CIOMS FORM

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		NOV	2024

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

Nausea [Nausea]
Aversion [Aversion]
acidity [Hyperchlorhydria]
Ozempic use for overweight/for reduce fat [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 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection

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

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

17. INDICATION(S) FOR USE
#1) Overweight (For reducing fat) (Overweight)

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

19. THERAPY DURATION
#1) Unknown

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

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

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	Overweight (Overweight)
Unknown to Ongoing	Current Condition	Hypertension (Hypertension)

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.
1425708

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

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Nausea(Nausea)" beginning on NOV-2024 , "Aversion(Aversion)" beginning on NOV-2024 , "acidity(Hyperacidity)" beginning on NOV-2024 , "Ozempic use for overweight/for reduce fat(Product use in unapproved indication)" beginning on NOV-2024 and concerned a Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from NOV-2024 and ongoing for "Overweight (For reducing fat)",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-NOV-2024 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Overweight, Hypertension, High cholesterol.

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK;

Action taken to Ozempic 0.25/0.50 mg was reported as No Change.

The outcome for the event "Nausea(Nausea)" was Recovered.
The outcome for the event "Aversion(Aversion)" was Recovered.
The outcome for the event "acidity(Hyperacidity)" was Recovered.
The outcome for the event "Ozempic use for overweight/for reduce fat(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Nausea(Nausea) : Unknown
Aversion(Aversion) : Unknown
acidity(Hyperacidity) : Unknown
Ozempic use for overweight/for reduce fat(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Nausea(Nausea) : Possible
Aversion(Aversion) : Unlikely
acidity(Hyperacidity) : Unlikely
Ozempic use for overweight/for reduce fat(Product use in unapproved indication) : Possible

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	High cholesterol (Blood cholesterol increased);