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		66 Years	Male	71.00 kg		JUN	2025

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

hypoglycemia (less than 54 mg/dl) [Hypoglycaemia]
diarrhea [Diarrhoea]

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

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,

(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) IDeg PDS290 (Insulin Degludec 100 U/mL) Solution for injection, 100 U/mL

(Continued on Additional Information Page)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 30 IU, qd	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2019 / Unknown	#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPH
#2) CREON (PANCREATIN) ; JAN-2024 / Ongoing
#3) OMEPRAZOLE (OMEPRAZOLE) ; JAN-2025 / Ongoing
#4) BIOGAIA [LACTOBACILLUS REUTERI] (LACTOBACILLUS REUTE

(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 to Ongoing	Current Condition Duration not reported	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition Duration not reported	Overweight (Overweight)

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.
1479590

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

24c. DATE RECEIVED BY MANUFACTURER
09-JUL-2025

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

DATE OF THIS REPORT
28-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

nutrition support through NovoDia call center, individual workshops, group workshops and free A1c test.

Patient's height: 175 cm.

Patient's weight: 71 kg.

Patient's BMI: 23.18367350.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "hypoglycemia (less than 54 mg/dl)(Hypoglycemia)" beginning on JUN-2025 , "diarrhea(Diarrhea)" beginning on JUN-2025 and concerned a 66 Years old Male patient who was treated with Tresiba 100 U/ml FlexTouch (Insulin Degludec 100 U/mL) from 2019 and ongoing for "type 2 diabetes",

Dosage Regimens:
Tresiba 100 U/ml FlexTouch: ??-???-2019 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: type 2 diabetes, Overweight, lactose intolerance, liver problem.

Concomitant medications included - JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE](METFORMIN HYDROCHLORIDE, SITAGLIPTIN PHOSPHATE), CREON(PANCREATIN), OMEPRAZOLE, BIOGAIA LACTOBACILLUS REUTERI.

Lab Data included:
Lab Data Test as Reported: Blood glucose
Test Name: Blood glucose
Results: < 54
Unit: mg/dL
Comments:

Batch Numbers:
Tresiba 100 U/ml FlexTouch: UNK, UNK;

Action taken to Tresiba 100 U/ml FlexTouch was reported as Dose Decreased.

On JUN-2025 the outcome for the event "hypoglycemia (less than 54 mg/dl)(Hypoglycemia)" was Recovered.
On JUN-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.

Reporter's causality (Tresiba 100 U/ml FlexTouch) -
hypoglycemia (less than 54 mg/dl)(Hypoglycemia) : Unlikely
diarrhea(Diarrhea) : Unlikely

Company's causality (Tresiba 100 U/ml FlexTouch) -
hypoglycemia (less than 54 mg/dl)(Hypoglycemia) : Possible
diarrhea(Diarrhea) : Unlikely

Reporter Comment: Treatment Received: Honey, juices, and candies for hypoglycemia

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose	< 54 mg/dL	

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) IDeg PDS290 (Insulin Degludec 100 U/mL) Solution for injection, 100 U/mL; Regimen #2	18 IU, qd; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus)	Ongoing; Unknown

Mfr. Control Number: 1479590

ADDITIONAL INFORMATION

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

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

#1) JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE] (METFORMIN HYDROCHLORIDE, SITAGLIPTIN PHOSPHATE) ; JAN-2025 / Ongoing

#4) BIOGAIA [LACTOBACILLUS REUTERI] (LACTOBACILLUS REUTERI) Tablet ; JAN-2025 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition Duration not reported	Lactose intolerance (Lactose intolerance);
Unknown to Ongoing	Current Condition under study, she does not know if it is there or in another organ	Liver disorder (Liver disorder);