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
infection [Infection]
Amputation in his 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

24b. MFR CONTROL NO.
1414561

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

24c. DATE RECEIVED BY MANUFACTURER
16-APR-2025

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

DATE OF THIS REPORT
25-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1414561

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 "infection(Infection)" beginning on 31-MAR-2024 , "Amputation in his 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.
Treatment Received with "Many antibiotics" such as cephalexin and vancomycin (does not remember the names of the other antibiotics).

Batch Numbers:
NovoRapid: Requested;

Action taken to NovoRapid was reported as Drug discontinued temporarily.

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

Reporter's causality (NovoRapid) -
infection(Infection) : Unlikely
Amputation in his foot(Foot amputation) : Unlikely

Company's causality (NovoRapid) -
infection(Infection) : Unlikely
Amputation in his foot(Foot amputation) : Unlikely

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) 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

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

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