

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 12 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY						Unk		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
when I do the needle change procedure and the movement as the nurse informed me, I give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount [Device use issue]
I should apply and the cartridge where the medication goes came loose/disconnected (where I put the needle), so I can put it [Device connection loose]

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

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # HL2024; Exp.Dt. 15-JUL-2026} #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) #1) 1.6 mg, daily #2)	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #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) #1) Unknown #2) Unknown	19. THERAPY DURATION #1) 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. PV202500012659	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 08-MAY-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 12-MAY-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 4	NAME AND ADDRESS WITHHELD.

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

A 12-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: HL2024, Expiration Date: 15Jul2026) at 1.6 mg daily and second regimen (Batch/Lot number: unknown) at 1 mg daily, Device Expiration Date: 31Dec2026. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE USE ISSUE (non-serious), described as "when I do the needle change procedure and the movement as the nurse informed me, I give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount"; DEVICE CONNECTION ISSUE (non-serious), described as "I should apply and the cartridge where the medication goes came loose/disconnected (where I put the needle), so I can put it". The action taken for somatropin was unknown.

Causality for "when i do the needle change procedure and the movement as the nurse informed me, i give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount" and "i should apply and the cartridge where the medication goes came loose/disconnected (where i put the needle), so i can put it" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 26Feb2025 for somatropin (device constituent): Site investigation (Pfizer 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. Device investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Cartridge/Holder Loose, 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.

Product Quality Group provided investigational results on 31Mar2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: This complaint for The patient assistant says, "I need someone to help me, when I do the needle change procedure and the movement as the nurse informed me, I give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount I should apply and the cartridge where the medication goes came loose/disconnected (where I put the needle), so I can put it. for Genotropin/Genotonorm U2 Pen was investigated by the manufacturing site.

Product Quality Group provided investigational results on 08May2025 for somatropin (device constituent): Site investigation (Pfizer 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. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Injection Knob/Dial Issue, was reported. The Issue of, Cartridge/Holder Loose, was already investigated under INV-335482. 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). Additional Complaint Issues of Unable/Difficult to Set/Draw Dose was reported. This Complaint Issue is considered a cascading event. All complaint investigations are trended. There is no current trend alert documented.

Additional information: As of 03Apr2025, reporter stated they finished setting the device and when they tried to dial 0.4 mg it did not dial, also stated that when setting the numbers on the device was getting a bit hard (it was not light). As of 05Apr2025, nurse reported that the patient's mother complaint about the pen's button not working properly, but nurse stated this was not true as she checked it and everything was working normally, it was just a bit hard to press the button but it was normal.

Follow-up (26Feb2025): This is a spontaneous follow-up report received from product quality group. Updated information: investigation results.

Follow-up (19Mar2025): Follow-up attempts are completed.

Follow-up (31Mar2025): This is a follow-up report from the product quality group. Updated information included: investigation results, action taken and expiration date.

Follow-up (03Apr2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: (164974). Updated information includes new events of device mechanical issue, device physical property issue and device difficult to use.

Follow-up (05Apr2025): This is a spontaneous follow-up report received from a Nurse, Program ID: (164974). Updated information: Dosage regimen, Device expiration date, clinical course.

Follow-up (15Apr2025): This is a follow-up report from the product quality group. Updated information included: event removed (Resistance to movement in device, Device difficult to use and Device mechanical jam).

Follow-up (08May2025): This is a follow-up report from product quality group providing investigation result

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
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ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

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#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2	1 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection; Regimen #1	; Unknown	Unknown	Unknown; Unknown