

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	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	Unk	Unk	Unk	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 hormone tube was defective [Device defective]

Case Description: This is a spontaneous report received from a Pharmacist from product quality group.

A patient (age and gender not provided) received somatropin (GENOTROPIN PEN), (Lot number: HN2503, Expiration Date: 31Aug2026).

(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 # HN2503; Exp.Dt. 31-AUG-2026} #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) UNK #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. 202500113334		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 06-AUG-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous		
DATE OF THIS REPORT 08-AUG-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2		

08-Aug-2025 12:52

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 DEFECTIVE (non-serious), outcome "unknown", described as "The hormone tube was defective".

Product Quality Group provided investigational results on 22Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site investigation (Pfizer Manufacturing Site): The complaint for "The hormone tube was defective." of "Genotropin Dual Injectable" and "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, pictures of complaint sample, evaluation of reference sample, an analysis of the complaint history for the involved scope and Annual Product Review for the cartridge. The investigation included reviewing Annual Product Review for the U2 pen. Quantity of returned complaint samples: 2 pictures. The reported defect was not present on the returned pictures. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot(s) of the reported lot "HN2503" and for the pen no lot was available. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution.

Product Quality Group provided investigational results on 06Aug2025 for somatropin (device constituent): Medical Device Combination Product Investigation Summary and Conclusion: This complaint of "The hormone tube was defective. The patient said: "I have a situation. I have already informed to the program. The hormone tube was defective. A nurse has already sent me and reviewed the cartridge and she said it was defective and that is how she put it in the report.", for Genotropin Pen 12 was investigated.

Causality for "the hormone tube was defective" was determined associated to device constituent of somatropin (malfunction).

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

Follow-up (22Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Suspect drug details (action taken updated to not applicable) and Investigation results.

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

Follow-up (06Aug2025): This is a follow-up report from product quality group providing investigation results.
Updated information: product details.