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		48 Years	Female	88.00 kg	19	DEC	2024

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

cramps [Muscle spasms]
her fasting glucose levels are "higher than before [Blood glucose increased]
Bloating [Abdominal distension]
diarrhea [Diarrhoea]
Gas [Flatulence]
constipation [Constipation]
burps with a taste similar to eggs (unusual-tasting burps) [Eructation]
significant acid reflux (heartburn) [Gastrooesophageal reflux disease]
nauseous [Nausea]

(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) 0.5 mg, qw	#1) Subcutaneous
#2) UNK (36 clicks), qw	#2) Subcutaneous

17. INDICATION(S) FOR USE
#1) Prediabetes (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) 19-DEC-2024 / Unknown	#1) Unknown
#2) Ongoing	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) LEVOTHYROXINE (LEVOTHYROXINE) ; 2009 / Ongoing
#2) SALBUTAMOL (SALBUTAMOL) ; 2014 / Ongoing
#3) MONTELUKAST (MONTELUKAST) ; 2014 / Ongoing
#4) LORATADINE (LORATADINE) ; 2014 / Ongoing
#5) BECLOMETHASONE [BECLOMETASONE] (BECLOMETHASONE [BECL
#6) OXIS (FORMOTEROL FUMARATE) ; 2014 / Ongoing **(Continued on Additional Information Page)**

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	Obesity (Obesity)
Unknown to Ongoing	Current Condition duration not reported	Asthma (Asthma)

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.
1359165

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

24c. DATE RECEIVED BY MANUFACTURER
28-APR-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

excessively sleepy [Hypersomnia]
slurring speech [Dysarthria]
She felt very unwell, [Malaise]
low-spirited [Depressed mood]
Ozempic 1mg use in 36 clicks [Wrong technique in product usage process]
Ozempic use for Prediabetes and obesity [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 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: 153 cm.

Patient's weight: 88 kg.

Patient's BMI: 37.592379.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "cramps(Cramp)" beginning on FEB-2025 , "her fasting glucose levels are "higher than before(Fasting blood glucose increased)" beginning on FEB-2025 , "Bloating(Bloating)" beginning on FEB-2025 , "diarrhea(Diarrhea)" beginning on APR-2025 , "Gas(Gas)" beginning on FEB-2025 , "constipation(Constipation)" beginning on FEB-2025 , "burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping)" beginning on FEB-2025 , "significant acid reflux (heartburn)(Acid reflux (esophageal))" beginning on JAN-2025 , "nauseous(Nauseous)" beginning on 19-JAN-2025 ******* There are more than 9 events available in this case, The list of all the events - "excessively sleepy(Sleep excessive),slurring speech(Slurred speech),She felt very unwell,(Feeling unwell),nauseous(Nauseous),Ozempic 1mg use in 36 clicks(Wrong technique in product usage process),diarrhea(Diarrhea),significant acid reflux (heartburn)(Acid reflux (esophageal)),Ozempic use for Prediabetes and obesity(Product use in unapproved indication),low-spirited(Feeling sad),her fasting glucose levels are "higher than before(Fasting blood glucose increased),cramps(Cramp),Gas(Gas),Bloating(Bloating),constipation(Constipation),burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping)" ******* and concerned a 48 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 19-DEC-2024 for "Prediabetes", "obesity", , Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from unknown start date and ongoing for "prediabetes", "obesity",

Dosage Regimens:
Ozempic 0.25/0.50 mg: 19-DEC-2024 to Not Reported;
Ozempic 1.0 mg:

Current Condition: Obesity, Asthma, Prediabetes, Hypothyroidism.

Concomitant medications included - LEVOTHYROXINE, SALBUTAMOL, MONTELUKAST, LORATADINE, BECLOMETHASONE [BECLOMETASONE], OXIS(FORMOTEROL FUMARATE), NUBELT(BUPROPION HYDROCHLORIDE, NALTREXONE HYDROCHLORIDE).

Lab Data included:
Test Date: FEB-2025
Lab Data Test as Reported: Fasting blood glucose
Test Name: Blood glucose
Results: 120
Unit: mg/dL
Comments:

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

Action taken to Ozempic 0.25/0.50 mg was reported as No Change.
Action taken to Ozempic 1.0 mg was reported as No Change.

The outcome for the event "cramps(Cramp)" was Recovering/resolving.
The outcome for the event "her fasting glucose levels are "higher than before(Fasting blood glucose increased)" was

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Recovering/resolving.
The outcome for the event "Bloating(Bloating)" was Recovering/resolving.
On APR-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.
The outcome for the event "Gas(Gas)" was Recovering/resolving.
The outcome for the event "constipation(Constipation)" was Recovering/resolving.
On APR-2025 the outcome for the event "burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping)" was Recovered.
The outcome for the event "significant acid reflux (heartburn)(Acid reflux (esophageal))" was Recovering/resolving.
On 19-JAN-2025 the outcome for the event "nauseous(Nauseous)" was Recovered.
******* There are more than 9 events available in this case *******

Reporter's causality (Ozempic 0.25/0.50 mg) -
cramps(Cramp) : Possible
her fasting glucose levels are "higher than before(Fasting blood glucose increased) : Possible
Bloating(Bloating) : Possible
diarrhea(Diarrhea) : Possible
Gas(Gas) : Possible
constipation(Constipation) : Possible
burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping) : Possible
significant acid reflux (heartburn)(Acid reflux (esophageal)) : Possible
nauseous(Nauseous) : Unlikely

Company's causality (Ozempic 0.25/0.50 mg) -
cramps(Cramp) : Unlikely
her fasting glucose levels are "higher than before(Fasting blood glucose increased) : Unlikely
Bloating(Bloating) : Possible
diarrhea(Diarrhea) : Possible
Gas(Gas) : Possible
constipation(Constipation) : Possible
burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping) : Possible
significant acid reflux (heartburn)(Acid reflux (esophageal)) : Possible
nauseous(Nauseous) : Possible

Reporter's causality (Ozempic 1.0 mg) -
cramps(Cramp) : Unknown
her fasting glucose levels are "higher than before(Fasting blood glucose increased) : Unknown
Bloating(Bloating) : Unknown
diarrhea(Diarrhea) : Possible
Gas(Gas) : Unknown
constipation(Constipation) : Unknown
burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping) : Unknown
significant acid reflux (heartburn)(Acid reflux (esophageal)) : Possible
nauseous(Nauseous) : Unknown

Company's causality (Ozempic 1.0 mg) -
cramps(Cramp) : Unlikely
her fasting glucose levels are "higher than before(Fasting blood glucose increased) : Unlikely
Bloating(Bloating) : Possible
diarrhea(Diarrhea) : Possible
Gas(Gas) : Possible
constipation(Constipation) : Possible
burps with a taste similar to eggs (unusual-tasting burps)(Malodorous burping) : Possible
significant acid reflux (heartburn)(Acid reflux (esophageal)) : Possible
nauseous(Nauseous) : Possible

Reporter Comment: Patient's current weight 1: 84.8 kg
Patient's current weight 1: 85 kg

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	FEB-2025	Blood glucose	120 mg/dL	

Mfr. Control Number: 1359165

ADDITIONAL INFORMATION

13. Relevant Tests

On an unknown date, patient's initial weight was 88 kg
On an unknown date in FEB-2025, patient's fasting blood glucose levels were higher than before ((referring to about 120 mg/dl, while usually being less than 100 mg/dl).

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	Prediabetes (Glucose tolerance impaired) obesity (Obesity)	19-DEC-2024 / 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	UNK (36 clicks), qw; Subcutaneous	prediabetes (Glucose tolerance impaired) obesity (Obesity)	Ongoing; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#5) BECLOMETHASONE [BECLOMETASONE] (BECLOMETHASONE [BECLOMETASONE]) ; 2014 / Ongoing

#7) NUBELT (BUPROPION HYDROCHLORIDE, NALTREXONE HYDROCHLORIDE) Tablet ; MAR-2025 / Ongoing

23. OTHER RELEVANT HISTORY continued

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 duration not reported	Hypothyroidism (Hypothyroidism);