

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 8 Years	3. SEX Female	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					Unk			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
the vial always ends up with a lot of air [Device physical property issue]

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

An 8-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 2 mg daily (2.0 mg, daily (every night)).

(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		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) 2.0 mg, daily (every night) #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. PV202500095817	
24c. DATE RECEIVED BY MANUFACTURER 20-AUG-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 25-AUG-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.

25-Aug-2025 11:59

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 PHYSICAL PROPERTY ISSUE (non-serious), outcome "unknown", described as "the vial always ends up with a lot of air".

Causality for "the vial always ends up with a lot of air" was determined associated to device constituent of somatropin (malfunction).

Additional information: The patient's caregiver stated: 'I've been having problems with the medication Genotropin for several months. When I insert the hormone, the vial always ends up with a lot of air. They've already replaced the pen twice, and the same issue keeps happening. The pen that lasted the longest was the last one they gave me. The girl at the place where I pick up the medication told me to contact you to check if there's a manufacturing issue with the medication, or if the device could be replaced, because they don't have any available at the location.

Product Quality Group provided investigational results on 20Aug2025 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. The Complaint Issue, Cannot Remove Air, 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 (INX#100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Causality for "the vial always ends up with a lot of air" 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.

Follow-up (20Aug2025): This is a spontaneous follow-up report from product quality group providing investigation results. Updated information: event details ((Event "Device chemical property issue" recoded to "Device physical property issue") and investigation results.