# 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 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year |
| PRIVACY | COSTA RICA | | PRIVACY | | 36 Years | Female | 74.00 kg | | OCT | 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
abdominoplasty, in the postoperative phase [Abdominoplasty]
nausea [Nausea]
vomiting [Vomiting]
Ozempic dual dose for weight loss [Product use in unapproved indication]
Ozempic application by clicks [Wrong technique in product usage process]

Case Description: Study ID: 199-NovoDia

Study description: Trial Title: Patient support programme to support **(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
**(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)
#1 ) 40 clicks,qw

16. ROUTE(S) OF ADMINISTRATION
#1 ) Subcutaneous

17. INDICATION(S) FOR USE
#1 ) weight loss (Weight control)

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

18. THERAPY DATES(from/to)
#1 ) OCT-2024 / Unknown

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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

## 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.
**1482440**

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

24c. DATE RECEIVED BY MANUFACTURER
16-JUL-2025

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

DATE OF THIS REPORT
25-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

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: 158 cm.

Patient's weight: 74 kg.

Patient's BMI: 29.64268550.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "abdominoplasty, in the postoperative phase(Abdominoplasty)" beginning on 25-JUN-2025 , "nausea(Nausea)" with an unspecified onset date , "vomiting(Vomiting)" with an unspecified onset date , "Ozempic dual dose for weight loss(Product use in unapproved indication)" beginning on OCT-2024 , "Ozempic application by clicks(Wrong technique in product usage process)" beginning on OCT-2024 and concerned a 36 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from OCT-2024 to JUN-2025 for "weight loss",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-OCT-2024 to Not Reported, Not Reported to ??-JUN-2025;

Medical history was not provided.

Treatment medications included - NALTREVA(BUPROPION HYDROCHLORIDE, NALTREXONE HYDROCHLORIDE), analgesics(non codable)

On an unspecified date of Oct 2024, the patient began administering Ozempic at a dose of 40 clicks.

On June 25, 2025, the patient underwent an abdominoplasty and was currently in the postoperative phase.

On an unspecified date of Jan 2025, the patient stopped taking the suspected medication 15 days prior to the surgery. The endocrinologist advised the patient to resume the medication; however, the patient was hesitant to restart it due to feelings of significant nausea and vomiting, which the patient attributes to an unusual sensation from the surgical wound, that's why patient held of suspect.

On an unknown date, the patient experienced mild nausea and vomiting after the dose increased. The patient using Naltreva asa treatment medication. and both the endocrinologist and nutritionist suggested that Naltreva was likely responsible for the nausea, rather than Ozempic. The patient noted that the duration spent solely on Ozempic was very brief, and during that time, even at a dosage of 44 clicks, they did not experience any vomiting. They believe the nausea to be related to the Naltreva pill rather than Ozempic. The patient discontinued Naltreva one month before the surgery, nausea was decreased.

Batch Numbers:
Ozempic 0.25/0.50 mg: requested

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

The outcome for the event "abdominoplasty, in the postoperative phase(Abdominoplasty)" was Recovering/resolving.
The outcome for the event "nausea(Nausea)" was Recovering/resolving.
The outcome for the event "vomiting(Vomiting)" was Recovering/resolving.
On JUN-2025 the outcome for the event "Ozempic dual dose for weight loss(Product use in unapproved indication)" was Recovered.
On JUN-2025 the outcome for the event "Ozempic application by clicks(Wrong technique in product usage process)" was Recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
abdominoplasty, in the postoperative phase(Abdominoplasty) : Unknown
nausea(Nausea) : Unlikely
vomiting(Vomiting) : Unlikely
Ozempic dual dose for weight loss(Product use in unapproved indication) : Unknown
Ozempic application by clicks(Wrong technique in product usage process) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
abdominoplasty, in the postoperative phase(Abdominoplasty) : Unlikely
nausea(Nausea) : Possible
vomiting(Vomiting) : Possible
Ozempic dual dose for weight loss(Product use in unapproved indication) : Possible
Ozempic application by clicks(Wrong technique in product usage process) : Possible

Mfr. Control Number: 1482440

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

Company comment
Abdominoplasty is assessed as an unlisted event and Nausea, Vomiting are assessed as listed events according to Novo Nordisk current reference safety information on Ozempic.
Abdominoplasty is a procedure to remove excess skin and fat from the abdomen. Information on indication for the surgery, relevant medical history, concomitant drugs, investigation reports are unavailable which limits thorough medical evaluation. Considering the limited information available and nature of the event, abdominoplasty is unlikely related to the suspect.
This single case report is not considered to change the current knowledge of the safety profile of the suspect product.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>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 #2 | 44 clicks,qw;<br>Subcutaneous | weight loss (Weight control) | Unknown / JUN-2025;<br>Unknown |