**CIOMS FORM**

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH Day | Month | Year | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET Day | Month | Year |
|---|---|---|---|---|---|---|---|---|---|---|
| PRIVACY | COSTA RICA | | PRIVACY | | 53 Years | Male | 103.00 kg | 31 | MAR | 2024 |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
Hospitalised due to an infection [Infection]
Amputation in foot [Foot amputation]

Case Description: Study ID: 199-NovoDia

Study description: Trial Title: Patient support programme to support physician and their daily work to maintain an optimal diabetic control of patients through added value services such as treatment starter kit, nutrition support through NovoDia call center, individual workshops, group

**(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 ) NovoRapid (Insulin Aspart 100 U/mL) Solution for injection, 100 U/mL

**(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1 ) 20 IU, bid (Continued on Additional Information Page)

16. ROUTE(S) OF ADMINISTRATION
#1 ) Subcutaneous

17. INDICATION(S) FOR USE
#1 ) Type 2 diabetes (Type 2 diabetes mellitus)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)
#1 ) OCT-2023 / JUL-2024

19. THERAPY DURATION
#1 ) Unknown

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 ) IRBESARTAN (IRBESARTAN) ; 2005 / Ongoing
#2 ) AMLODIPINE (AMLODIPINE) ; 2005 / Ongoing
#3 ) ASPIRINE (ACETYLSALICYLIC ACID) ; 2000 / Ongoing
#4 ) JARDIANCE DUO (EMPAGLIFLOZIN, METFORMIN HYDROCHLORI

**(Continued on Additional Information Page)**

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Historical Condition | Charcot arthropathy (Neuropathic arthropathy) |
| | She previously suffered from Charcot arthropathy. (For this reason, amputation occurred.) | |
| Unknown to Ongoing | Current Condition | Type 2 diabetes mellitus (Type 2 diabetes mellitus) |
| | Duration not reported | |

## IV. MANUFACTURER INFORMATION

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
World Wide #: CR-NOVOPROD-1414561

24b. MFR CONTROL NO.
**1414561**

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
20-JUN-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
27-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

workshops and free A1c test.

Patient's height: 177 cm.

Patient's weight: 103 kg.

Patient's BMI: 32.87688720.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "Hospitalised due to an infection(Infection)" beginning on 31-MAR-2024 , "Amputation in foot(Foot amputation)" beginning on 2024 and concerned a 53 Years old Male patient who was treated with NovoRapid (Insulin Aspart 100 U/mL) from OCT-2023 to JUL-2024 for "Type 2 diabetes".

Dosage Regimens:
NovoRapid: ??-OCT-2023 to ??-JUL-2024;

Current Condition: Type 2 diabetes (Duration not reported), hypertension
Historical Condition: Charcot arthropathy.

Concomitant medications included - IRBESARTAN, AMLODIPINE, ASPIRINE(ACETYLSALICYLIC ACID), JARDIANCE DUO(EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE).

Treatment medications included - CEPHALEXINE(CEFALEXIN), VANCOMYCIN.

In 2024, the patient had an amputation in his foot (indicates that the surgery was planned in advance). He was previously suffered from Charcot arthropathy.(For this reason, amputation occurred).

On 31-Mar-2024, the patient was hospitalized due to an infection (not specified), for which he spent 2 and a half months in the hospital. Patient was discharged on an unknown date in JUL-2024

Treatment Received with "Many antibiotics" such as cephalexin and vancomycin (does not remember the names of the other antibiotics).

Batch Number of NovoRapid was requested but could not be obtained

Action taken to NovoRapid was reported as Drug discontinued temporarily.

On JUL-2024 the outcome for the event "Hospitalised due to an infection(Infection)" was Recovered.
On 2024 the outcome for the event "Amputation in foot(Foot amputation)" was Recovered.

Reporter's causality (NovoRapid) -
Hospitalised due to an infection(Infection) : Unlikely
Amputation in foot(Foot amputation) : Unlikely

Company's causality (NovoRapid) -
Hospitalised due to an infection(Infection) : Unlikely
Amputation in foot(Foot amputation) : Unlikely

Since last submission case was updated with the following information:
Hospitalization start and stop date added for event “Infection”
Verbatim was changed to “Hospitalised due to an infection”
Narrative updated accordingly

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1414561
Reference Notes:

**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 |
|---|---|---|---|

Mfr. Control Number: 1414561

## ADDITIONAL INFORMATION

**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 ) NovoRapid (Insulin Aspart 100 U/mL) Solution for injection, 100 U/mL; Regimen #1 | 20 IU, bid (In the morning and at noon; if necessary, also at night); Subcutaneous | Type 2 diabetes (Type 2 diabetes mellitus) | OCT-2023 / JUL-2024; Unknown |

**22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued**

#4 ) JARDIANCE DUO (EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE) ; 2022 / Ongoing

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown to Ongoing | Current Condition | Hypertension (Hypertension); |