

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 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 cartridge broke it was that it sounded like an explosion [Device breakage]
when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother [Wrong technique in device usage process]

Case Description: The initial case was missing the following minimum criteria: Adverse event. Upon receipt of follow up information on 25Feb2025, this case now contains all required information to be considered valid.

(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)	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. PV202500024487	
24c. DATE RECEIVED BY MANUFACTURER 29-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 05-MAY-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.

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

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

A 10-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown). The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE BREAKAGE (non-serious), described as "the cartridge broke it was that it sounded like an explosion"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother". The action taken for somatropin was unknown.

Causality for "the cartridge broke it was that it sounded like an explosion" and "when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 07Apr2025 for somatropin (device constituent): Site Investigation (Puurs): 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 "Cartridge Glass Broken/Cracked During Loading/Unloading" 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.

Product Quality Group provided investigational summary and conclusion on 29Apr2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of The patient assistant says, "There was something that I was very concerned about and I wanted someone to help me, I was going to remove the cartridge, the cartridge broke it was that it sounded like an explosion (it made noise) the cartridge had to last a week, so I want Pfizer provide me with the explanation and check my Pen. Additional information reported that Nurse reports that when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother for Genotropin/Genotonorm U2 Pen was investigated by the manufacturing site. Site Investigation (Puurs): 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 "Cartridge Glass Broken/Cracked During Loading/Unloading" 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.

Follow-up(07Apr2025): This is a follow-up report from product quality group providing investigation results.

Updated information: Investigation results added.

Follow-up (17Apr2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up(29Apr2025): This is a follow-up report from product quality group providing investigation results.

Updated information: Investigation results updated.