

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 58 Years	3. SEX Female	3a. WEIGHT 72.40 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER	
		Day	Month	Year			Day	Month	Year			
										PRIVACY	MAY	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
diarrhea [Diarrhoea]
foul-smelling gas [Flatulence]
numerous burps [Eructation]

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
 (Continued on Additional Information Page)

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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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) TRIVERAM IP (AMLODIPINE BESILATE, ATORVASTATIN CALCIUM, PERINDOPRIL ARGININE) ; APR-2025 / 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	Obesity (Obesity)
Unknown to Ongoing	Current Condition	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. 1437127	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 15-MAY-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 26-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

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: 151 cm.

Patient's weight: 72.4 kg.

Patient's BMI: 31.75299330.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "diarrhea(Diarrhea)" beginning on MAY-2025 , "foul-smelling gas(Malodorous flatulence)" beginning on MAY-2025 , "numerous burps(Burping)" beginning on MAY-2025 and concerned a 58 Years old Female 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: Obesity, Type 2 diabetes mellitus, High Blood Pressure, Fatty Liver Grade 3.

Concomitant medications included - TRIVERAM IP(AMLODIPINE BESILATE, ATORVASTATIN CALCIUM, PERINDOPRIL ARGININE).

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 "diarrhea(Diarrhea)" was Recovering/resolving.

The outcome for the event "foul-smelling gas(Malodorous flatulence)" was Recovering/resolving.

The outcome for the event "numerous burps(Burping)" was Recovering/resolving.

Reporter's causality (Ozempic 0.25/0.50 mg) -

diarrhea(Diarrhea) : Possible

foul-smelling gas(Malodorous flatulence) : Possible

numerous burps(Burping) : Possible

Company's causality (Ozempic 0.25/0.50 mg) -

diarrhea(Diarrhea) : Possible

foul-smelling gas(Malodorous flatulence) : Possible

numerous burps(Burping) : Possible

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);
Unknown to Ongoing	Current Condition	Fatty liver (Hepatic steatosis);