SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		7 Years	Male	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Sometimes a little drop of medicine appears up there.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # R7825; Exp.Dt. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.4 mg, daily	#1) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Unknown
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) 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.
PV202500041777

24c. DATE RECEIVED BY MANUFACTURER
04-APR-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Also, when I'm done, a little drop remains/device is leaking [Device leakage]

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

A 7-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: R7825, Expiration Date: May2027) at 0.4 mg daily, second regimen (Lot number: lr7825, Expiration Date: May2027) at 0.4 mg daily and third regimen (Lot number: nd7549, Expiration Date: May2027) at 0.4 mg daily, Device Lot Number: D154, Device Expiration Date: 31Mar2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious), outcome "unknown", described as "Sometimes a little drop of medicine appears up there. Also, when I'm done, a little drop remains/device is leaking".

Additional Information: The nurse reported "The patient's mother complained that the button wasn't working properly, but that wasn't true. I received it and everything worked fine. It was just a bit stiff when pressing the button, but that was normal". The patient's caregiver said: "I don't know if it's normal, but when I gave the injection, as I inserted the needle, a small drop of medication sometimes appeared right at the top. Also, when I finished, a drop remained. Am I doing something wrong?". It should be noted that the caregiver did not have access to the batch number or expiration date of the pen or the medication. Upon follow-up received on 15Apr2025, the patient's caregiver informed: "Yesterday, we had a virtual appointment with the nurse. When we mentioned the pen releasing a few drops, he told us that this was putting the medication. He said that if it continued happening even after following his instructions, we should contact them again for further guidance or to consider a replacement". Upon follow-up received on 12May2025, the patient's caregiver informed: "I had reported a pen because it always released a few drops before and after the injection." A verification appointment had previously been scheduled, and the nurse confirmed that a replacement was indeed necessary. Upon follow-up received on 15May2025, the nurse stated: "During the guidance session with the patient on 14May, the caregiver reported that the device was leaking. By evaluating the device, it was possible to define the placebo and indeed, by placing the needle in the device with the placebo without any dose, the device begins to drip slowly. It is also observed that after dosing and administration of the medication, the corresponding ten seconds are counted, including counting up to the corresponding ten seconds after the injection time, it continues to drip after administration of the medication, slow dripping, but it is observed that it has leaks, so it suggests that a device change be made in this case". Upon follow-up received on 21May2025, the patient's caregiver informed: "I had requested a pen replacement. The nurse came and reported it, but I haven't received it yet. How long does that usually take?" He also mentioned: "According to the nurse, the pen was in good condition, but it still released a few drops before and after use".

Product Quality Group provided investigational results on 16Apr2025 for somatropin (device constituent): Investigation Summary and Conclusion: 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.

Causality for "sometimes a little drop of medicine appears up there. also, when i'm done, a little drop remains/device is leaking" was determined associated to device constituent of somatropin (malfunction).

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 {Lot # lr7825; Exp.Dt. MAY-2027}; Regimen #2	0.4 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # nd7549; Exp.Dt. MAY-2027}; Regimen #3	0.4 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D154}; Regimen #1	; Unknown	Unknown	Unknown; Unknown