

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 5 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 device is giving me problems, but it is not going down [Device mechanical jam]
The dosage that the doctor prescribed is 0.68 mg and she gives him 0.8 mg [Drug dose prescribing error]

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

A 5-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 0.8 mg daily.

(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? ☐ YES ☐ NO ☒ NA
15. DAILY DOSE(S) #1) 0.8 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? ☐ YES ☐ NO ☒ 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. PV202500045594	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 06-MAY-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous	
DATE OF THIS REPORT 12-MAY-2025	25a. REPORT TYPE ☒ INITIAL ☐ FOLLOWUP:	

12-May-2025 13:36

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 MECHANICAL ISSUE (non-serious), described as "The device is giving me problems, but it is not going down"; PRODUCT PRESCRIBING ERROR (non-serious), described as "The dosage that the doctor prescribed is 0.68 mg and she gives him 0.8 mg". The action taken for somatropin was unknown.

Causality for "the device is giving me problems, but it is not going down" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 06May2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. Two distinct Complaint Issues of "Injection Knob/Dial Issue" and "Excess Dose" were reported. However, these two distinct Complaint Issues map to same Hazard/Hazardous Situation. The Risk Management File was reviewed to confirm that the Hazard(s) and Hazardous Situation(s) associated with the Complaint Issue are documented in the Hazard Analysis (INX# 100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: The patient's assistant states: "The problem is that the device I use to inject the child is giving me problems, but it is not going down. I need to program them so they can check the pen to see if it's defective or if I'm doing it wrong." She also mentions that the dosage the doctor prescribed is 0.68 mg, and she gives him 0.8 mg.

Follow-up (06May2025): This is a follow-up report from the product quality group. Updated information included: investigation results.