

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 12 Years	3. SEX Female	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)
 where it marked the quantity, it stopped presenting the numbers on the screen [Device readings not obtained]
 placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it
 stopped working [Improper use of device]

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

A 12-year-old female patient received somatropin (GENOTROPIN PEN),

(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 (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 (at night) #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. PV202500083464	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 09-JUL-2025	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 22-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

first regimen (Lot number: LK3089, Expiration Date: Feb2027) at 1.8 mg daily (1.8 mg, daily (at night)) and second regimen (Lot number: HF4891, Expiration Date: Jan2026) at 1.8 mg daily (1.8 mg, daily (at night)), Device Lot Number: L092, Device Expiration Date: 31Jan2026. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "where it marked the quantity, it stopped presenting the numbers on the screen"; DEVICE USE ISSUE (non-serious), described as "placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working". The action taken for somatropin was unknown.

Causality for "where it marked the quantity, it stopped presenting the numbers on the screen" and "placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working" was determined associated to device constituent of somatropin (malfunction).

Additional information: Caregiver reported that patient had been using Genotropin every day for over a year. Just that now the device where the injection was given, where it marked the quantity, it stopped presenting the numbers on the screen. Patient was not seeing the dose. Caregiver thought it was that the battery was running out, he tried but it did not turn on the screen. The nurse indicated that the caregivers had gone out somewhere and placed the device in a small beach cooler with ice, and when the device came into contact with the ice, it stopped working, the numbers could no longer be seen. She noticed that there was only enough left for the dose on the same day of the consultation.

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 {Lot # HF4891; Exp.Dt. JAN-2026}; Regimen #2	1.8 mg, daily (at night); Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L092}; Regimen #1	; Unknown	Unknown	Unknown; Unknown