

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	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
		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)  
The pen didn't work and wouldn't let her put in the medication [Device issue]  
improper handling of the device [Wrong technique in device usage process]

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), (Batch/Lot number: unknown) at 1.4 mg 1x/day.

(Continued on Additional Information Page)

☐ PATIENT DIED

☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION

☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY

☐ LIFE THREATENING

## 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?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 1.4 mg, 1x/day #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 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. <b>PV202500086135</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>15-JUL-2025</b>	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 <b>28-JUL-2025</b>	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.

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**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 ISSUE (non-serious), outcome "unknown", described as "The pen didn't work and wouldn't let her put in the medication"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), outcome "unknown", described as "improper handling of the device". The action taken for somatropin was unknown.

Causality for "the pen didn't work and wouldn't let her put in the medication" and "improper handling of the device" 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.

Additional information: The patient's mother indicates that she began genotropin treatment last week. She comments that yesterday, 14Jul2025, when she changed the medication inside the pen, the pen didn't work and wouldn't let her insert the medication. Further information is not available because communication is lost.

As for 16Jul2025 the nurse indicated that there was improper handling of the device by the patient's mother.

Follow-up (16Jul2025): This is a spontaneous follow-up report received from a nurse.

Updated information included: New reporters, dosage regimen, new event.

The initial case was missing the following minimum criteria: as there is no indication that the consumer experienced an adverse event under GENOTROPIN PEN. Upon receipt of follow-up information on 15Jul2025, this case now contains all required information to be considered valid.

Follow-up (15Jul2025): This is a spontaneous follow-up report received from product quality group. Updated information included: Reportability Determination.