CIOMS FORM

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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		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)

Other Serious Criteria: Medically Significant
blindness [Blindness]
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: Study ID: 199-NovoDia

(Continued on Additional Information Page)

- ☐ 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) 0.25 mg, qw (Continued on Additional Information Page)

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 / 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
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
27-JUN-2025

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

DATE OF THIS REPORT
04-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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 Solicited Report from COSTA RICA was reported by a Consumer as "blindness(blindness)" with an unspecified onset date , "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 Not Reported, Not Reported to 16-AUG-2024;

Current Condition: Insulin resistance, Glasses for vision.

Since 18-JUN-2025 the patient started using Ozempic 1 mg for insulin resistance indication and started taking 0.5 mg dose from Ozempic 1 mg pen
Since an unknown date Ozempic did not work for her and did not lose weight.
Since an unknown date in JUL-2024 the patient experienced headaches and later began to see blurry. She also mentioned that she used glasses, but they were for the computer, and when she started the treatment, she began to see blurry (blurry vision)
The patient stopped administering the medication; she did not know if she got used to it, but it seemed to have returned to normal (referring to the blurriness effect disappearing) and indicated that after the effects, she had to buy new glasses with a different prescription (lens prescription) due to the damage caused by the effects. The blurriness effects continued.

The patient commented that they no longer used it because since an unknown date it caused them blindness.

Batch Numbers:
Ozempic 1.0 mg: PP5L097, PP5L097;

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

The outcome for the event "blindness(blindness)" was Not Reported.
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) -
blindness(blindness) : Possible
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) -
blindness(blindness) : Unlikely
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

This case was reclassified from non serious to serious upon FU received On 27-JUN-2025 due to addition of event Blindness with seriousness criteria medically significant

Since last submission the case has been updated with the following

Mfr. Control Number: 1418312

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Suspect product dosage regimen updated
Dechallenge updated
New serious event Blindness updated
Canada and USNDA listedness updated
Narrative updated accordingly

Company comment:
Blindness, vision blurred are assessed as unlisted events and headache, wrong technique in product usage process and product use in unapproved indication are assessed as listed events according to the Novo Nordisk current Company Core Data Sheet information on Ozempic.
The case is confounded by the medical history of insulin resistance.
Limited information regarding event onset latency, final diagnosis, complete medical history, family history and social history, treatment received, and concomitant medications precludes thorough medical evaluation of the case.
Considering the nature of event and known safety profile of suspect product, the causality for the event blindness is assessed as unlikely related to the suspect product.
This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

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	0.25 mg, qw (from week 1 to week 5); Subcutaneous	insulin resistance (Insulin resistance)	18-JUN-2024 / Unknown; Unknown
#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 #2	0.5 mg, qw (in week 6); Subcutaneous	insulin resistance (Insulin resistance)	Unknown / 16-AUG-2024; Unknown