

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 11 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ 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)
when the dose was set the device administered more than the quantity set [Incorrect dose administered by device]
when the dose was set the device administered more than the quantity set [Device delivery system issue]

Case Description: This is a spontaneous report received from a Nurse, Program ID: 164974.

An 11-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1 mg.

(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? ☐ YES ☐ NO ☒ NA
15. DAILY DOSE(S) #1) 1 mg #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? ☐ YES ☐ NO ☒ 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. PV202500057328	
24c. DATE RECEIVED BY MANUFACTURER 23-MAY-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☒ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous	
DATE OF THIS REPORT 29-MAY-2025	25a. REPORT TYPE ☒ INITIAL ☐ FOLLOWUP:	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.

29-May-2025 12:40

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: INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious), DEVICE DELIVERY SYSTEM ISSUE (non-serious) and all described as "when the dose was set the device administered more than the quantity set". The action taken for somatropin was unknown.

Causality for "when the dose was set the device administered more than the quantity set" was determined associated to device constituent of somatropin.

Additional information: Reporter stated that when the dose was set the device administered more than the quantity set, it did not stay at the milligrams set, so when 1 mg was set, it did not administer that. On 23May2025 nurse reported that caregiver did not take the pen to the appointment so it was not possible to correct the turns she gives. Caregiver believed it could be applying maybe more, maybe less.

Follow-up (23May2025). This is a spontaneous follow-up report received from a nurse. Updated information included: clinical course.