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		70 Years	Female	84.00 kg	22	APR	2025

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

diarrhea [Diarrhoea]

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

(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 1.34 mg/mL) Solution for injection

15. DAILY DOSE(S)
#1) 0.25 mg, qw

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) type 2 diabetes (Type 2 diabetes mellitus)

18. THERAPY DATES(from/to)
#1) APR-2025 / Ongoing

19. THERAPY DURATION
#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)
#1) NPH INSULIN (NPH INSULIN) ; 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.	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition Duration not reported.	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.
1417709

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

24c. DATE RECEIVED BY MANUFACTURER
22-APR-2025

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1417709

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

workshops and free A1c test.

Patient's height: 161 cm.

Patient's weight: 84 kg.

Patient's BMI: 32.40615720.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "diarrhea(Diarrhea)" beginning on 22-APR-2025 and concerned a 70 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "type 2 diabetes",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-APR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes, Obesity, Asthma, Diabetic neuropathy, High testosterone.

Concomitant medications included - NPH INSULIN.

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.

Reporter's causality (Ozempic 0.25/0.50 mg) -
diarrhea(Diarrhea) : Possible

Company's causality (Ozempic 0.25/0.50 mg) -
diarrhea(Diarrhea) : Possible

Reporter Comment: Concomitant drug : Regular insulin (Non-codable)
Treatment drug : rehydration solution(Non-codable)
Patient ate fried chicken last night before diarrhoea and Product Start Date for insulins: many years ago.

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.	Diabetic neuropathy (Diabetic neuropathy);
Unknown to Ongoing	Current Condition Duration not reported.	Testosterone high (Blood testosterone increased);