

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 14 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY					30	JUL	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
The patient's pen is stuck but shows up on the screen [Device mechanical jam]

Case Description: This is a spontaneous report and received from Consumer or other non HCPs from product quality group.

A 14-year-old male patient received somatropin (GENOTROPIN PEN), since May2025 (Batch/Lot number: unknown) at 1.4 mg, Device Lot Number: L092. The patient's relevant medical history and concomitant medications were not reported.

(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 for injection {Lot # L092}		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA
15. DAILY DOSE(S) #1) 1.4 mg #2) 1.4 mg	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) MAY-2025 / Unknown #2) MAY-2025 / 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. 202500153855	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 02-SEP-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous	
DATE OF THIS REPORT 02-SEP-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 2	

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

The following information was reported: DEVICE MECHANICAL ISSUE (non-serious) with onset 30Jul2025 at 09:45, outcome "unknown", described as "The patient's pen is stuck but shows up on the screen".

The reporter considered "the patient's pen is stuck but shows up on the screen" not related to somatropin. Causality for "the patient's pen is stuck but shows up on the screen" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 13Aug2025 for somatropin (device constituent): No further investigation is required as no valid lot number or returned sample is 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. The Complaint Issue, Injection Knob/Dial Issue, was reported. 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 (INX100281795), Version (9.0). All complaint investigations are trended. There is not a current trend alert documented.

Product Quality Group provided investigational results on 26Aug2025 for somatropin (device constituent): Final Approval Date: 26Aug2025. MDCP Investigation Summary and Conclusion: The complaint of (The patient's pen is stuck but shows up on the screen. A review by a registered nurse is requested, following coordination with the call center via PRIVACY request.) for (Genotropin Pen) was not investigated by the manufacturing site.

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (13Aug2025): This is a follow-up report from product quality group providing investigation results.

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (25Aug2025, 26Aug2025): This is a follow-up report from product quality group: Updated information: Lot number and investigation conclusion.

Amendment: This follow-up report is being submitted to amend previously reported information: product strength added.