leaking the medication"; DEVICE FAILURE (non-serious), described as "the brown gummy that indicates the doses administered did not go down and continued to stay with the air". The action taken for somatropin was unknown.

Causality for "when the dose was set the device administered more than the quantity set", "medication continued to come out and it came out of the patient's skin.", "the case was leaking the medication" and "the brown gummy that indicates the doses administered did not go down and continued to stay with the air" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 18Jul2025 and 21Jul2025 for somatropin: Investigation Summary and Conclusion: Site Investigation (PUURS): 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. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The complaint issue, Excess Dose, 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 no current trend alert documented.

Additional information: Reporter stated that when the dose was set the device administered more than the quantity set, it did not stay at the milligrams set, so when 1 mg was set, it did not administer that. On 23May2025 nurse reported that caregiver did not take the pen to the appointment so it was not possible to correct the turns she gives. Caregiver believed it could be applying maybe more, maybe less. As of 04Jul2025, patient's caregiver reported that when administering the medication to the patient, she inserted the vial into the case, but the case was leaking the medication, she did all the steps and the respective procedure, she eliminated the air, but she saw that it still had air. Last night, when she gave the dose to the patient and it was leaking medicine through the needle, and when she inserted it into the child, the brown gummy that indicates the doses administered did not go down and continued to stay with the air. So instead of inserting everything with the needle in place (count the 10 seconds after applying it) the medication continued to come out and it came out of the patient's skin. Reporter was given a the contact of a nurse and was advised not to administer the medication until it was checked by the nurse. Upon a follow-up received on 09Jul2025, nurse stated that at first, there was an issue with the pen, but upon closer inspection, she realized the problem was due to the medication, which had a very small amount left, making it difficult for it to dispense. She tried several times and eventually identified the cause. In the end, the patient was satisfied. As of 10Jul2025, patient's mother stated that "Yesterday they administered the medication on the child and it seemed that the cartridge was having problems because it did not let the device deliver with pressure, the nurse took a photo to report it, she showed her the other cartridges that they had used (which did work) the amount, the cartridge had like a gray gummy in the middle, that makes it expel it, but then it did not get as far as it had to go."

Follow-up (23May2025). This is a spontaneous follow-up report received from a nurse. Updated information included: clinical course.
Follow-up (27Jun2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (04Jul2025). This is a spontaneous follow-up report received from Consumer or other non HCP, Program ID: 164974.
Updated information includes: new events of "accidental exposure to product","exposure via skin contact", device leakage and device failure to prime, additional information.

Follow-up (09Jul2025). This is a spontaneous follow-up report received from a nurse, Program ID: 164974.
Updated information included: clinical course.

Follow-up (10Jul2025). This is a spontaneous follow-up report received from a nurse, Program ID: 164974.
Updated information included: event added of "device mechanical issue", clinical course.

Follow-up (18Jul2025 and 21Jul2025): This is a spontaneous follow-up report from product quality group.
Updated information: investigation results and event data (removed: Device mechanical issue).

Mfr. Control Number: PV202500057328

## ADDITIONAL INFORMATION

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

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # LK3089; Exp.Dt. FEB-2027}; Regimen #2 | UNK; Unknown | Unknown | Unknown;<br>Unknown |
| #2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # LD7551}; Regimen #1 | ; Unknown | Unknown | Unknown;<br>Unknown |