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	Female	80.00 kg	18	JUN	2024

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

blurry vision [Vision blurred]
Headache [Headache]
Patient taking 0.5 mg dose from ozempic 1 mg pen [Wrong technique in product usage process]
Ozempic use for insulin resistance [Product use in unapproved indication]

Case Description: ***This is an auto generated narrative***

Study ID: 199-NovoDia

(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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot #

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.5 mg qw

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

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) 18-JUN-2024 / 16-AUG-2024

19. THERAPY DURATION
#1) 59 days

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
JUN-2024 to Ongoing	Current Condition	Insulin resistance (Insulin resistance)
Unknown to Ongoing	Current Condition	Eyeglasses wearer (Corrective lens user)

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.
1418312

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
26-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1418312

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 153 cm.

Patient's weight: 80 kg.

Patient's BMI: 34.174890.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "blurry vision(Blurry vision)" beginning on JUL-2024 , "Headache(Headache)" beginning on JUL-2024 , "Patient taking 0.5 mg dose from ozempic 1 mg pen(Wrong technique in product usage process)" beginning on 18-JUN-2024 , "Ozempic use for insulin resistance(Product use in unapproved indication)" beginning on 18-JUN-2024 and concerned a 49 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 18-JUN-2024 to 16-AUG-2024 for "insulin resistance",

Dosage Regimens:
Ozempic 1.0 mg: 18-JUN-2024 to 16-AUG-2024;

Current Condition: Insulin resistance, Glasses for vision.

Batch Numbers:
Ozempic 1.0 mg: PP5L097;

Action taken to Ozempic 1.0 mg was reported as Product discontinued due to AE.

The outcome for the event "blurry vision(Blurry vision)" was Not recovered.
On AUG-2024 the outcome for the event "Headache(Headache)" was Recovered.
On 16-AUG-2024 the outcome for the event "Patient taking 0.5 mg dose from ozempic 1 mg pen(Wrong technique in product usage process)" was Recovered.
On 16-AUG-2024 the outcome for the event "Ozempic use for insulin resistance(Product use in unapproved indication)" was Recovered.

Reporter's causality (Ozempic 1.0 mg) -
blurry vision(Blurry vision) : Possible
Headache(Headache) : Possible
Patient taking 0.5 mg dose from ozempic 1 mg pen(Wrong technique in product usage process) : Unknown
Ozempic use for insulin resistance(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -
blurry vision(Blurry vision) : Unlikely
Headache(Headache) : Possible
Patient taking 0.5 mg dose from ozempic 1 mg pen(Wrong technique in product usage process) : Possible
Ozempic use for insulin resistance(Product use in unapproved indication) : Possible

Reporter Comment: -blurry vision: the condition is still present; the patient details that had to get glasses. (lens prescription).

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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L097; Exp.Dt. DEC-2026}; Regimen #1	0.5 mg qw; Subcutaneous	insulin resistance (Insulin resistance)	18-JUN-2024 / 16-AUG-2024; 59 days