

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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|--|----------------------------------|------------------|----------------|------|---------|--------|------------|--------------------|------------|------|---|
| 1. PATIENT INITIALS (first, last) PRIVACY | 1a. COUNTRY COSTA RICA | 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 <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER |
| | | Day | Month | Year | Unk | Male | Unk | Day | Month | Year | |
| | | | PRIVACY | | | | | | Unk | | |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
**Bad fasting glucose control (increases) [Blood glucose increased]
occasional hypoglycemia [Hypoglycaemia]**

Case Description: ***This is an auto generated narrative***

This non-serious Spontaneous case from COSTA RICA was reported by a Consumer as "Bad fasting glucose control (increases)(Fasting blood glucose increased)" with an unspecified onset date, "occasional hypoglycemia(Hypoglycemia)" with an unspecified onset date, and concerned a Adult Male patient who was treated with Tresiba FlexTouch (Insulin Degludec) from

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

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| 14. SUSPECT DRUG(S) (include generic name) #1) Tresiba FlexTouch (Insulin Degludec) Solution for injection (Continued on Additional Information Page) | | 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 | 16. ROUTE(S) OF ADMINISTRATION #1) Unknown | |
| 17. INDICATION(S) FOR USE #1) Product used for unknown indication (P) (Continued on Additional Information Page) | | 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) Ongoing | 19. THERAPY DURATION #1) Unknown | |

III. CONCOMITANT DRUG(S) AND HISTORY

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| 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 to Ongoing Current Condition Diabetes (Diabetes mellitus) Type and duration not reported. | |

IV. MANUFACTURER INFORMATION

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|---|---|---|
| 24a. NAME AND ADDRESS OF MANUFACTURER Novo Nordisk A/S Lise Grimmeshave Vandtaarnsvej 114 Soeborg, DK-2860 DENMARK Phone: +45 44448888 | | 26. REMARKS Medically Confirmed: No |
| | 24b. MFR CONTROL NO. 1439774 | 25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. |
| 24c. DATE RECEIVED BY MANUFACTURER 20-MAY-2025 | 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 23-JUN-2025 | 25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP: | |

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued
unknown start date and ongoing for "Product used for unknown indication",

Dosage Regimens:
Tresiba FlexTouch:

Current Condition: Diabetes.

Batch Numbers:
Tresiba FlexTouch: ASKU

Action taken to Tresiba FlexTouch was reported as No Change.

The outcome for the event "Bad fasting glucose control (increases)(Fasting blood glucose increased)" was Not Reported.
The outcome for the event "occasional hypoglycemia(Hypoglycemia)" was Not Reported.

14-19. SUSPECT DRUG(S) continued

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to); 19. THERAPY DURATION |
|---|---|---|--|
| #1) Tresiba FlexTouch (Insulin Degludec) Solution for injection; Regimen #1 | UNK; Unknown | Product used for unknown indication (Product used for unknown indication) | Ongoing; Unknown |