

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 <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> 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]
 setting the numbers on the device was getting a bit hard (it was not light). [Device difficult to use]
 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]
 when they tried to dial 0.4 mg it did not dial [Device mechanical jam]
 when they tried to dial 0.4 mg it did not dial [Resistance to movement in
 (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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 05-APR-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 09-APR-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

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

device]

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

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 DIFFICULT TO USE (non-serious), described as "setting the numbers on the device was getting a bit hard (it was not light)."; 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"; DEVICE MECHANICAL ISSUE (non-serious), DEVICE PHYSICAL PROPERTY ISSUE (non-serious) and all described as "when they tried to dial 0.4 mg it did not dial". 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", "setting the numbers on the device was getting a bit hard (it was not light).", "i should apply and the cartridge where the medication goes came loose/disconnected (where i put the needle), so i can put it" and "when they tried to dial 0.4 mg it did not dial" 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.

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.

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; Regimen #2	1 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE ; Unknown		Unknown	Unknown;

ADDITIONAL INFORMATION

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
CONSTITUENT)) Solution for injection; Regimen #1			Unknown