

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 7 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						02	JUN	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
The pen was damaged, the plastic part that goes on top was damaged [Device breakage]
It caused him pain and discomfort [Injection site pain]
It caused him pain and discomfort [Injection site discomfort]

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

A 7-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: Ir7825, Expiration Date: May2027) at 0.6 mg 1x/day, Device

(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 # Ir7825; Exp.Dt. MAY-2027} #2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # Ib7549}		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 0.6 mg, 1x/day #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 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. PV202500067101	
24c. DATE RECEIVED BY MANUFACTURER 03-JUN-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 05-JUN-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.

05-Jun-2025 17:39

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

Lot Number: lb7549, Device Expiration Date: Mar2027. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: INJECTION SITE PAIN (non-serious), INJECTION SITE DISCOMFORT (non-serious) all with onset 02Jun2025, outcome "unknown" and all described as "It caused him pain and discomfort"; DEVICE BREAKAGE (non-serious), outcome "unknown", described as "The pen was damaged, the plastic part that goes on top was damaged". The action taken for somatropin was unknown.

Causality for "the pen was damaged, the plastic part that goes on top was damaged" and "it caused him pain and discomfort" was determined associated to device constituent of somatropin (malfunction).

Additional Information: The patient manager indicated: "My son is undergoing GENOTROPIN treatment, but the pen was damaged, the plastic part that goes on top was damaged. It urges me because yesterday (02Jun2025) we did the process and it did cause him pain and discomfort." He also indicated: "Here in the country they do not sell the pen, I call everywhere and they do not sell it."