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	Female	121.00 kg		MAY	2025

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

'loose stools' (diarrhea) [Diarrhoea]
bad belching [Eructation]
bad belching, and has felt unwell [Malaise]
Ozempic dosage: 18 clicks [Wrong technique in product usage process]
Ozempic prescribed for obesity and insulin resistance [Off label use]

Case Description: ***This is an auto generated narrative***

Study ID: 199-NovoDia

(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) 18 clicks QW	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) obesity (Obesity)

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) MAY-2025 / Ongoing	#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) ; Ongoing
#2) VITAMIN D3 (VITAMIN D3) ; Ongoing
#3) COLMIBE (ATORVASTATIN CALCIUM, EZETIMIBE) ; Ongoing
#4) MAGNESIUM CITRATE (MAGNESIUM CITRATE) ; 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	Dyslipidemia (Dyslipidaemia)

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.
1452176

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

24c. DATE RECEIVED BY MANUFACTURER
04-JUN-2025

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 165 cm.

Patient's weight: 121 kg.

Patient's BMI: 44.44444440.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "'loose stools' (diarrhea)(Loose stools)" beginning on MAY-2025 , "bad belching(Belching)" beginning on MAY-2025 , "bad belching, and has felt unwell(Feeling unwell)" beginning on MAY-2025 , "Ozempic dosage: 18 clicks(Wrong technique in product usage process)" beginning on MAY-2025 , "Ozempic prescribed for obesity and insulin resistance(Off label use in unapproved indication)" beginning on MAY-2025 and concerned a 35 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from MAY-2025 and ongoing for "obesity", "insulin resistance",

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

Current Condition: Obesity, Dyslipidaemia, Hypothyroidism, Microscopic hematuria, Insulin resistance.

Concomitant medications included - LEVOTHYROXINE, VITAMIN D3, COLMIBE(ATORVASTATIN CALCIUM, EZETIMIBE), MAGNESIUM CITRATE.

Batch Numbers:
Ozempic 1.0 mg: UNK;

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

On MAY-2025 the outcome for the event "'loose stools' (diarrhea)(Loose stools)" was Recovered.
On MAY-2025 the outcome for the event "bad belching(Belching)" was Recovered.
On MAY-2025 the outcome for the event "bad belching, and has felt unwell(Feeling unwell)" was Recovered.
The outcome for the event "Ozempic dosage: 18 clicks(Wrong technique in product usage process)" was Not recovered.
The outcome for the event "Ozempic prescribed for obesity and insulin resistance(Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
'loose stools' (diarrhea)(Loose stools) : Possible
bad belching(Belching) : Possible
bad belching, and has felt unwell(Feeling unwell) : Possible
Ozempic dosage: 18 clicks(Wrong technique in product usage process) : Unknown
Ozempic prescribed for obesity and insulin resistance(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -
'loose stools' (diarrhea)(Loose stools) : Possible
bad belching(Belching) : Possible
bad belching, and has felt unwell(Feeling unwell) : Unlikely
Ozempic dosage: 18 clicks(Wrong technique in product usage process) : Possible
Ozempic prescribed for obesity and insulin resistance(Off label use in unapproved indication) : Possible

Reporter Comment: Concomitant : Omega 3(non codable)
Treatment drug : Espasmodigestomen(non codable)

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	18 clicks QW; Subcutaneous	obesity (Obesity) insulin resistance (Insulin	MAY-2025 / Ongoing; Unknown

Mfr. Control Number: 1452176

ADDITIONAL INFORMATION

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
injection, 1 mg; Regimen #1		resistance)	

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition	Microscopic hematuria (Haematuria);
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance);