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		37 Years	Female	108.10 kg		MAR	2024

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

Other Serious Criteria: Medically Significant
pancreatitis [Pancreatitis]
calculus in gallbladder, removed the patient's gallbladder [Cholelithiasis]
ozempic for obesity and high blood pressure [Product use in unapproved indication]
Ozempic administered in clicks [Wrong technique in product usage process]

Case Description: 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) 37 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-2024 / NOV-2024

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) COSYREL (BISOPROLOL FUMARATE, PERINDOPRIL ARGININE) ; APR-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 Duration not reported	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension)

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.
1463420

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

24c. DATE RECEIVED BY MANUFACTURER
19-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

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: 156 cm.

Patient's weight: 108.1 kg.

Patient's BMI: 44.41978960.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "pancreatitis(Pancreatitis)" beginning on NOV-2024 , "calculus in gallbladder, removed the patient's gallbladder(Calculus in gallbladder)" beginning on NOV-2024 , "ozempic for obesity and high blood pressure(Product use in unapproved indication)" beginning on MAR-2024 , "Ozempic administered in clicks(Wrong technique in product usage process)" beginning on MAR-2024 and concerned a 37 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from MAR-2024 to NOV-2024 for "Obesity", "high blood pressure",

Dosage Regimens:
Ozempic 1.0 mg: ??-MAR-2024 to ??-NOV-2024;

Current Condition: Obesity(Duration not reported), high blood pressure.

Concomitant medications included - COSYREL(BISOPROLOL FUMARATE, PERINDOPRIL ARGININE).

On Mar-2024 Ozempic was taken for for obesity and high blood pressure in clicks

On Nov-2024 patient mentions that had pancreatitis as a result of the treatment (according to the patient's perception).

On Nov-2024 the patient started vomiting after having dinner, and couldn't stop vomiting. After vomiting so much, the patient was having difficulty breathing, so the patient decided to go to the doctor. Upon arriving at the emergency room, they performed a lipase test, which came back at 19,000. They did an ERCP (endoscopic retrograde cholangiopancreatography) and removed the patient's gallbladder (because there was a stone, meaning a calculus). The patient was hospitalized for 4 days.

The patient doesn't know what treatment for the event was received.

Batch Numbers:
Ozempic 1.0 mg: was not reported

Action taken to Ozempic 1.0 mg was reported as Product discontinued.

On NOV-2024 the outcome for the event "pancreatitis(Pancreatitis)" was Recovered.
On NOV-2024 the outcome for the event "calculus in gallbladder, removed the patient's gallbladder(Calculus in gallbladder)" was Recovered.
On NOV-2024 the outcome for the event "ozempic for obesity and high blood pressure(Product use in unapproved indication)" was Recovered.
On NOV-2024 the outcome for the event "Ozempic administered in clicks(Wrong technique in product usage process)" was Recovered.

Reporter's causality (Ozempic 1.0 mg) -
pancreatitis(Pancreatitis) : Possible
calculus in gallbladder, removed the patient's gallbladder(Calculus in gallbladder) : Possible
ozempic for obesity and high blood pressure(Product use in unapproved indication) : Unknown
Ozempic administered in clicks(Wrong technique in product usage process) : Unknown

Company's causality (Ozempic 1.0 mg) -
pancreatitis(Pancreatitis) : Possible
calculus in gallbladder, removed the patient's gallbladder(Calculus in gallbladder) : Possible
ozempic for obesity and high blood pressure(Product use in unapproved indication) : Possible
Ozempic administered in clicks(Wrong technique in product usage process) : Possible

No consent for safety follow-up questions, hence no further follow-up is possible.

Mfr. Control Number: 1463420

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	NOV-2024	Endoscopic retrograde cholangiopancreatography On 00-NOV-2024, Endoscopic retrograde cholangiopancreatography was performed which showed gall bladder stone		
2	NOV-2024	Lipase On 00-NOV-2024 lipase test was 19,000 (units were not reported)		

13. Relevant Tests

On 00-NOV-2024 lipase test was 19,000 (units were not reported)
On 00-NOV-2024, Endoscopic retrograde cholangiopancreatography was performed which showed gall bladder stone

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 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #1	37 clicks qw; Subcutaneous	Obesity (Obesity) high blood pressure (Hypertension)	MAR-2024 / NOV-2024; Unknown