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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	DOMINICAN REPUBLIC		PRIVACY		10 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)

I do not know what I am doing wrong/I need the nurse to tell me what I am doing wrong [Health care provider instructions for product use lacking]
really nervous [Nervous]
has a lot of muscle and it is turning very purple / bruises immediately appear on his thighs [Injection site bruising]

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)

- ☐ 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
#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) 1.2 mg, daily (at night)	#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.
PV202500022478

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

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

DATE OF THIS REPORT
06-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 10-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 1.2 mg daily (1.2 mg, daily (at night)) and second regimen (Batch/Lot number: unknown) at 1 mg daily (1.0 mg, daily). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), outcome "unknown", described as "I do not know what I am doing wrong/I need the nurse to tell me what I am doing wrong"; NERVOUSNESS (non-serious), outcome "unknown", described as "really nervous"; INJECTION SITE BRUISING (non-serious), outcome "unknown", described as "has a lot of muscle and it is turning very purple / bruises immediately appear on his thighs". The action taken for somatropin was unknown.

Additional information: "when I inject him in his arms, nothing comes out, but in his thighs they immediately appear the bruises".

Product Quality Group provided investigational results on 26Mar2025 for somatropin (device constituent): Investigation Summary and Conclusion: 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, Injection Failure/Blocked, 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 (INX100281795), Version (9.0). All complaint investigations are trended. There is no current trend alert documented.

Batch/lot number is not provided, and it cannot be obtained.

Follow-up (01Mar2025): This is a spontaneous report received from a Consumer or other non HCP and a Nurse, Program ID: 164974.
Updated information: Event recoded to injection site bruising) and clinical course.

Follow-up (26Mar2025): This is a spontaneous follow-up report received from product quality group. Updated information included: investigation results.
Follow-up (11Apr2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.
Follow-up (28Apr2025): This is a spontaneous follow-up report received from product quality group.
Updated information: reportability assessment changed from Reportable to not device related. Event recoded "Wrong Technique In Device Usage Process" from to "Health care provider instructions for product use lacking".

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	1.0 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection; Regimen #1	; Unknown	Unknown	Unknown; Unknown