

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 6 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 spilled half of it [Device leakage]
pen broke, it jammed [Device breakage]
the patient uses the 5.3 mg version, but they were given the 12 mg one [Device dispensing error]
patient should receive 6 mg, and other days 8 mg [Drug prescription issue]

Case Description: The initial case was missing the following minimum criteria: Adverse event. Upon receipt of follow up information on 21Jul2025, this case now contains all required information to be considered valid.

(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 # L092}		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) 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. PV202500088959	
24c. DATE RECEIVED BY MANUFACTURER 21-JUL-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 01-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.

01-Aug-2025 16:23

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

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

A 6-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LK3089, Expiration Date: Feb2027) at 0.7 mg daily, Device Lot Number: L092. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DEVICE LEAKAGE (non-serious), described as "it spilled half of it"; DEVICE BREAKAGE (non-serious), described as "pen broke, it jammed"; DEVICE DISPENSING ERROR (non-serious), described as "the patient uses the 5.3 mg version, but they were given the 12 mg one"; PRODUCT PRESCRIBING ISSUE (non-serious), described as "patient should receive 6 mg, and other days 8 mg". The action taken for somatropin was unknown.

Causality for "it spilled half of it", "pen broke, it jammed" and "the patient uses the 5.3 mg version, but they were given the 12 mg one" was determined associated to device constituent of somatropin (malfunction).

Additional information: The patient's caregiver reports: "Six months ago, the Children's Hospital gave me the pen to inject the Genotropin hormone. On Saturday night, the pen broke, it jammed. I was changing to a new hormone cartridge, and it spilled half of it (it spilled when I was removing the air). The entire piston (button) came out, and the pen became extremely stiff. I called the Children's Hospital, and they told me they only provide pens during the week." The caregiver also mentions that they were given a completely different pen, as the patient uses the 5.3 mg version, but they were given the 12 mg one. They state that the doctor at the Children's Hospital prescribed the treatment as follows: some days the patient should receive 6 mg, and other days 8 mg. The caregiver was told the following at the hospital regarding the new pen: "We don't have any. Use this one if you want, and if not, just leave it." The caregiver expresses discomfort with this prescription, as it would require administering the medication multiple times using different devices for Genotropin.