

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH Day Month Year PRIVACY			2a. AGE 13 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year Unk			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
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) the device did not want to turn, it was kind of stuck and did not rotate [Device mechanical jam] Case Description: This is a spontaneous report received from a Consumer or other non HCP from product quality group, Program ID: 164974. A 13-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown). (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 for injection		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) #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. PV202500081150		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 03-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 16-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:		

16-Jul-2025 08:57

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

The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE MECHANICAL ISSUE (non-serious), outcome "unknown", described as "the device did not want to turn, it was kind of stuck and did not rotate".

The reporter considered "the device did not want to turn, it was kind of stuck and did not rotate" not related to somatropin. Causality for "the device did not want to turn, it was kind of stuck and did not rotate" was determined associated to device constituent of somatropin (malfunction).

Additional Information: The mother of the patient indicated: "The device did not want to turn, it was kind of stuck and did not rotate to measure the amount of mg that should be administered to the patient." The mother of the patient did not have the device information on hand to provide details.

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