

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 12 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)  
It hurt [Injection site pain]  
It itched [Injection site itching]

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

A 12-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.3 mg 1x/day.

(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 ) 1.3 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. <b>PV202500052612</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>12-JUN-2025</b>	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 <b>12-JUN-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.

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**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: INJECTION SITE PAIN (non-serious), outcome "unknown", described as "It hurt"; INJECTION SITE PRURITUS (non-serious), outcome "unknown", described as "It itched". The action taken for somatropin was unknown.

Causality for "It hurt" and "It itched" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 16May2025 for somatropin (device constituent): No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened.

Additional information: On 28Apr2025, the patient's mother prepared and applied the medication, however, it hurt, and it itched. This was the fifth dose. It had already happened before. It happened the first time it was used. The patient had used another brand, and she did not have any problems.

Follow-up (16May2025): This is a follow-up report from product quality group.  
Updated information included: investigation results for somatropin.

Batch/lot number is not provided, and it cannot be obtained.

Follow-up (12Jun2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.