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		45 Years	Female	75.00 kg		JAN	2025

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

constipation [Constipation]
reflux [Gastrooesophageal reflux disease]
Belching [Eructation]
Ozempic use for Overweight [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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg

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

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

17. INDICATION(S) FOR USE
#1) Overweight (Overweight)

18. THERAPY DATES(from/to)
#1) JAN-2025 / 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	Migraine (Migraine)

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.
1423734

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

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

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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: 164 cm.

Patient's weight: 75 kg.

Patient's BMI: 27.88518740.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "constipation(Constipation)" beginning on MAR-2025 , "reflux(Gastroesophageal reflux)" beginning on MAR-2025 , "Belching(Belching)" beginning on MAR-2025 , "Ozempic use for Overweight(Product use in unapproved indication)" beginning on JAN-2025 and concerned a 45 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from JAN-2025 and ongoing for "Overweight",

Dosage Regimens:
Ozempic 1.0 mg: ??-JAN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Overweight, migraines.

Treatment medications included - GRAVOL(DIMENHYDRINATE).

Batch Numbers:
Ozempic 1.0 mg: UNK;

Action taken to Ozempic 1.0 mg was reported as No Change.

The outcome for the event "constipation(Constipation)" was Recovering/resolving.
The outcome for the event "reflux(Gastroesophageal reflux)" was Recovering/resolving.
The outcome for the event "Belching(Belching)" was Recovering/resolving.
The outcome for the event "Ozempic use for Overweight(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
constipation(Constipation) : Possible
reflux(Gastroesophageal reflux) : Possible
Belching(Belching) : Possible
Ozempic use for Overweight(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -
constipation(Constipation) : Possible
reflux(Gastroesophageal reflux) : Possible
Belching(Belching) : Possible
Ozempic use for Overweight(Product use in unapproved indication) : Possible

Reporter Comment: treatment drug: Famodil (Meclizine) was non codable