

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

|  |                                 |                  |                |      |                              |                         |                          |                    |       |      |  |
|--|---------------------------------|------------------|----------------|------|------------------------------|-------------------------|--------------------------|--------------------|-------|------|--|
| 1. PATIENT INITIALS<br>(first, last)<br><b>PRIVACY</b> | 1a. COUNTRY<br><b>GUATEMALA</b> | 2. DATE OF BIRTH |                |      | 2a. AGE<br><b>6</b><br>Years | 3. SEX<br><b>Female</b> | 3a. WEIGHT<br><b>Unk</b> | 4-6 REACTION ONSET |       |      | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION<br><br><input type="checkbox"/> PATIENT DIED<br><br><input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION<br><br><input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY<br><br><input type="checkbox"/> LIFE THREATENING |
|  |                                 | Day              | Month          | Year |                              |                         |                          | 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)  
When they try to adjust it to set the eight millimeters, it doesn't work [Device mechanical issue]

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

A 6-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.8 mg daily (0.8 mg, daily (every night)) and second regimen (Lot number: LM4285, Expiration Date:

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

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|--|--|--|
| 14. SUSPECT DRUG(S) (include generic name)<br>#1 ) Genotropin Pen (SOMATROPIN) Solution for injection<br>#2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution (Continued on Additional Information Page) |  | 20. DID REACTION ABATE AFTER STOPPING DRUG?<br><br><input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA     |
| 15. DAILY DOSE(S)<br>#1 ) 0.8 mg, daily (every night)<br>#2 )  | 16. ROUTE(S) OF ADMINISTRATION<br>#1 ) Unknown<br>#2 ) Unknown |  |
| 17. INDICATION(S) FOR USE<br>#1 ) Unknown<br>#2 ) Unknown  |  | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION?<br><br><input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA |
| 18. THERAPY DATES(from/to)<br>#1 ) Unknown<br>#2 ) Unknown   | 19. THERAPY DURATION<br>#1 ) Unknown<br>#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.)<br>From/To Dates                      Type of History / Notes                      Description<br>Unknown |  |  |

## IV. MANUFACTURER INFORMATION

|  |   |   |
|--|---|---|
| 24a. NAME AND ADDRESS OF MANUFACTURER<br>Pfizer S.A.<br>Laura Arce Mora<br>Avenida Escazú, Torre Lexus, piso 7. Escazú<br>San jose, COSTA RICA |   | 26. REMARKS   |
|  | 24b. MFR CONTROL NO.<br><b>PV202500061096</b>   | 25b. NAME AND ADDRESS OF REPORTER<br>NAME AND ADDRESS WITHHELD.<br><br>NAME AND ADDRESS WITHHELD. |
| 24c. DATE RECEIVED BY MANUFACTURER<br><b>19-MAY-2025</b>   | 24d. REPORT SOURCE<br><input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE<br><input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous |   |
| DATE OF THIS REPORT<br><b>30-MAY-2025</b>  | 25a. REPORT TYPE<br><input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:  |   |

30-May-2025 10:11

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Feb2027) at 0.6 mg daily, Device Lot Number: HM4951, Device Expiration Date: 30Nov2026. 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 "When they try to adjust it to set the eight millimeters, it doesn't work". The action taken for somatropin was unknown.

The reporter considered "when they try to adjust it to set the eight millimeters, it doesn't work" not related to somatropin. Causality for "when they try to adjust it to set the eight millimeters, it doesn't work" was determined associated to device constituent of somatropin (malfunction).

Additional Information: The patient's caregiver states the pen no longer worked, so they would like to know what applies in this case. When they try to adjust it to set the eight millimeters, it doesn't work. Nurse states: "Upon arriving at the visit, the patient's caregiver reported that during a cartridge replacement, it got stuck. That's why they requested in-person assistance. The pen was evaluated and tested it with a placebo and confirmed that the pen is in perfect working condition. The cartridge was reinserted, the one that had gotten stuck, and left everything ready for them to continue the treatment. The pen is in perfect condition."

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

14-19. SUSPECT DRUG(S) continued

| 14. SUSPECT DRUG(S) (include generic name)  | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---------------------------|--|
| #1 ) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # LM4285; Exp.Dt. FEB-2027}; Regimen #2    | 0.6 mg, daily; Unknown                      | Unknown                   | Unknown;<br>Unknown                                  |
| #2 ) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # HM4951}; Regimen #1 | ; Unknown                                   | Unknown                   | Unknown;<br>Unknown                                  |