

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 17 Years	3. SEX Female	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) her head is hurting a lot [Headache] seems to be a flu episode [Flu] Case Description: This is a spontaneous report received from a Consumer or other non HCP and a Nurse, Program ID: 164974. A 17-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.4 mg 1x/day for growth disorder. The patient's relevant medical history and concomitant medications were not reported. (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 type="checkbox"/> NA
15. DAILY DOSE(S) #1) 1.4 mg, 1x/day #2)	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #2) Unknown	
17. INDICATION(S) FOR USE #1) treatment for growth (Growth disorder) #2) treatment for growth (Growth disorder)		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. PV202500099865		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 19-AUG-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.
DATE OF THIS REPORT 26-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:		

26-Aug-2025 12:17

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

The following information was reported: HEADACHE (non-serious), outcome "unknown", described as "her head is hurting a lot"; INFLUENZA (non-serious), outcome "unknown", described as "seems to be a flu episode". The action taken for somatropin was unknown.

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

Additional Information: A relative of the patient stated that "what happens was that a niece of mine was given the GENOTROPIN treatment for growth, and she tells me that her head is hurting a lot, I wanted to know what it could be." Counseling with nursing is coordinated as part of the benefits of the program. On 19Aug2025, a nurse reported the patient's mother had requested a consultation because the patient had mentioned she was experiencing a headache, nasal congestion, and flu-like symptoms. It seems to be a flu episode. Patient's mother was asked if it had anything to do with the product, and she said no, that everything was fine with the product. In fact, she had understood it well and said there had been no problem with it.

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

Follow-up (19Aug2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974

Updated information included: New reporter added, reaction data (new event "seems to be a flu episode"); clinical course