

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	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 <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					07	APR	2025		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
 The pen leaked a little bit of medicine because she was doing the procedure wrong [Wrong technique in device usage process]
 the liquid leaked out [Device leakage]

Case Description: The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 09Apr2025, this case now contains all required information to be considered valid.

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

(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 # NK3098; Exp.Dt. 15-FEB-2027} #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) 1 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? <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. PV202500042984	
24c. DATE RECEIVED BY MANUFACTURER 28-APR-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 06-MAY-2025	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.

06-May-2025 14:27

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

A 10-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: NK3098, Expiration Date: 15Feb2027) at 1 mg daily. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE LEAKAGE (non-serious) with onset 07Apr2025, described as "the liquid leaked out"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "The pen leaked a little bit of medicine because she was doing the procedure wrong". The action taken for somatropin was unknown.

Causality for "the pen leaked a little bit of medicine because she was doing the procedure wrong" and "the liquid leaked out" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 28Apr2025 for somatropin (device constituent): 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. DEI: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Leaking During Loading, 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.

Additional information: A patient representative explained that it turned out that yesterday (07Apr2025), when they changed the ampoule for the first time, one of them broke. It did not break, but the liquid leaked out. The glass itself did not break; they changed two ampoules, and what it did was leak the liquid. On 09Apr2025, the nurse indicated that the patient had doubts since when she inserted the needle into the pen, the pen leaked a little bit of medicine because she was doing the procedure wrong, and then it was clarified to her and later she understood better.

Follow-up (28Apr2025): This is a spontaneous follow-up report from product quality group.

Updated information: expiration date and investigation results.