**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 | | 35 Years | Female | 100.00 kg | | JUN | 2025 |

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

diarrhea [Diarrhoea]
Ozempic used for 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,

**(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

15. DAILY DOSE(S)
#1 ) 0.25 mg, qw

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

17. INDICATION(S) FOR USE
#1 ) obesity (Obesity)

18. THERAPY DATES(from/to)
#1 ) JUN-2025 / Ongoing

19. THERAPY DURATION
#1 ) Unknown

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

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

## 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 | Migraine (Migraine) |

## 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.
**1473714**

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

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

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

DATE OF THIS REPORT
21-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1473714

## ADDITIONAL INFORMATION

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

nutrition support through NovoDia call center, individual workshops, group workshops and free A1c test.

Patient's height: 168 cm.

Patient's weight: 100 kg.

Patient's BMI: 35.430839.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "diarrhea(Diarrhea)" beginning on JUN-2025 , "Ozempic used for obesity(Product use in unapproved indication)" beginning on JUN-2025 and concerned a 35 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from JUN-2025 and ongoing for "obesity",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, occasional migraines, Hernia in the spine.

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK;

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

On JUN-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.
The outcome for the event "Ozempic used for obesity(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
diarrhea(Diarrhea) : Possible
Ozempic used for obesity(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
diarrhea(Diarrhea) : Possible
Ozempic used for obesity(Product use in unapproved indication) : Possible

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown to Ongoing | Current Condition | Spinal cord herniation (Spinal cord herniation); |