

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 14 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)
not give the full dose from each vial [Incomplete dose administered]
a large amount of medication was spilling [Device leakage]
not give the full dose from each vial [Device delivery system issue]

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

A 14-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LK3089, Expiration Date: Feb2027) at 1.3 mg 1x/day (1.3 mg, 1x/day (at night)) and second regimen (Lot number: LD7551,
(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 # LK3089; Exp.Dt. FEB-2027} #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) 1.3 mg, 1x/day (at night) #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. PV202500080455	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 21-AUG-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 26-AUG-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

26-Aug-2025 15:51

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

Expiration Date: Jan2027), Device Lot Number: D129, Device Expiration Date: 31Jan2027. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: INCORRECT DOSE ADMINISTERED (non-serious), DEVICE DELIVERY SYSTEM ISSUE (non-serious) and all described as "not give the full dose from each vial"; DEVICE LEAKAGE (non-serious), described as "a large amount of medication was spilling ". The action taken for somatropin was unknown.

Causality for "not give the full dose from each vial" and "a large amount of medication was spilling " was determined associated to device constituent of somatropin (malfunction).

Additional information: The person in charge of the patient stated she noticed that a large amount of medication was spilling every time she tried to administer the dose. She could not give the full dose from each vial, which should be about four doses per vial; she was only able to give about three doses, and sometimes even less than three. Some of it was spilling.

Product Quality Group provided investigational results on 21Aug2025 for somatropin (device constituent): Investigation Summary and Conclusion: 21Aug2025. Site investigation: Container Leaking During Prep/Use. The complaint for "a large amount of medication is leaking every time you're going to dose" of "Genotropin Pen" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of 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 "D129". 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, Leaking During Prep/Use, 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 (INX#100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented. Investigation Summary Complete Date(GMT): 21Aug2025.

Follow-up (14Aug2025): Follow-up attempts are completed.

Follow-up (21Aug2025): This is a follow-up report from product quality group providing investigation results

Updated information: Device lot# and expiry date updated. New dosage regimen tab added for new lot# and expiry date.

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 {Lot # LD7551; Exp.Dt. JAN-2027}; Regimen #2	UNK; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D129}; Regimen #1	; Unknown	Unknown	Unknown; Unknown