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		57 Years	Female	89.20 kg		MAY	2025

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

Very constipation, could not go to the bathroom [Constipation]
Nausea [Nausea]
Ozempic used for obesity and 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)

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) 0.5 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) 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) FANTER (DAPAGLIFLOZIN) ; APR-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	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.
1455325

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

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

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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: 163 cm.

Patient's weight: 89.2 kg.

Patient's BMI: 33.572961.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Very constipation, could not go to the bathroom(Constipation)" beginning on 07-JUN-2025 , "Nausea(Nausea)" beginning on 07-JUN-2025 , "Ozempic used for obesity and prediabetes(Product use in unapproved indication)" beginning on MAY-2025 and concerned a 57 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 "Obesity", "prediabetes",

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

Current Condition: Obesity, Prediabetes, Arterial hypertension
Procedure: Colostomy, No gallbladder.

Concomitant medications included - FANTER(DAPAGLIFLOZIN).

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK;

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

On 09-JUN-2025 the outcome for the event "Very constipation, could not go to the bathroom(Constipation)" was Recovered.
On 09-JUN-2025 the outcome for the event "Nausea(Nausea)" was Recovered.
The outcome for the event "Ozempic used for obesity and prediabetes(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Very constipation, could not go to the bathroom(Constipation) : Possible
Nausea(Nausea) : Possible
Ozempic used for obesity and prediabetes(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Very constipation, could not go to the bathroom(Constipation) : Possible
Nausea(Nausea) : Possible
Ozempic used for obesity and prediabetes(Product use in unapproved indication) : Possible

Reporter Comment: Treatment Received: suppository, magnesia Rey, tea from tsen leaves, all for constipation(non codable)

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	0.5 mg, qw; Subcutaneous	Obesity (Obesity) prediabetes (Glucose tolerance impaired)	MAY-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Arterial hypertension (Hypertension);
Unknown	Procedure Performed 31 years ago	Colostomy (Colostomy);
Unknown	Procedure	Gallbladder removal (Cholecystectomy);

Mfr. Control Number: 1455325

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
	due to surgery some time ago	