CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	PANAMA		PRIVACY		54 Years	Female	83.00 kg	10	MAY	2025

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

Eat very little the patient feels satisfied very quickly (increased satiety) [Early satiety]
The patient has felt very tired [Fatigue]
headaches very frequently [Headache]
no hunger [Decreased appetite]
Ozempic use for Pre-diabetes. [Product use in unapproved indication]

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

Study ID: 199-NovoDia

(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

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

15. DAILY DOSE(S)
#1) 0.25 mg, qw

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

17. INDICATION(S) FOR USE
#1) Pre-diabetes (Glucose tolerance impaired)

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

18. THERAPY DATES(from/to)
#1) 10-MAY-2025 / Ongoing

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) METFORMIN (METFORMIN) ; 2025 / Ongoing
#2) ROSUVASTATIN (ROSUVASTATIN) ; 2025 / 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	Prediabetes (Glucose tolerance impaired)
Unknown to Ongoing	Current Condition that have been present for several years	Cervical vertebra injury (Spinal column injury)

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.
1472729

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

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 162 cm.

Patient's weight: 83 kg.

Patient's BMI: 31.62627650.

This non-serious Solicited Report from PANAMA was reported by a Consumer as "Eat very little the patient feels satisfied very quickly (increased satiety)(Early satiety)" beginning on 12-MAY-2025 , "The patient has felt very tired(Tiredness)" beginning on 16-JUN-2025 , "headaches very frequently(Frequent headaches)" beginning on 16-JUN-2025 , "no hunger(Appetite lost)" beginning on 12-MAY-2025 , "Ozempic use for Pre-diabetes.(Product use in unapproved indication)" beginning on 10-MAY-2025 and concerned a 54 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 10-MAY-2025 and ongoing for "Pre-diabetes",

Dosage Regimens:
Ozempic 0.25/0.50 mg: 10-MAY-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Prediabetes, Cervica injuries, lumbar injuries, High Low-Density Lipoprotein.

Concomitant medications included - METFORMIN, ROSUVASTATIN.

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK;

Action taken to Ozempic 0.25/0.50 mg was reported as No Change.

The outcome for the event "Eat very little the patient feels satisfied very quickly (increased satiety)(Early satiety)" was Not recovered.
The outcome for the event "The patient has felt very tired(Tiredness)" was Not recovered.
The outcome for the event "headaches very frequently(Frequent headaches)" was Not recovered.
The outcome for the event "no hunger(Appetite lost)" was Not recovered.
The outcome for the event "Ozempic use for Pre-diabetes.(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Eat very little the patient feels satisfied very quickly (increased satiety)(Early satiety) : Possible
The patient has felt very tired(Tiredness) : Possible
headaches very frequently(Frequent headaches) : Possible
no hunger(Appetite lost) : Possible
Ozempic use for Pre-diabetes.(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Eat very little the patient feels satisfied very quickly (increased satiety)(Early satiety) : Unlikely
The patient has felt very tired(Tiredness) : Possible
headaches very frequently(Frequent headaches) : Possible
no hunger(Appetite lost) : Possible
Ozempic use for Pre-diabetes.(Product use in unapproved indication) : Possible

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition that have been present for several years	Lumbar vertebra injury (Spinal column injury);
Unknown to Ongoing	Current Condition	Low density lipoprotein increased (Low density lipoprotein increased);