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	COSTA RICA		PRIVACY		48 Years	Female	69.30 kg		MAY	2025

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

nausea [Nausea]
constipation [Constipation]
constipation [Constipation]
Ozempic used for obesity and insulin resistance [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

(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) Prediabetes (Glucose tolerance impaired)

(Continued on Additional Information Page)

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

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

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) NEBILET (NEBIVOLOL HYDROCHLORIDE) ; 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	Prediabetes (Glucose tolerance impaired)
Unknown to Ongoing	Current Condition	Obesity (Obesity)
	duration not reported.	

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.
1459361

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

24c. DATE RECEIVED BY MANUFACTURER
12-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: 154 cm.

Patient's weight: 69.3 kg.

Patient's BMI: 29.22077920.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nausea(Nausea)" beginning on MAY-2025 , "constipation(Constipation)" beginning on MAY-2025 , "constipation(Constipation)" beginning on JUN-2025 , "Ozempic used for obesity and insulin resistance(Product use in unapproved indication)" beginning on MAY-2025 and concerned a 48 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from MAY-2025 and ongoing for "Prediabetes", "obesity",

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

Current Condition: Prediabetes, Obesity, Hypertension, Fatty liver.

Concomitant medications included - NEBILET(NEBIVOLOL HYDROCHLORIDE).

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK, UNK;

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

On MAY-2025 the outcome for the event "nausea(Nausea)" was Recovered.
On MAY-2025 the outcome for the event "constipation(Constipation)" was Recovered.
The outcome for the event "constipation(Constipation)" was Recovering/resolving.
The outcome for the event "Ozempic used for obesity and insulin resistance(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
nausea(Nausea) : Possible
constipation(Constipation) : Possible
constipation(Constipation) : Possible
Ozempic used for obesity and insulin resistance(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
nausea(Nausea) : Possible
constipation(Constipation) : Possible
constipation(Constipation) : Possible
Ozempic used for obesity and insulin resistance(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	Prediabetes (Glucose tolerance impaired) obesity (Obesity)	MAY-2025 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection; Regimen #2	0.5 mg, qw; Subcutaneous	Prediabetes (Glucose tolerance impaired) obesity (Obesity)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing 09-Jul-2025 08:45	Current Condition	Hypertension (Hypertension);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Fatty liver (Hepatic steatosis);