

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 9 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 device was damaged, it is not indicating the dose and it does not inject [Device image display issue]
 The device was damaged, it is not indicating the dose and it does not inject [Device defective]
 the mother is not performing the right steps [Wrong technique in device usage process]

Case Description: This is a spontaneous report and received from Consumer or other non HCPs 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 #2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution (Continued on Additional Information Page)		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) 0.5 mg, 1x/day #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. 202500042464	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 23-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 28-APR-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

28-Apr-2025 10:12

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

A 9-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.5 mg 1x/day and second regimen (Batch/Lot number: unknown) at 0.9 mg 1x/day. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DEVICE DEFECTIVE (non-serious) and all described as "The device was damaged, it is not indicating the dose and it does not inject"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "the mother is not performing the right steps". The action taken for somatropin was unknown.

The reporter considered "the device was damaged, it is not indicating the dose and it does not inject" and "the mother is not performing the right steps" not related to somatropin. Causality for "the device was damaged, it is not indicating the dose and it does not inject" and "the mother is not performing the right steps" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 26Mar2025 for somatropin (device constituent): Site Investigation: 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. Two distinct Complaint Issues of "Display Not Functioning" and "Injection Failure/Blocked" were reported. "Display Not Functioning" maps to the Hazard/Hazardous Situation of "H06-02 Hazard "Electromagnetic Energy"/Hazardous Situation "Non-functional electronics or LCD" and "Injection Failure/Blocked" maps to the Hazard/Hazardous Situation of "H10-01 Hazard "Delivery Quantity"/Hazardous Situation "Dose not administered (single) or delay of dose administration in pediatric/adult population". 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 no current trend alert documented.

Product Quality Group provided investigational summary and conclusion on 23Apr2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: This complaint for "The device has been damaged, it is not indicating the dose and it is not injecting. Patient's mother indicates that she wants nursing advice because a month ago they changed her device to a new one and the new one no longer works, she indicates that it does not inject." for GENOTROPIN PEN 5.3 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. Two distinct Complaint Issues of "Display Not Functioning" and "Injection Failure/Blocked" were reported. "Display Not Functioning" maps to the Hazard/Hazardous Situation of "H06-02 Hazard "Electromagnetic Energy"/Hazardous Situation "Non-functional electronics or LCD" and "Injection Failure/Blocked" maps to the Hazard/Hazardous Situation of "H10-01 Hazard "Delivery Quantity"/Hazardous Situation "Dose not administered (single) or delay of dose administration in pediatric/adult population". 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 no current trend alert documented.

Additional information: The device has been damaged, it is not indicating the dose and it is not injecting. Patient's mother indicates that she wants nursing advice because a month ago they changed her device to a new one and the new one no longer works, she indicates that it does not inject. On 27Feb2025: Nurse indicates: "The mother mentions that the device does not work, at the time of my evaluate and perform the step by step, everything works properly, it is because the mother is not performing the right steps"

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

Follow-up (26Mar2025): This is a follow-up report from product quality group providing investigation results

Follow-up (11Apr2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up(23Apr2025): This is a follow-up report from product quality group providing investigation results.

Updated information: Investigation results updated.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S): 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2	0.9 mg, 1x/day; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE ; Unknown		Unknown	Unknown;

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
CONSTITUENT)) Solution for injection; Regimen #1			Unknown