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		Unk	Female	Unk			2024

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

nausea [Nausea]
doctor prescribed the Ozempic for insulin resistance [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,

(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 {Lot #

(Continued on Additional Information Page)

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

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

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

17. INDICATION(S) FOR USE
#1) insulin resistance (Insulin resistance)

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

18. THERAPY DATES(from/to)
#1) 2024 / 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)

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	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.
1440698

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

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

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

DATE OF THIS REPORT
10-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1440698

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nausea(Nausea)" beginning on 2024 , "doctor prescribed the Ozempic for insulin resistance(Off label use in unapproved indication)" beginning on 2024 and concerned a Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 2024 for "insulin resistance",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-???-2024 to Not Reported, Not Reported to Not Reported;

Current Condition: insulin resistance.

Batch Numbers:
Ozempic 0.25/0.50 mg: PP5N237, PP5N237;

Action taken to Ozempic 0.25/0.50 mg was Not reported.

The outcome for the event "nausea(Nausea)" was Recovered.
The outcome for the event "doctor prescribed the Ozempic for insulin resistance(Off label use in unapproved indication)" was Not Reported.

Reporter's causality (Ozempic 0.25/0.50 mg) -
nausea(Nausea) : Unknown
doctor prescribed the Ozempic for insulin resistance(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
nausea(Nausea) : Possible
doctor prescribed the Ozempic for insulin resistance(Off label use in unapproved indication) : Possible

Reporter Comment: The patient is treated for this indication first time.
The patient indicates that the medication Ozempic was prescribed to her approximately in September or October 2024.

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 {Lot # PP5N237; Exp.Dt. MAY-2027}; Regimen #1	0.25 mg, UNK; Unknown	insulin resistance (Insulin resistance)	2024 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5N237; Exp.Dt. MAY-2027}; Regimen #2	0.5 mg, UNK; Unknown	insulin resistance (Insulin resistance)	Unknown; Unknown