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		49 Years	Male	131.00 kg		NOV	2023

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

a lot of anxiety [Anxiety]
a lot of diarrhea [Diarrhoea]
Ozempic dosage of 0.

(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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.75 mg, qw

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

17. INDICATION(S) FOR USE
#1) Type 2 diabetes (Type 2 diabetes mellitus)

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) NOV-2023 / 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)

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	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition	Obesity (Obesity)

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.
1476545

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

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1476545

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

75 mg [Product use issue]

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: 165 cm.

Patient's weight: 131 kg.

Patient's BMI: 48.117539.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "a lot of anxiety(Anxiety)" beginning on JUL-2025 , "a lot of diarrhea(Diarrhea)" beginning on JUL-2025 , "Ozempic dosage of 0. 75 mg(Unapproved dose administered)" beginning on NOV-2023 and concerned a 49 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from NOV-2023 and ongoing for "Type 2 diabetes", "Obesity",

Dosage Regimens:
Ozempic: ??-NOV-2023 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes, Obesity.

Batch Numbers:
Ozempic: ASKU;

Action taken to Ozempic was reported as No Change.

The outcome for the event "a lot of anxiety(Anxiety)" was Not recovered.
The outcome for the event "a lot of diarrhea(Diarrhea)" was Not recovered.
The outcome for the event "Ozempic dosage of 0. 75 mg(Unapproved dose administered)" was Not recovered.

Reporter's causality (Ozempic) -
a lot of anxiety(Anxiety) : Possible
a lot of diarrhea(Diarrhea) : Possible
Ozempic dosage of 0. 75 mg(Unapproved dose administered) : Unknown

Company's causality (Ozempic) -
a lot of anxiety(Anxiety) : Unlikely
a lot of diarrhea(Diarrhea) : Possible
Ozempic dosage of 0. 75 mg(Unapproved dose administered) : Possible

Reporter Comment: the patient ate a little banana, which did not relieve the anxiety. Subsequently, the patient ate chocolate.
The patient has observed that fatty foods sometimes cause diarrhea, and other times they do not.

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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL; Regimen #1	0.75 mg, qw; Subcutaneous	Type 2 diabetes (Type 2 diabetes mellitus) Obesity (Obesity)	NOV-2023 / Ongoing; Unknown