

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 1 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)
device did not work/the device is damaged [Device defective]

Case Description: The initial case was missing the following minimum criteria: Adverse event.

(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) 0.2 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. PV202500066052	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 29-MAY-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 11-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	NAME AND ADDRESS WITHHELD.

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

Upon receipt of follow up information on 29May2025, this case now contains all required information to be considered valid.

This is a spontaneous report received from a Physician and a Nurse from product quality group, Program ID: 164974.

An 1-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.2 mg daily and second regimen (Batch/Lot number: unknown) at 0.5 mg daily, Device Lot Number: 0126. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE DEFECTIVE (non-serious), outcome "unknown", described as "device did not work/the device is damaged".

Causality for "device did not work/the device is damaged" was determined associated to device constituent of somatropin (malfunction).

Additional information: The patient lives in the United States and syringes have been damaged, appointment with the nurse scheduled because the device did not work, doctor states that he did not order the medication because the device is damaged, the nurse indicated that there was a quality complaint because the pen was in poor condition.

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

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	0.5 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # 0126}; Regimen #1	; Unknown	Unknown	Unknown; Unknown