

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 10 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)
broke a vial/broke a cartridge [Device breakage]

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

A 10-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.4 mg 1x/day (1.4 mg, 1x/day (at night)).

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Genotropin Pen (SOMATROPIN) Solution for injection #2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA
15. DAILY DOSE(S) #1) 1.4 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? ☐ 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. PV202500077352	
24c. DATE RECEIVED BY MANUFACTURER 23-AUG-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous	
DATE OF THIS REPORT 23-AUG-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 1	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.

23-Aug-2025 04:25

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

The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE BREAKAGE (non-serious), outcome "unknown", described as "broke a vial/broke a cartridge".

Additional information: The patient's caregiver had a question about a GENOTROPIN cartridge. Her son was using GENOTROPIN, and his husband bought a GENOTROPIN C cartridge from a place that sells it in redacted. Her question was whether the cartridge had to be the same as the GENOTROPIN sold here in redacted, because his husband broke a vial and got one to replace it, but from another place, but from a supplement store that sells products for gyms. She also mentioned that the rubber on the GENOTROPIN C was on the outside, unlike the Pfizer Genotropin, which had the rubber on the inside. Lot Drug lot number is F95581, Expiry date is Nov2027; Pen lot number is JW1066, Pen expiration date is Jan2026 (pending clarification). On 07Jul2025, the nurse stated that when he/she got to the office, the person in charge had questions about a medication, but this medication was not purchased here in redacted. The distributor did not give or sell it or redacted Social Security. This medication was then purchased in redacted, called GENOTROPIN C, and was purchased outside of Pfizer's authorized distributors. GENOTROPIN C cartridges were evaluated, noting that the cartridges were seen as counterfeit and it was suggested to the patient's manager not to be used because they were counterfeit, as is normally a factory-made cartridge manufactured by Pfizer. Note that the nurse never viewed Pfizer products at the consultancy, only GENOTROPIN C. Sample of the product is not available to be returned.

The reporter considered "broke a vial/broke a cartridge" not related to somatropin. Causality for "broke a vial" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 11Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation was needed for this complaint.

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

Follow-up (23Aug2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.