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		39 Years	Female	108.00 kg		NOV	2024

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

A lot inflammation [Inflammation]
bad breath [Breath odour]
Vomit for about 3 days [Vomiting]
A lot of gas [Flatulence]
Constipation [Constipation]
belching [Eructation]
gas [Flatulence]
constipation [Constipation]
gas [Flatulence]
ME: misunderstood the doctor's instructions and administered 1 mg for 3 **(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
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1 mg, qd	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) type 2 diabetes (Type 2 diabetes mellitus)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) NOV-2024 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) NPH INSULIN (NPH INSULIN) ; NOV-2024 / Ongoing
#2) DAPAGLIFLOZIN (DAPAGLIFLOZIN) ; NOV-2024 / Ongoing
#3) BISOBLOC (BISOPROLOL FUMARATE) ; NOV-2024 / Ongoing

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	Obesity (Obesity)
NOV-2024 to Ongoing	Current Condition duration not reported	Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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.
1393317

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

24c. DATE RECEIVED BY MANUFACTURER
05-AUG-2025

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

DATE OF THIS REPORT
19-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

consecutive days [Product communication issue]
ME:Ozempic applied with clicks [Wrong technique in product usage process]
MEmisunderstood doctor's instructions and administered 9 clicks for consecutive days [Inappropriate schedule of product administration]

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

Patient's height: 170 cm.

Patient's weight: 108 kg.

Patient's BMI: 37.37024220.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "A lot inflammation(Inflammation)" beginning on 2025 , "bad breath(Bad breath)" beginning on 2025 , "Vomit for about 3 days(Vomiting)" beginning on NOV-2024 , "A lot of gas(Gas)" beginning on DEC-2024 , "Constipation(Constipation)" beginning on JAN-2025 , "belching(Belching)" beginning on JAN-2025 , "gas(Gas)" beginning on JAN-2025 , "constipation(Constipation)" beginning on 2025 , "gas(Gas)" beginning on 2025 ******* There are more than 9 events available in this case, The list of all the events - "MEmisunderstood doctor's instructions and administered 9 clicks for consecutive days(Once weekly dose taken more frequently),belching(Belching),gas(Gas),ME: misunderstood the doctor's instructions and administered 1 mg for 3 consecutive days(Patient misunderstanding health care provider instructions for product use),Vomit for about 3 days(Vomiting),A lot of gas(Gas),Constipation(Constipation),ME:Ozempic applied with clicks(Wrong technique in product usage process),A lot inflammation(Inflammation),constipation(Constipation),gas(Gas),bad breath(Bad breath)" ******* and concerned a 39 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from NOV-2024 to 22-JUL-2025 for "type 2 diabetes", "obesity",

Dosage Regimens:
Ozempic 1.0 mg: ??-NOV-2024 to Not Reported, Not Reported to Not Reported, Not Reported to Not Reported, Not Reported to 22-JUL-2025;

Current Condition: Obesity, type 2 diabetes, Asthma, hypertension.

Concomitant medications included - NPH INSULIN, DAPAGLIFLOZIN, BISOBLOC(BISOPROLOL FUMARATE).

Batch Numbers:
Ozempic 1.0 mg: UNK, UNK, UNK, UNK;

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

On JUL-2025 the outcome for the event "A lot inflammation(Inflammation)" was Recovered.
On JUL-2025 the outcome for the event "bad breath(Bad breath)" was Recovered.
On NOV-2024 the outcome for the event "Vomit for about 3 days(Vomiting)" was Recovered.
On DEC-2024 the outcome for the event "A lot of gas(Gas)" was Recovered.
The outcome for the event "Constipation(Constipation)" was Recovered.
The outcome for the event "belching(Belching)" was Recovered.
The outcome for the event "gas(Gas)" was Recovered.
On JUL-2025 the outcome for the event "constipation(Constipation)" was Recovered.
On JUL-2025 the outcome for the event "gas(Gas)" was Recovered.
******* There are more than 9 events available in this case *******

Reporter's causality (Ozempic 1.0 mg) -
A lot inflammation(Inflammation) : Possible
bad breath(Bad breath) : Possible
Vomit for about 3 days(Vomiting) : Possible
A lot of gas(Gas) : Possible
Constipation(Constipation) : Possible
belching(Belching) : Possible
gas(Gas) : Possible

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

constipation(Constipation) : Possible
gas(Gas) : Possible

Company's causality (Ozempic 1.0 mg) -
A lot inflammation(Inflammation) : Unlikely
bad breath(Bad breath) : Unlikely
Vomit for about 3 days(Vomiting) : Possible
A lot of gas(Gas) : Possible
Constipation(Constipation) : Possible
belching(Belching) : Possible
gas(Gas) : Possible
constipation(Constipation) : Possible
gas(Gas) : Possible

Reporter Comment: Current weight- 110 kg.

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; Regimen #1	1 mg, qd; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus) obesity (Obesity)	NOV-2024 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #2	9 clicks daily; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus) obesity (Obesity)	Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #3	18 clicks a week (qw); Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus) obesity (Obesity)	Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #4	0.25 mg; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus) obesity (Obesity)	Unknown / 22-JUL-2025; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition duration not reported	Asthma (Asthma);
Unknown to Ongoing	Current Condition duration not reported	Hypertension (Hypertension);