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		33 Years	Female	103.00 kg		MAR	2025

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

headaches stronger than usual [Headache]
vomited on several occasions, on different days, after eating.

(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) UNK

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) MAR-2025 / 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)
#1) DAPAGLIFLOZIN (DAPAGLIFLOZIN) ; MAR-2025 / Ongoing
#2) OMEGA 3 FATTY ACID (DOCOSAHEXAENOIC ACID, EICOSAPENT

(Continued on Additional Information Page)

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	Headache (Headache)

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.
1417674

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

24c. DATE RECEIVED BY MANUFACTURER
11-JUN-2025

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

DATE OF THIS REPORT
04-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1417674

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Vomiting]
Ozempic prescribed for obesity: off label [Off label use]

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

Patient's height: 159 cm.

Patient's weight: 103 kg.

Patient's BMI: 40.74205930.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "headaches stronger than usual(Headache aggravated)" beginning on APR-2025 , "vomited on several occasions, on different days, after eating.(Vomiting)" beginning on MAY-2025 , "Ozempic prescribed for obesity: off label (Off label use in unapproved indication)" beginning on MAR-2025 and concerned a 33 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from MAR-2025 and ongoing for "Obesity",

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

Current Condition: Obesity, headaches, Hypertriglyceridaemia, Heart murmur, Blood glucose abnormal.

Concomitant medications included - DAPAGLIFLOZIN, OMEGA 3 FATTY ACID(DOCOSAHEXAENOIC ACID, EICOSAPENTAENOIC ACID).

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK, UNK;

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

The outcome for the event "headaches stronger than usual(Headache aggravated)" was Recovering/resolving.
On MAY-2025 the outcome for the event "vomited on several occasions, on different days, after eating.(Vomiting)" was Recovered.
The outcome for the event "Ozempic prescribed for obesity: off label (Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
headaches stronger than usual(Headache aggravated) : Possible
vomited on several occasions, on different days, after eating.(Vomiting) : Possible
Ozempic prescribed for obesity: off label (Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
headaches stronger than usual(Headache aggravated) : Possible
vomited on several occasions, on different days, after eating.(Vomiting) : Possible
Ozempic prescribed for obesity: off label (Off label use in unapproved indication) : Possible

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 #2	0.5 mg, qw; Subcutaneous	Obesity (Obesity)	APR-2025 / Ongoing; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) OMEGA 3 FATTY ACID (DOCOSAHEXAENOIC ACID, EICOSAPENTAENOIC ACID) ; FEB-2025 / Ongoing

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Hypertriglyceridemia (Hypertriglyceridaemia);
Unknown to Ongoing	Current Condition	Heart murmur (Cardiac murmur);
Unknown to Ongoing	Current Condition	Blood glucose abnormal (Blood glucose abnormal);