

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 8 Years	3. SEX Female	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)
lost more than half of the medication [Device leakage]
made the decision not to administer the medication to the patient for the time being [Drug dose omission by device]
when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device [Health care provider instructions for product use lacking]

Case Description: This is a spontaneous report received from a Consumer or other non HCP and a Nurse, 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 # LR7825; Exp.Dt. MAY-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) 1.6 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. PV202500056642	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 20-JUN-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. NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 26-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

26-Jun-2025 08:23

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

An 8-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LR7825, Expiration Date: May2027) at 1.6 mg daily and second regimen (Batch/Lot number: unknown) at 0.6 mg daily, Device Lot Number: D126. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), described as "when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device"; DEVICE LEAKAGE (non-serious), described as "lost more than half of the medication"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "made the decision not to administer the medication to the patient for the time being". The action taken for somatropin was unknown.

Additional Information: The patient manager indicated: "My GENOTROPIN device, saw that it no longer allows me to mark there the units that I need to administer to my daughter and saw that yesterday (07May2025) that I was going to change it, I lost more than half of the medication because when I wanted to see, it shot up by itself and the medication came out. So, I want to see if someone can support me or how I can acquire a new device, I make the space, I interrupt my activities there in order to solve that, because yes, as I say, yesterday when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device the dose that I have to administer to my daughter." On 09May2025, the nurse indicated: "There was a quality complaint from the person in charge, when he made the replacement of the cartridge of GENOTROPIN 12mg, when they wanted to put the ideal dose which is 0.6mg, they could only put 0.2mg, and the cartridge spilled completely, leaving a minimal part in the cartridge." The person in charge made the decision not to administer the medication to the patient for the time being, until it was verified that it works properly. Took into account that the counseling with the patient's caregiver was virtual, however, the nurse recommended that face-to-face counseling should be coordinated to verify the pen. At the time of making the satisfaction survey call, the patient's mother did not report any report and did not refer that she needs other advice. Upon a follow-up received on 20Jun2025, the nurse stated that during this virtual consultation held on 08May at 4:00 PM with patient, the caregiver reported that while performing the cartridge replacement, she attempted to set the dose to 0.6 mg (the patient's prescribed dose). However, after the replacement, she was only able to load 0.2 mg, and an entire cartridge spilled, leaving only a minimal amount remaining. The caregiver stated that she followed the procedure correctly, noting that she had already performed three cartridge replacements previously. In the nurse opinion, an in-person inspection of the device was necessary to ensure it was in proper working condition

Causality for "when i had to load the new dose, i had that inconvenience and it no longer allows me to dose in the device", "lost more than half of the medication" and "made the decision not to administer the medication to the patient for the time being" was determined associated to device constituent of somatropin (malfunction).

Follow-up (20Jun2025): Follow-up attempts are completed.

Follow-up (20Jun2025): This is a spontaneous follow-up report received from a Consumer or other non HCP and a Nurse.
Updated information: product details (dosage regimen) and 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	0.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE ; Unknown CONSTITUENT)) Solution for injection {Lot # D126}; Regimen #1		Unknown	Unknown; Unknown