

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 5 Years	3. SEX Male	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 needle expelled the medication [Device leakage]

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

A 5-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LR7824, Expiration Date: Jun2027) at 0.3 mg daily.

(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 # LR7824; Exp.Dt. JUN-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 checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 0.3 mg, daily #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. PV202500077345	
24c. DATE RECEIVED BY MANUFACTURER 26-JUN-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 14-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.

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

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 "the needle expelled the medication".

Causality for "the needle expelled the medication" was determined associated to device constituent of somatropin (malfunction).

Additional information: patient's caregiver stated: they have problems with the device, that after she gives it to him, she have to count 10 seconds, and after she takes the needle out of the child, the needle expelled the medication, it is being wasted.