CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	PANAMA		PRIVACY		41 Years	Female	89.00 kg	19	APR	2025	☐ PATIENT DIED

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
perforated appendix [Appendicitis perforated]
ozempic prescribed for prediabetes and obesity [Off label use]

Case Description: 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

(Continued on Additional Information Page)

- ☒ 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)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.5 mg, qw	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) 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) 06-FEB-2025 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

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	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.
1446026

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

24c. DATE RECEIVED BY MANUFACTURER
29-MAY-2025

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

DATE OF THIS REPORT
06-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1446026

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

workshops and free A1c test.

Patient's height: 165 cm.

Patient's weight: 89 kg.

Patient's BMI: 32.69054180.

This serious Solicited Report from PANAMA was reported by a Consumer as "perforated appendix(Ruptured appendix)" beginning on 19-APR-2025 , "ozempic prescribed for prediabetes and obesity(Off label use in unapproved indication)" with an unspecified onset date and concerned a 41 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 06-FEB-2025 and ongoing for "Prediabetes", "obesity",

Dosage Regimens:
Ozempic 0.25/0.50 mg: 06-FEB-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity(duration not reported), prediabetes.

Treatment medications included - MAGNESIUM.

On 19-APR-2025, the patient underwent emergency surgery due to a perforated appendix and stated that she was really well before the incident and on the same day she experienced severe pain, which was why she went to the hospital (hospitalization discharge summary not reported) where she was told that she needed to be operated on immediately.

On an unknown date, the patient resumed the treatment and the patient currently feels very well.

Batch Numbers:
Ozempic 0.25/0.50 mg: not available

Action taken to Ozempic 0.25/0.50 mg was reported as Drug discontinued temporarily.

The outcome for the event "perforated appendix(Ruptured appendix)" was Recovering/resolving.
The outcome for the event "ozempic prescribed for prediabetes and obesity(Off label use in unapproved indication)" was Recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
perforated appendix(Ruptured appendix) : Unlikely
ozempic prescribed for prediabetes and obesity(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
perforated appendix(Ruptured appendix) : Unlikely
ozempic prescribed for prediabetes and obesity(Off label use in unapproved indication) : Possible

No consent for safety follow up, no further information available.

company comment:
Perforated appendix is assessed as unlisted event according to Novo Nordisk current CCDS information on Ozempic.
Information on past surgical history, medical history, previous episodes of pain , final diagno-sis, clinical course of events in hospital, clinical and laboratory investigations is not available. Obesity and prediabetes are confounding factors as chronic inflammation related to prediabe-tes and increased intra-abdominal pressure from obesity may increase the risk of perforation. Hence, considering the nature of event and information available a possible causal relation-ship cannot be ruled out.
This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

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)	06-FEB-2025 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290	UNK; Subcutaneous	Prediabetes (Glucose	Ongoing;

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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
0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection; Regimen #2		tolerance impaired) obesity (Obesity)	Unknown