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		46 Years	Female	81.00 kg		APR	2025

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

Diarrhea [Diarrhoea]
Headaches [Headache]
Ozempic use for Overweight and insulin resistance [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

(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) Overweight (Overweight)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) APR-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) VITAMIN D3 (VITAMIN D3) ; 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	Overweight (Overweight)
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance)

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.
1439736

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

24c. DATE RECEIVED BY MANUFACTURER
20-MAY-2025

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

DATE OF THIS REPORT
03-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1439736

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: 173 cm.

Patient's weight: 81 kg.

Patient's BMI: 27.06405160.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Diarrhea(Diarrhea)" beginning on MAY-2025 , "Headaches(Headache)" beginning on MAY-2025 , "Ozempic use for Overweight and insulin resistance(Product use in unapproved indication)" beginning on APR-2025 and concerned a 46 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "Overweight", "Insulin resistance",

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

Current Condition: Overweight, Insulin resistance, Low vitamin D levels.

Concomitant medications included - VITAMIN D3.

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 "Diarrhea(Diarrhea)" was Recovering/resolving.
The outcome for the event "Headaches(Headache)" was Recovering/resolving.
The outcome for the event "Ozempic use for Overweight and insulin resistance(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Diarrhea(Diarrhea) : Possible
Headaches(Headache) : Possible
Ozempic use for Overweight and insulin resistance(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Diarrhea(Diarrhea) : Possible
Headaches(Headache) : Possible
Ozempic use for Overweight and insulin resistance(Product use in unapproved indication) : Possible

Reporter Comment: Multivitamin (non specified, non codable) used as concomitant medication for Personal taste.
Materna G - Balance (Myo-inositol and probiotics) (non codable) used as concomitant medication for Insulin resistance.
Treatment received is Enterogermina (non specified, non codable)

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 #1	UNK; Subcutaneous	Overweight (Overweight) Insulin resistance (Insulin resistance)	APR-2025 / Unknown; Unknown
#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	Overweight (Overweight) Insulin resistance (Insulin resistance)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Vitamin D low (Vitamin D decreased);

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ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description