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		54 Years	Male	88.20 kg		MAR	2025

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

gastritis (understood as pain in the 'epigastric' region) [Gastritis]
Nausea [Nausea]
foul breath (similar to that of eggs) and unpleasant burping [Eructation]
pain in the 'epigastric' region [Abdominal pain upper]
Ozempic prescribed for Obesity and Prediabetes [Off label use]
Ozempic dosage: 18 clicks [Wrong technique in product usage process]

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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg

(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 18 clicks, 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) MAR-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) PROPRANOLOL (PROPRANOLOL) ; 2020 / Ongoing
#2) MELATONIN (MELATONIN) ; Ongoing
#3) MAGNESIUM (MAGNESIUM) ; 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 Duration not reported	Prediabetes (Glucose tolerance impaired)
Unknown to Ongoing	Current Condition Duration not reported	Obesity (Obesity)

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.
1426804

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

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1426804

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: 169 cm.

Patient's weight: 88.2 kg.

Patient's BMI: 30.88127170.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "gastritis (understood as pain in the 'epigastric' region)(Gastritis)" beginning on APR-2025 , "Nausea(Nausea)" beginning on APR-2025 , "foul breath (similar to that of eggs) and unpleasant burping(Malodorous burping)" beginning on APR-2025 , "pain in the 'epigastric' region(Pain epigastric)" beginning on APR-2025 , "Ozempic prescribed for Obesity and Prediabetes(Off label use in unapproved indication)" beginning on MAR-2025 , "Ozempic dosage: 18 clicks(wrong technique in product usage process)" beginning on MAR-2025 and concerned a 54 Years old Male patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from MAR-2025 and ongoing for "Obesity", "Prediabetes",

Dosage Regimens:
Ozempic 1.0 mg: ??-MAR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Prediabetes, Obesity, Hypertension, For sleeping.

Concomitant medications included - PROPRANOLOL, MELATONIN, MAGNESIUM.

Batch Numbers:
Ozempic 1.0 mg: UNK;

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

On APR-2025 the outcome for the event "gastritis (understood as pain in the 'epigastric' region)(Gastritis)" was Recovered.
On APR-2025 the outcome for the event "Nausea(Nausea)" was Recovered.
On APR-2025 the outcome for the event "foul breath (similar to that of eggs) and unpleasant burping(Malodorous burping)" was Recovered.
On APR-2025 the outcome for the event "pain in the 'epigastric' region(Pain epigastric)" was Recovered.
The outcome for the event "Ozempic prescribed for Obesity and Prediabetes(Off label use in unapproved indication)" was Not recovered.
The outcome for the event "Ozempic dosage: 18 clicks(wrong technique in product usage process)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
gastritis (understood as pain in the 'epigastric' region)(Gastritis) : Possible
Nausea(Nausea) : Possible
foul breath (similar to that of eggs) and unpleasant burping(Malodorous burping) : Possible
pain in the 'epigastric' region(Pain epigastric) : Possible
Ozempic prescribed for Obesity and Prediabetes(Off label use in unapproved indication) : Unknown
Ozempic dosage: 18 clicks(wrong technique in product usage process) : Unknown

Company's causality (Ozempic 1.0 mg) -
gastritis (understood as pain in the 'epigastric' region)(Gastritis) : Possible
Nausea(Nausea) : Possible
foul breath (similar to that of eggs) and unpleasant burping(Malodorous burping) : Possible
pain in the 'epigastric' region(Pain epigastric) : Possible
Ozempic prescribed for Obesity and Prediabetes(Off label use in unapproved indication) : Possible
Ozempic dosage: 18 clicks(wrong technique in product usage process) : 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 1.0	18 clicks, qw;	Obesity (Obesity)	MAR-2025 / Ongoing;

Mfr. Control Number: 1426804

ADDITIONAL INFORMATION

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
mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #1	Subcutaneous	Prediabetes (Glucose tolerance impaired)	Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition Duration not reported	Hypertension (Hypertension);
Unknown to Ongoing	Current Condition	Sleep disorder (Sleep disorder);