

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 13 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)
 2 days of not injecting him/and it's been four days without my son being able to receive the hormone [Drug dose omission by device]
 caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work [Wrong technique in device usage process]
 it is damaged [Device defective]
 caregiver wasted a dose of medication trying to figure out how to fix it [Device leakage]
 the pen, had a low battery, so the dose indicator did not appear on the screen [Device image display issue]

(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 # KC8721; Exp.Dt. JAN-2027} #2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection		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) 1.4 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. PV202500052615	
24c. DATE RECEIVED BY MANUFACTURER 02-MAY-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 12-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

25b. NAME AND ADDRESS OF REPORTER
 NAME AND ADDRESS WITHHELD.
 NAME AND ADDRESS WITHHELD.
 NAME AND ADDRESS WITHHELD.

12-May-2025 12:00

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 13-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: KC8721, Expiration Date: Jan2027) at 1.4 mg daily. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DRUG DOSE OMISSION BY DEVICE (non-serious), described as "2 days of not injecting him/and it's been four days without my son being able to receive the hormone"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work"; DEVICE DEFECTIVE (non-serious), described as "it is damaged"; DEVICE LEAKAGE (non-serious), described as "caregiver wasted a dose of medication trying to figure out how to fix it"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "the pen, had a low battery, so the dose indicator did not appear on the screen". The action taken for somatropin was temporarily withdrawn.

Additional information: The patient's caregiver stated his son's pen got damaged, that they would send someone and replace the pen. Additionally, caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work. It's been 2 days since she last injected him. The patient's mother reported that the pen got damaged, it shows an error and the error won't go away. She stated it's been four days without my son being able to receive the hormone, and she urgently need to resolve this. On 02May2025, the nurse indicated that what was reported was that the device, the pen, had a low battery, so the dose indicator did not appear on the screen. Nurse explained to the patient's mother how to use the pen without needing to see the dose on the screen, but she indicated that they wanted a new pen. On 03May2025, patient's mother stated that all of this was a waste of time. In fact, the same guy told to the patient's mother that if he had known it was this over the phone, he would have resolved it. It was a waste of time for both. The pen just had a low battery, patient's mother don't even know why, because theoretically it should last until 2027. He couldn't even provide to the patient's mother what she needed, which is a new pen. Patient's mother still without the pen, the nurse was of no help, and her son is still without the hormone. Patient's mother dealing with this for a week.

Causality for "2 days of not injecting him/and it's been four days without my son being able to receive the hormone", "caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work", "it is damaged", "caregiver wasted a dose of medication trying to figure out how to fix it" and "the pen, had a low battery, so the dose indicator did not appear on the screen" was determined associated to device constituent of somatropin (malfunction).

Follow-up (02May2025 and 03May2025): This is a follow-up report from a Nurse, Program ID: 164974.

Updated information: new event added (the pen, had a low battery, so the dose indicator did not appear on the screen) and clinical course.