**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 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year |
| PRIVACY | COSTA RICA | | PRIVACY | | 49 Years | Female | 107.90 kg | | JAN | 2024 |

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

stinking" belching (strong in smell, egg-like)/sulfur burps [Eructation]
diarrhoea [Diarrhoea]
diarrhea [Diarrhoea]
a lot of acidity [Hyperchlorhydria]

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 0.25/0.5 mg (SEMAGLUTIDE) Solution for injection
**(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 ) 0.5 mg, qw | #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) | 19. THERAPY DURATION |
|---|---|
| #1 ) DEC-2021 / Unknown | #1 ) Unknown |

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 ) LEVOTHYROXINE (LEVOTHYROXINE) ; 1998 / Ongoing
#2 ) OMEPRAZOLE (OMEPRAZOLE) ; Ongoing
#3 ) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METF
#4 ) IRBESARTAN (IRBESARTAN) ; 2001 / Unknown
#5 ) LOVASTATIN (LOVASTATIN) ; Ongoing
#6 ) TOPIRAMATE (TOPIRAMATE) ; 2016 / Ongoing **(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 |
|---|---|---|
| Unknown to Ongoing | Current Condition duration not reported | Type 2 diabetes mellitus (Type 2 diabetes mellitus) |
| Unknown to Ongoing | Current Condition duration not reported | Morbid obesity (Obesity) |

## 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.
**1169290**

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

24c. DATE RECEIVED BY MANUFACTURER
31-MAY-2025

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

## 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: 155 cm.

Patient's weight: 107.9 kg.

Patient's BMI: 44.91155050.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping)" beginning on JAN-2024 , "diarrhoea(Diarrhoea)" beginning on MAR-2024 , "diarrhea(Diarrhea)" with an unspecified onset date , "a lot of acidity(Hyperacidity)" with an unspecified onset date and concerned a 49 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from DEC-2021 and ongoing for "Type 2 Diabetes Mellitus",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-DEC-2021 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes mellitus, Morbid obesity, High cholesterol, Gastritis, Hypothyroidism, Arterial hypertension
Procedure: Intragastric balloon.

Concomitant medications included - LEVOTHYROXINE, OMEPRAZOLE, XIGDUO(DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE), IRBESARTAN, LOVASTATIN, TOPIRAMATE.

Batch Numbers:
Ozempic 0.25/0.50 mg: ASKU, ASKU;

Action taken to Ozempic 0.25/0.50 mg was reported as Dose Decreased.

The outcome for the event "stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping)" was Recovering/resolving.
On MAR-2024 the outcome for the event "diarrhoea(Diarrhoea)" was Recovered.
The outcome for the event "diarrhea(Diarrhea)" was Unknown.
The outcome for the event "a lot of acidity(Hyperacidity)" was Unknown.

Reporter's causality (Ozempic 0.25/0.50 mg) -
stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping) : Possible
diarrhoea(Diarrhoea) : Possible
diarrhea(Diarrhea) : Unknown
a lot of acidity(Hyperacidity) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
stinking" belching (strong in smell, egg-like)/sulfur burps(Malodorous burping) : Possible
diarrhoea(Diarrhoea) : Possible
diarrhea(Diarrhea) : Possible
a lot of acidity(Hyperacidity) : Unlikely

**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 0.25/0.5 mg (SEMAGLUTIDE) Solution for injection; Regimen #2 | 0.25 mg, qw; Subcutaneous | Type 2 Diabetes Mellitus (Type 2 diabetes mellitus) | Ongoing; Unknown |

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

#3 ) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE) ; 2018 / Ongoing

## ADDITIONAL INFORMATION

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown to Ongoing | Current Condition duration not reported | High cholesterol (Blood cholesterol increased); |
| Unknown to Ongoing | Current Condition duration not reported | Gastritis (Gastritis); |
| Unknown to Ongoing | Current Condition duration not reported | Hypothyroidism (Hypothyroidism); |
| Unknown to Ongoing | Current Condition duration not reported | Arterial hypertension (Hypertension); |
| Unknown | Procedure | Bariatric gastric balloon insertion (Bariatric gastric balloon insertion); |