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		33 Years	Female	60.20 kg		MAY	2025

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

hypoglycemias [Hypoglycaemia]
Hyperglycemias [Hyperglycaemia]

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
#2) NovoRapid FlexPen (Insulin Aspart 100 U/mL) Solution for injection, 100 U/mL

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 17 IU, qd	#1) Subcutaneous
#2) 10 IU, tid	#2) Unknown

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 05-MAY-2025 / Ongoing	#1) Unknown
#2) 2024 / Ongoing	#2) Unknown

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)

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	Obesity (Obesity)
Unknown to Ongoing	Current Condition Duration not reported	Type 1 diabetes mellitus (Type 1 diabetes mellitus)

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.
1449454

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

24c. DATE RECEIVED BY MANUFACTURER
30-MAY-2025

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

DATE OF THIS REPORT
04-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: 160 cm.

Patient's weight: 60.2 kg.

Patient's BMI: 23.515625.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "hypoglycemias(Hypoglycemia)" beginning on MAY-2025 , "Hyperglycemias(Hyperglycemia)" beginning on MAY-2025 and concerned a 33 Years old Female patient who was treated with IDeg PDS290 (Insulin Degludec 100 U/mL) from 05-MAY-2025 and ongoing for "Type 1 diabetes mellitus", , NovoRapid FlexPen (Insulin Aspart 100 U/mL) from 2024 and ongoing for "Type 1 diabetes mellitus",

Dosage Regimens:
IDeg PDS290: 05-MAY-2025 to Not Reported (Dosage Regimen Ongoing);
NovoRapid FlexPen: ??-???-2024 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, type 1 diabetes mellitus.

Lab Data included:
Test Date: MAY-2025
Lab Data Test as Reported: Blood glucose
Test Name: Blood glucose
Results: 398
Unit: mg/dL

Test Date: MAY-2025
Lab Data Test as Reported: Blood glucose
Test Name: Blood glucose
Results: 429
Unit: mg/dL

Test Date: MAY-2025
Lab Data Test as Reported: Blood glucose
Test Name: Blood glucose
Results: 45
Unit: mg/dL

Test Date: MAY-2025
Lab Data Test as Reported: Blood glucose
Test Name: Blood glucose
Results: 49
Unit: mg/dL

Test Date: MAY-2025
Lab Data Test as Reported: Blood glucose
Test Name: Blood glucose
Results: 52
Unit: mg/dL

Batch Numbers:
IDeg PDS290: UNK;
NovoRapid FlexPen: UNK;

Action taken to IDeg PDS290 was reported as No Change.
Action taken to NovoRapid FlexPen was reported as No Change.

On MAY-2025 the outcome for the event "hypoglycemias(Hypoglycemia)" was Recovered.

04-Jul-2025 07:40

Mfr. Control Number: 1449454

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

On MAY-2025 the outcome for the event "Hyperglycemias(Hyperglycemia)" was Recovered.

Reporter's causality (IDeg PDS290) -
hypoglycemias(Hypoglycemia) : Unlikely
Hyperglycemias(Hyperglycemia) : Unlikely

Company's causality (IDeg PDS290) -
hypoglycemias(Hypoglycemia) : Possible
Hyperglycemias(Hyperglycemia) : Unlikely

Reporter's causality (NovoRapid FlexPen) -
hypoglycemias(Hypoglycemia) : Unlikely
Hyperglycemias(Hyperglycemia) : Unlikely

Company's causality (NovoRapid FlexPen) -
hypoglycemias(Hypoglycemia) : Possible
Hyperglycemias(Hyperglycemia) : Unlikely

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAY-2025	Blood glucose	429 mg/dL	
2	MAY-2025	Blood glucose	398 mg/dL	
3	MAY-2025	Blood glucose	49 mg/dL	
4	MAY-2025	Blood glucose	52 mg/dL	
5	MAY-2025	Blood glucose	45 mg/dL	