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		28 Years	Female	72.00 kg		NOV	2024

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]
foul-smelling belching(rotten egg taste) [Eructation]
diarrhea [Diarrhoea]
stomach discomfort. [Abdominal discomfort]
stomach pain [Abdominal pain upper]
stomach inflammation [Gastritis]
stomach discomfort.

(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
#2) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 **(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 + 5 clicks	#1) Subcutaneous
#2) 19 clicks qw	#2) Subcutaneous

17. INDICATION(S) FOR USE
#1) pre-diabetes (Glucose tolerance impaired)
#2) Prediabetes (Glucose tolerance impaired) **(Continued on Additional Information Page)**

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) NOV-2024 / Unknown	#1) Unknown
#2) MAY-2025 / MAY-2025	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) VENLAFAXINE (VENLAFAXINE) ; 2020 / Ongoing
#2) CONCOR (BISOPROLOL FUMARATE) ; 2024 / 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	Pre-diabetes (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.
1358963

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

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

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Abdominal discomfort]
stomach distension [Gastric dilatation]
ozempic for prediabetes and obesity [Product use in unapproved indication]
Ozempic dosage calculated in clicks [Wrong technique in product usage process]

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

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: 163 cm.

Patient's weight: 72 kg.

Patient's BMI: 27.099251.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nausea(Nausea)" beginning on DEC-2024 , "constipation(Constipation)" beginning on DEC-2024 , "foul-smelling belching(rotten egg taste)(Malodorous burping)" beginning on DEC-2024 , "diarrhea(Diarrhoea)" beginning on MAR-2025 , "stomach discomfort.(Stomach discomfort)" beginning on FEB-2025 , "stomach pain(Stomach pain)" beginning on MAR-2025 , "stomach inflammation(Stomach inflammation)" beginning on MAR-2025 , "stomach discomfort.(Stomach discomfort)" beginning on MAR-2025 , "stomach distension(Distended stomach)" beginning on MAR-2025 ******* There are more than 9 events available in this case, The list of all the events - "Ozempic dosage calculated in clicks(Wrong technique in product usage process),nausea(Nausea),ozempic for prediabetes and obesity(Product use in unapproved indication),constipation(Constipation),foul-smelling belching(rotten egg taste)(Malodorous burping),stomach pain(Stomach pain),stomach inflammation(Stomach inflammation),stomach distension(Distended stomach),stomach discomfort.(Stomach discomfort),diarrhea(Diarrhoea),stomach discomfort.(Stomach discomfort)" ******* and concerned a 28 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from NOV-2024 to MAY-2025 for "pre-diabetes", "Obesity", , Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from MAY-2025 for "Prediabetes", "obesity",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-NOV-2024 to Not Reported, Not Reported to Not Reported;
Ozempic 1.0 mg: ??-MAY-2025 to ??-MAY-2025;

Current Condition: Pre-diabetes, Obesity, Insulin resistance, postural tachycardia, Generalized anxiety.

Concomitant medications included - VENLAFAXINE, CONCOR(BISOPROLOL FUMARATE).

Treatment medications included - RIBOLAC RIFAXIMIN, AERO OM SIMETICONE, DIMETHICONE, DISLEP(LEVOSULPIRIDE), SERTAL COMPUESTO [CLONIXIN LYSINATE;PARGEVERINE](CLONIXIN LYSINATE, PARGEVERINE).

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK, UNK;
Ozempic 1.0 mg: ASKU;

Action taken to Ozempic 0.25/0.50 mg was reported as Dose Decreased.
Action taken to Ozempic 1.0 mg was Not reported.

The outcome for the event "nausea(Nausea)" was Recovering/resolving.
On FEB-2025 the outcome for the event "constipation(Constipation)" was Recovered.
On 01-JUN-2025 the outcome for the event "foul-smelling belching(rotten egg taste)(Malodorous burping)" was Recovered.
On 01-JUN-2025 the outcome for the event "diarrhea(Diarrhoea)" was Recovered.
On FEB-2025 the outcome for the event "stomach discomfort.(Stomach discomfort)" was Recovered.
On 01-JUN-2025 the outcome for the event "stomach pain(Stomach pain)" was Recovered.
The outcome for the event "stomach inflammation(Stomach inflammation)" was Recovering/resolving.
The outcome for the event "stomach discomfort.(Stomach discomfort)" was Recovering/resolving.
The outcome for the event "stomach distension(Distended stomach)" was Recovering/resolving.
******* There are more than 9 events available in this case *******

Reporter's causality (Ozempic 0.25/0.50 mg) -

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

nausea(Nausea) : Possible
constipation(Constipation) : Possible
foul-smelling belching(rotten egg taste)(Malodorous burping) : Possible
diarrhea(Diarrhoea) : Possible
stomach discomfort.(Stomach discomfort) : Possible
stomach pain(Stomach pain) : Possible
stomach inflammation(Stomach inflammation) : Possible
stomach discomfort.(Stomach discomfort) : Possible
stomach distension(Distended stomach) : Possible

Company's causality (Ozempic 0.25/0.50 mg) -
nausea(Nausea) : Possible
constipation(Constipation) : Possible
foul-smelling belching(rotten egg taste)(Malodorous burping) : Possible
diarrhea(Diarrhoea) : Possible
stomach discomfort.(Stomach discomfort) : Possible
stomach pain(Stomach pain) : Possible
stomach inflammation(Stomach inflammation) : Possible
stomach discomfort.(Stomach discomfort) : Possible
stomach distension(Distended stomach) : Unlikely

Reporter's causality (Ozempic 1.0 mg) -
nausea(Nausea) : Unknown
constipation(Constipation) : Unknown
foul-smelling belching(rotten egg taste)(Malodorous burping) : Possible
diarrhea(Diarrhoea) : Possible
stomach discomfort.(Stomach discomfort) : Unknown
stomach pain(Stomach pain) : Possible
stomach inflammation(Stomach inflammation) : Unknown
stomach discomfort.(Stomach discomfort) : Unknown
stomach distension(Distended stomach) : Unknown

Company's causality (Ozempic 1.0 mg) -
nausea(Nausea) : Possible
constipation(Constipation) : Possible
foul-smelling belching(rotten egg taste)(Malodorous burping) : Possible
diarrhea(Diarrhoea) : Possible
stomach discomfort.(Stomach discomfort) : Possible
stomach pain(Stomach pain) : Possible
stomach inflammation(Stomach inflammation) : Possible
stomach discomfort.(Stomach discomfort) : Possible
stomach distension(Distended stomach) : Unlikely

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 + 5 clicks; Subcutaneous	pre-diabetes (Glucose tolerance impaired) Obesity (Obesity)	NOV-2024 / 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	0.25 mg + 10 clicks ('0.40); Subcutaneous	pre-diabetes (Glucose tolerance impaired) Obesity (Obesity)	Unknown; Unknown
#2) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #1	19 clicks qw; Subcutaneous	Prediabetes (Glucose tolerance impaired) obesity (Obesity)	MAY-2025 / MAY-2025; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
	Duration not reported	
Unknown to Ongoing	Current Condition Duration not reported	Tachycardia (Tachycardia);
Unknown to Ongoing	Current Condition Duration not reported	Generalized anxiety disorder (Generalised anxiety disorder);