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		56 Years	Female	70.00 kg	03	JUN	2025

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

Nausea [Nausea]
Headache [Headache]
Ozempic prescribed for 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)

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

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

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

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

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

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

18. THERAPY DATES(from/to)
#1) 03-JUN-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) ILTUX (OLMESARTAN MEDOXOMIL) ; 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	Constipation (Constipation)

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.
1452173

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

24c. DATE RECEIVED BY MANUFACTURER
04-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

workshops and free A1c test.

Patient's height: 165 cm.

Patient's weight: 70 kg.

Patient's BMI: 25.71166210.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Nausea(Nausea)" beginning on 04-JUN-2025 , "Headache(Headache)" beginning on 04-JUN-2025 , "Ozempic prescribed for Obesity(Off label use in unapproved indication)" beginning on 03-JUN-2025 and concerned a 56 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 03-JUN-2025 and ongoing for "Obesity",

Dosage Regimens:
Ozempic 0.25/0.50 mg: 03-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Constipation, Fatty liver, High blood pressure.

Concomitant medications included - ILTUX(OLMESARTAN MEDOXOMIL).

**********Manually update [summary of event details, including relevant tests, laboratory values]
Reported Term - "Nausea(Nausea)"
Onset date - 04-JUN-2025
Reported Term - "Headache(Headache)"
Onset date - 04-JUN-2025
Reported Term - "Ozempic prescribed for Obesity(Off label use in unapproved indication)"
Onset date - 03-JUN-2025
**********.

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK;

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

The outcome for the event "Nausea(Nausea)" was Not recovered.
The outcome for the event "Headache(Headache)" was Not recovered.
The outcome for the event "Ozempic prescribed for Obesity(Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Nausea(Nausea) : Possible
Headache(Headache) : Possible
Ozempic prescribed for Obesity(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Nausea(Nausea) : Possible
Headache(Headache) : Possible
Ozempic prescribed for Obesity(Off label use in unapproved indication) : Possible

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Fatty liver (Hepatic steatosis);
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);