

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>GUATEMALA</b>	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	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	Unk	Female	Unk	Day	Month	Year	
		<b>PRIVACY</b>							<b>Unk</b>		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)  
the medication does not come out of the needle [Device delivery system no flow]  
problem with the device, on Saturday we could no longer inject my daughter [Drug dose omission by device]

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

A female patient (unknown if pregnant) 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 ) UNK #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. <b>PV202500059164</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>28-MAY-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>02-JUN-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

---

**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 DELIVERY SYSTEM ISSUE (non-serious), described as "the medication does not come out of the needle"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "problem with the device, on Saturday we could no longer inject my daughter". The action taken for somatropin was unknown.

Additional Information: Product Quality Group provided investigational results on 28May2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): 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. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Injection Failure/Blocked, was reported. The Risk Management File was reviewed to confirm that the Hazard(s) and Hazardous Situation(s) associated with the Complaint Issue are documented in the Hazard Analysis (INX# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Causality for "problem with the device, on saturday we could no longer inject my daughter" and "the medication does not come out of the needle" was determined associated to device constituent of somatropin (malfunction).

Follow-up (28May2025): This is a spontaneous follow-up report from product quality group providing investigation results.