

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</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	Unk	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 device got damaged, the battery didn't work, or due to misuse by the caregiver [Device defective]  
 the device got damaged, the battery didn't work, or due to misuse by the caregiver [Device battery issue]

Case Description: This is a spontaneous report and received from Consumer or other non HCPs from product quality group.

A patient (age and gender not provided) 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 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 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>202500161195</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>07-AUG-2025</b>	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. NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT <b>19-AUG-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

19-Aug-2025 10:25

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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: DEVICE DEFECTIVE (non-serious), DEVICE POWER SOURCE ISSUE (non-serious), outcome "unknown" and all described as "the device got damaged, the battery didn't work, or due to misuse by the caregiver".

The reporter considered "the device got damaged, the battery didn't work, or due to misuse by the caregiver" not related to somatropin. Causality for "the device got damaged, the battery didn't work, or due to misuse by the caregiver" was determined associated to device constituent of somatropin (malfunction).

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