

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>DOMINICAN REPUBLIC</b>	2. DATE OF BIRTH			2a. AGE <b>9</b> Years	3. SEX <b>Male</b>	3a. WEIGHT <b>Unk</b>	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	
			<b>PRIVACY</b>					<b>Unk</b>			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)  
the device is wasting (leaking) the product and discarding the medication [Device leakage]  
the device appears to lock when first applied and also during use [Device mechanical jam]

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

A 9-year-old male patient received somatropin (GENOTROPIN PEN), since Jun2025 (Batch/Lot number: unknown) at 0.7 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 #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 ) 0.7 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 ) JUN-2025 / 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. <b>PV202500097031</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>07-AUG-2025</b>	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 <b>20-AUG-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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**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 device is wasting (leaking) the product and discarding the medication"; DEVICE MECHANICAL ISSUE (non-serious), outcome "unknown", described as "the device appears to lock when first applied and also during use".

Causality for "the device is wasting (leaking) the product and discarding the medication" and "the device appears to lock when first applied and also during use" was determined associated to device constituent of somatropin (malfunction).

Additional information: the patient assistant indicates that the device is wasting (leaking) the product and discarding the medication. He says he received a free one in the lab, but it didn't last a month. Indicates that the device appears to lock when first applied and also during use. Mention that the medication should last 8 days, but it is not that way, and that you have even leaked an entire cartridge. In addition, he comments that he will stop the medication, since neither the program nor the laboratory performs the replacement, indicates that he has been on treatment for 2 months

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