

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 10 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)  
 it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Device image display issue]  
 it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Device battery issue]  
 it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Product communication issue]

(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 # LK3089; Exp.Dt. FEB-2027} #2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # HF4891}		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 ) 0.8 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. <b>PV202500057990</b>		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>13-MAY-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous		NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT <b>21-MAY-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:		

21-May-2025 16:23

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

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

A 10-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LK3089, Expiration Date: Feb2027) at 0.8 mg daily, Device Lot Number: HF4891, Device Expiration Date: Jan2026. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DEVICE POWER SOURCE ISSUE (non-serious), PRODUCT COMMUNICATION ISSUE (non-serious), outcome "unknown" and all described as "it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose".

Causality for "it's not giving him the dose when they put in the dose. it's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose" was determined associated to device constituent of somatropin (malfunction).

Additional information: The Genotropin pen was not working, it's not giving him the dose when they put in the dose. it's not resetting to zero. They test it out to see if it was the needle or the cartridge, they change the cartridge but It's the pen that's not giving the dose...it's not setting the dose. As of 13May2025, reporter stated the device did not set the dose of the medication it only show two lines.

Follow-up (13May2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information includes drug and device lot number and expiration date, new event of "device battery issue", additional information.