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		65 Years	Female	68.00 kg		FEB	2024

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

bone pain [Bone pain]
has a strong craving for sugar [Food craving]
constipation [Constipation]
diarrhea [Diarrhoea]
exhaustion/fatigue [Fatigue]
Medication error: the patient uses less than 0.25 mg Ozempic dose [Product use issue]

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

(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) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot #
#2) IDeg PDS290 (Insulin Degludec 100 U/mL) Solution for injection, 100 **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.25 mg, qw	#1) Subcutaneous
#2) 30 IU, qd	#2) Subcutaneous

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) FEB-2024 / Unknown	#1) Unknown
#2) 2018 / Ongoing	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) METFORMIN (METFORMIN) ; Ongoing

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)

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.
1414158

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

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

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

DATE OF THIS REPORT
10-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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 workshops and free A1c test.

Patient's height: 159 cm.

Patient's weight: 68 kg.

Patient's BMI: 26.89767020.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "bone pain(Bone pain)" beginning on FEB-2024 , "has a strong craving for sugar(Sugar craving)" beginning on 2024 , "constipation(Constipation)" beginning on FEB-2024 , "diarrhea(Diarrhea)" beginning on FEB-2024 , "exhaustion/fatigue(Fatigue)" beginning on FEB-2024 , "Medication error: the patient uses less than 0.25 mg Ozempic dose(Unapproved dose administered)" with an unspecified onset date and concerned a 65 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from FEB-2024 and ongoing for "Type 2 diabetes", , IDeg PDS290 (Insulin Degludec 100 U/mL) from 2018 and ongoing for "Type 2 diabetes",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-FEB-2024 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);
IDeg PDS290: ??-???-2018 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes mellitus.

Concomitant medications included - METFORMIN.

Batch Numbers:
Ozempic 0.25/0.50 mg: PP5N237, PP5N237;
IDeg PDS290: ASKU;

Action taken to Ozempic 0.25/0.50 mg was reported as Dose Decreased.
Action taken to IDeg PDS290 was Not reported.

The outcome for the event "bone pain(Bone pain)" was Not recovered.
The outcome for the event "has a strong craving for sugar(Sugar craving)" was Not Reported.
The outcome for the event "constipation(Constipation)" was Not recovered.
The outcome for the event "diarrhea(Diarrhea)" was Not recovered.
The outcome for the event "exhaustion/fatigue(Fatigue)" was Not recovered.
The outcome for the event "Medication error: the patient uses less than 0.25 mg Ozempic dose(Unapproved dose administered)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
bone pain(Bone pain) : Possible
has a strong craving for sugar(Sugar craving) : Possible
constipation(Constipation) : Possible
diarrhea(Diarrhea) : Possible
exhaustion/fatigue(Fatigue) : Possible
Medication error: the patient uses less than 0.25 mg Ozempic dose(Unapproved dose administered) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
bone pain(Bone pain) : Unlikely
has a strong craving for sugar(Sugar craving) : Unlikely
constipation(Constipation) : Possible
diarrhea(Diarrhea) : Possible
exhaustion/fatigue(Fatigue) : Possible
Medication error: the patient uses less than 0.25 mg Ozempic dose(Unapproved dose administered) : Possible

Reporter's causality (IDeg PDS290) -
bone pain(Bone pain) : Unlikely
has a strong craving for sugar(Sugar craving) : Unlikely
constipation(Constipation) : Unlikely
diarrhea(Diarrhea) : Unlikely

Mfr. Control Number: 1414158

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

exhaustion/fatigue(Fatigue) : Unlikely
Medication error: the patient uses less than 0.25 mg Ozempic dose(Unapproved dose administered) : Unknown

Company's causality (IDeg PDS290) -
bone pain(Bone pain) : Unlikely
has a strong craving for sugar(Sugar craving) : Unlikely
constipation(Constipation) : Unlikely
diarrhea(Diarrhea) : Unlikely
exhaustion/fatigue(Fatigue) : Unlikely
Medication error: the patient uses less than 0.25 mg Ozempic dose(Unapproved dose administered) : Possible

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) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5N237; Exp.Dt. MAY-2027}; Regimen #1	0.25 mg, qw; Subcutaneous	Type 2 diabetes (Type 2 diabetes mellitus)	FEB-2024 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5N237; Exp.Dt. MAY-2027}; Regimen #2	UNK (dose reduced); Subcutaneous	Type 2 diabetes (Type 2 diabetes mellitus)	Ongoing; Unknown
#2) IDeg PDS290 (Insulin Degludec 100 U/mL) Solution for injection, 100 U/mL; Regimen #1	30 IU, qd; Subcutaneous	Type 2 diabetes (Type 2 diabetes mellitus)	2018 / Ongoing; Unknown