

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					13	MAY	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
cartridge contents dropped more than usual from 12 to 6 [Device fluid leak]
cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount [Inaccurate delivery by device]
mother is worried that she does not know for sure if she gave her all that amount [Incorrect dose administered by device]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from product quality group.

(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 # LR7825; Exp.Dt. MAY-2027} #2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # LR7825}		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) 2.0 mg, daily at night #2) 2.0 mg/noche	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #2) Unknown	
17. INDICATION(S) FOR USE #1) Growth hormone deficiency (Growth hormone deficiency) #2) Growth hormone deficiency (Growth hormone deficiency)		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) JUL-2024 / Unknown #2) JUL-2024 / 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 Relevant Med History Hypothyroidism (Hypothyroidism)	

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. 202500101162	
24c. DATE RECEIVED BY MANUFACTURER 10-JUL-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 15-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.

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

A 12-year-old male patient received somatropin (GENOTROPIN PEN), since Jul2024 (Lot number: LR7825, Expiration Date: May2027) at 2 mg daily (2.0 mg, daily at night) for growth hormone deficiency, Device Lot Number: L207, Device Expiration Date: 31Oct2026. The patient's relevant medical history included: "Hypothyroidism" (unspecified if ongoing). The patient's concomitant medications were not reported.

The following information was reported: DEVICE LEAKAGE (non-serious) with onset 13May2025 at 21:30, described as "cartridge contents dropped more than usual from 12 to 6"; DEVICE DELIVERY SYSTEM ISSUE (non-serious) with onset 13May2025 at 21:30, described as "cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount"; INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious) with onset 13May2025 at 21:30, described as "mother is worried that she does not know for sure if she gave her all that amount". The action taken for somatropin was unknown.

Causality for "cartridge contents dropped more than usual from 12 to 6", "cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount" and "mother is worried that she does not know for sure if she gave her all that amount" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 07Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: The complaint for 'marked the 2mg dose and that when administering the drug, she was able to notice that the contents of the cartridge fell more' of 'Genotropin Pen Injectable' was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of a reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot of the reported lot L207. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. 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.

Product Quality Group provided investigational summary and conclusion on 10Jul2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of when administering the medication she could notice that the contents of the cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount" and "mother is worried that she does not know for sure if she gave her all that amount for Genotropin pen was investigated by the manufacturing site. Site Investigation (Puurs): Does Not Operate As Indicated The complaint for "marked the 2mg dose and that when administering the drug, she was able to notice that the contents of the cartridge fell more" of "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of a reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot of the reported lot L207. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. 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.

Follow-up (14May2025): This is a spontaneous follow-up report received from the product quality group.

Updated information: " Device fluid leak" was added as an event. This case has been upgraded to malfunction reportable.

Follow-up (26Jun2025): Follow-up attempts are completed.

Follow-up (07Jul2025): This is a spontaneous follow-up report received from product quality group. Updated information included: investigation results.

Follow-up(10Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Investigation results updated.