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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		65 Years	Female	78.50 kg		JUN	2025	☐ PATIENT DIED

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

Nausea [Nausea]
Headache [Headache]
Ozempic use for unapproved indication(obesity, prediabetes) [Product use in unapproved indication]

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

Study ID: 199-NovoDia

Study description: Trial Title: Patient support programme to support

(Continued on Additional Information Page)

☐ 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
(Continued on Additional Information Page)

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) Obesity (Obesity)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) JUN-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)

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 Obesity	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Prediabetes (Glucose tolerance impaired)

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.
1499261

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

24c. DATE RECEIVED BY MANUFACTURER
06-AUG-2025

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

DATE OF THIS REPORT
01-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1499261

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 152 cm.

Patient's weight: 78.5 kg.

Patient's BMI: 33.97680060.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Nausea(Nausea)" beginning on JUN-2025 , "Headache(Headache)" beginning on JUN-2025 , "Ozempic use for unapproved indication(obesity, prediabetes)(Product use in unapproved indication)" beginning on JUN-2025 and concerned a 65 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from JUN-2025 and ongoing for "Obesity", "Prediabetes",

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

Current Condition: Obesity, Prediabetes, High cholesterol.

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 "Nausea(Nausea)" was Recovering/resolving.
The outcome for the event "Headache(Headache)" was Recovering/resolving.
The outcome for the event "Ozempic use for unapproved indication(obesity, prediabetes)(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Nausea(Nausea) : Possible
Headache(Headache) : Possible
Ozempic use for unapproved indication(obesity, prediabetes)(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Nausea(Nausea) : Possible
Headache(Headache) : Possible
Ozempic use for unapproved indication(obesity, prediabetes)(Product use in unapproved indication) : 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; Regimen #1	0.25 mg, qw; Subcutaneous	Obesity (Obesity) Prediabetes (Glucose tolerance impaired)	JUN-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	High cholesterol (Blood cholesterol increased);