

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 13 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)
 I cannot give him the dose that the doctor imposed because it does not mark it on the screen [No image display on device]
 I cannot give him the dose that the doctor imposed because it does not mark it on the screen [Drug dose omission by device]
 It gets stuck sometimes [Resistance to movement in device]
 the device is expired / I cannot give him the dose that the doctor imposed because it does not mark it on the screen / the pen stopped working. [Device battery issue]
 the device is expired [Expired device used]

(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 (Continued on Additional Information Page)		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) 1.8 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. PV202500051816	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 30-APR-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 08-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

08-May-2025 08:35

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 13-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 1.8 mg daily, second regimen (Batch/Lot number: unknown) at 1 mg daily and third regimen (Batch/Lot number: unknown, Expiration Date: Jun2025) at 1.6 mg daily, Device Lot Number: W131, Device Expiration Date: Dec2023. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DRUG DOSE OMISSION BY DEVICE (non-serious), outcome "unknown" and all described as "I cannot give him the dose that the doctor imposed because it does not mark it on the screen"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious), outcome "unknown", described as "It gets stuck sometimes"; DEVICE POWER SOURCE ISSUE (non-serious), outcome "unknown", described as "the device is expired / I cannot give him the dose that the doctor imposed because it does not mark it on the screen / the pen stopped working."; EXPIRED DEVICE USED (non-serious), outcome "unknown", described as "the device is expired".

Causality for "i cannot give him the dose that the doctor imposed because it does not mark it on the screen", "it gets stuck sometimes", "the device is expired / i cannot give him the dose that the doctor imposed because it does not mark it on the screen / the pen stopped working." and "the device is expired" was determined associated to device constituent of somatropin (malfunction).

Additional information: Reporter states that he noted the device was expired because 1 month ago (Apr2025) the pen stopped working.

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 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Exp.Dt. JUN-2025}; Regimen #3	1.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W131}; Regimen #1	; Unknown	Unknown	Unknown; Unknown