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		38 Years	Female	Unk	10	JUN	2025

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

A lot of diarrhea and it has been very chronic (she eats and goes to the bathroom) [Diarrhoea]
Ozempic applied in 48 clicks [Wrong technique in product usage process]
Ozempic prescribed for weight loss [Off label use]

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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot #
(Continued on Additional Information Page)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 48 clicks, qw	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) weight loss (Weight control)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 12-MAY-2025 / Ongoing	#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

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	Diabetic (Diabetes mellitus)
	Type and 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.
1459019

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

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1459019

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.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "A lot of diarrhea and it has been very chronic (she eats and goes to the bathroom)(Chronic diarrhea)" beginning on 10-JUN-2025 , "Ozempic applied in 48 clicks(Wrong technique in product usage process)" beginning on 12-JUN-2025 , "Ozempic prescribed for weight loss(Off label use in unapproved indication)" beginning on 12-JUN-2025 and concerned a 38 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 12-MAY-2025 and ongoing for "weight loss",

Dosage Regimens:
Ozempic 1.0 mg: 12-MAY-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Diabetic.

Treatment medications included - DIACOR MEBENDAZOLE.

Batch Numbers:
Ozempic 1.0 mg: PP5M708;

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

The outcome for the event "A lot of diarrhea and it has been very chronic (she eats and goes to the bathroom)(Chronic diarrhea)" was Not recovered.
The outcome for the event "Ozempic applied in 48 clicks(Wrong technique in product usage process)" was Not recovered.
The outcome for the event "Ozempic prescribed for weight loss(Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
A lot of diarrhea and it has been very chronic (she eats and goes to the bathroom)(Chronic diarrhea) : Possible
Ozempic applied in 48 clicks(Wrong technique in product usage process) : Unknown
Ozempic prescribed for weight loss(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -
A lot of diarrhea and it has been very chronic (she eats and goes to the bathroom)(Chronic diarrhea) : Possible
Ozempic applied in 48 clicks(Wrong technique in product usage process) : Possible
Ozempic prescribed for weight loss(Off label use in unapproved indication) : Possible

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 {Lot # PP5M708; Exp.Dt. APR-2027}; Regimen #1	48 clicks, qw; Subcutaneous	weight loss (Weight control)	12-MAY-2025 / Ongoing; Unknown