

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	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								2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
vomited twice [Vomited]
nausea [Nausea]
the needle was hurting [Injection site pain]
pen was getting stuck in the part of the syringe [Resistance to movement in device]

Case Description: 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 # LR7825; Exp.Dt. MAY-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 type="checkbox"/> NA
15. DAILY DOSE(S) #1) 0.8 mg, daily (night time) #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 type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 2025 / 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. PV202500026807	
24c. DATE RECEIVED BY MANUFACTURER 07-JUL-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 10-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.

10-Jul-2025 08:59

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

An 8-year-old female patient received somatropin (GENOTROPIN PEN), since 2025 (Lot number: LR7825, Expiration Date: May2027) at 0.8 mg daily (0.8 mg, daily (night time)). The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE PHYSICAL PROPERTY ISSUE (non-serious) with onset 2025, outcome "unknown", described as "pen was getting stuck in the part of the syringe"; INJECTION SITE PAIN (non-serious) with onset 2025, outcome "unknown", described as "the needle was hurting"; VOMITING (non-serious), outcome "unknown", described as "vomited twice"; NAUSEA (non-serious), outcome "unknown". The action taken for somatropin was unknown.

Causality for "the needle was hurting" and "pen was getting stuck in the part of the syringe" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 07Jul2025 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, Component Damaged During Prep/Use, was reported. An additional Complaint Issue of Injection Failure/Blocked was reported. This Complaint Issue is considered a cascading event. 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# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: As of 17Jun2025, caregiver reported that the pen was getting stuck in the part of the syringe, when she pricked it got stuck and the needle was hurting, it had only been 3 months with the pen. As of 19Jun2025, a reporter indicated that upon checking it, it was confirmed that the needle holder had a spring which had lost its strength and no longer applied pressure to the button. It was possible to put it already out of the refrigeration and out of the refrigeration it worked very well.

Follow-up (13Apr2025): Follow-up attempts are completed.

Follow-up (17Jun2025). This is a spontaneous follow-up report received from a consumer. Updated information included: dose description, new events "pen was getting stuck in the part of the syringe" and "the needle was hurting" were added; clinical course updated.

Follow-up (19Jun2025): This is a Spontaneous follow-up report received from Nurse, Program ID: 164974. Updated information: Reporter information and additional information updated.

Follow-up (07Jul2025): This is a follow-up report from product quality group providing investigation results.