

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 6 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)
When they try to adjust it to set the eight millimeters, it doesn't work [Device mechanical issue]

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 6-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.8 mg daily (0.8 mg, daily (every night)), second regimen (Lot number: LN4285, Expiration Date: unknown)

(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 (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) 0.8 mg, daily (every 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. PV202500061096	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. 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	
DATE OF THIS REPORT 25-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

25-Jun-2025 12:20

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

Feb2027) at 0.6 mg daily and third regimen (Lot number: HM4951, Expiration Date: 30Nov2026), Device Lot Number: L209. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE MECHANICAL ISSUE (non-serious), outcome "unknown", described as "When they try to adjust it to set the eight millimeters, it doesn't work". The action taken for somatropin was unknown.

Additional Information: The patient's caregiver states the pen no longer worked, so they would like to know what applies in this case. When they try to adjust it to set the eight millimeters, it doesn't work. Nurse states: "Upon arriving at the visit, the patient's caregiver reported that during a cartridge replacement, it got stuck. That's why they requested in-person assistance. The pen was evaluated and tested it with a placebo and confirmed that the pen is in perfect working condition. The cartridge was reinserted, the one that had gotten stuck, and left everything ready for them to continue the treatment. The pen is in perfect condition". Upon a follow-up received on 20Jun2025, nurse stated that during this in-person consultation with patient on 20May at 4:00 pm, the person in charge reported that, at the time of replacing the cartridge, the pen no longer injected. Pen Lot Number: L209. Case Lot Number: HM4951. Expiration Date: Nov2026. Upon reviewing the pen using a placebo, it was confirmed that the device was in perfect working condition. Cartridge Lot Number LN4285, Expiration Date Feb2027, was left ready for use so that the patient could continue with the treatment. This was all the information available regarding this case.

Causality for "when they try to adjust it to set the eight millimeters, it doesn't work" was determined associated to device constituent of somatropin (malfunction).

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

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 (device lot number) 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 # LN4285; Exp.Dt. FEB-2027}; Regimen #2	0.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # HM4951; Exp.Dt. 30-NOV-2026}; Regimen #3	UNK; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L209}; Regimen #1	; Unknown	Unknown	Unknown; Unknown