

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	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 <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)
a full vial of Genotropin was wasted, but I don't know why, maybe I did something wrong [Device leakage]
Genotropin did not turn on when she rotated it to set the dose; it did not register the dose [Device image display error]
stored it in a disposable bag and then placed it in the cooler without its case..due to this practice, the device was damaged [Device moisture damage]
Introduced the device into a cooler that did not correspond to those provided by the program/stored it in a disposable bag and then placed it in the cooler without its case [Product storage error]

(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 # ME5841; Exp.Dt. SEP-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) 0.7 mg, 1x/day (Continuous use) #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. PV202500098721	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 23-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 28-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	NAME AND ADDRESS WITHHELD.

28-Aug-2025 17:04

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

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

A 10-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: ME5841, Expiration Date: Sep2027) at 0.7 mg 1x/day (0.7 mg, 1x/day (continuous use)) and second regimen (Lot number: LR7824, Expiration Date: Jun2027) at 0.7 mg 1x/day (0.7 mg, 1x/day (continuous use)), Device Lot Number: L092, Device Expiration Date: Jan2026. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE LEAKAGE (non-serious), described as "a full vial of Genotropin was wasted, but I don't know why, maybe I did something wrong"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "Genotropin did not turn on when she rotated it to set the dose; it did not register the dose"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious), described as "stored it in a disposable bag and then placed it in the cooler without its case..due to this practice, the device was damaged"; PRODUCT STORAGE ERROR (non-serious), described as "Introduced the device into a cooler that did not correspond to those provided by the program/stored it in a disposable bag and then placed it in the cooler without its case". The action taken for somatropin was unknown.

Additional Information: The patient's caregiver indicated: "I had been using Genotropin for a few months. The nurse came here to give me the training and everything about the process, and I had everything written down and did it exactly the same. However, a full vial of Genotropin was wasted, but I don't know why, maybe I did something wrong". Upon follow-up received on 23Aug2025, the nurse indicated that the patient's caregiver introduced the device into a cooler that did not correspond to those provided by the program. He commented that she stored it in a disposable bag and then placed it in the cooler without its case, as the device did not fit inside with it. He pointed out that, due to this practice, the device was damaged. Upon follow-up received on 25Aug2025, the patient's mother stated: "A nurse has already come to check my genotropin device and indicated that it was expired, which is why the device was showing letters on the screen, so I require a new device." Device lot number: AA141175.

Causality for "a full vial of genotropin was wasted, but i don't know why, maybe i did something wrong", "genotropin did not turn on when she rotated it to set the dose; it did not register the dose", "stored it in a disposable bag and then placed it in the cooler without its case..due to this practice, the device was damaged" and "introduced the device into a cooler that did not correspond to those provided by the program/stored it in a disposable bag and then placed it in the cooler without its case" was determined associated to device constituent of somatropin (malfunction).

Follow-up (20Aug2025): This is a spontaneous follow-up report received from a Consumer or other non HCP, Program ID: 164974. Updated information: New event: Device image display error. New dosage regimen tab added in order to include new lot# and expiry date.

Follow-up (23Aug2025 and 25Aug2025): This is a spontaneous follow-up report received from a Nurse and a Consumer or other non HCP; Program ID: [164974]

Updated information: suspect drug details (action taken updated to unknown), device details (lot number), new events added ('Product storage error' and 'Device moisture damage') 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 {Lot # LR7824; Exp.Dt. JUN-2027}; Regimen #2	0.7 mg, 1x/day (Continuous use); Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L092}; Regimen #1	; Unknown	Unknown	Unknown; Unknown