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		35 Years	Male	101.00 kg		APR	2025

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

belching [Eructation]
constipation [Constipation]

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

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) Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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

18. THERAPY DATES(from/to)
#1) MAR-2025 / Ongoing

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)
#1) LANTUS (INSULIN GLARGINE) ; MAR-2025 / Ongoing
#2) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METF

(Continued on Additional Information Page)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
MAR-2025 to Ongoing	Current Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition	Obesity (Obesity)
	Duration not reported	

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.
1422090

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

24c. DATE RECEIVED BY MANUFACTURER
25-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

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

Patient's height: 176 cm.

Patient's weight: 101 kg.

Patient's BMI: 32.60588840.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "belching(Belching)" beginning on APR-2025 , "constipation(Constipation)" beginning on APR-2025 and concerned a 35 Years old Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from MAR-2025 and ongoing for "Type 2 diabetes mellitus",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-MAR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes mellitus, Obesity.

Concomitant medications included - LANTUS(INSULIN GLARGINE), XIGDUO(DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE).

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 "belching(Belching)" was Recovering/resolving.
The outcome for the event "constipation(Constipation)" was Recovering/resolving.

Reporter's causality (Ozempic 0.25/0.50 mg) -
belching(Belching) : Possible
constipation(Constipation) : Possible

Company's causality (Ozempic 0.25/0.50 mg) -
belching(Belching) : Possible
constipation(Constipation) : Possible

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE) ; MAR-2025 / Ongoing