CIOMS FORM

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		40 Years	Female	Unk	30	JUN	2025

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

Intermittent diarrhea [Diarrhoea]
Excessive fatigue [Fatigue]
Diarrhea [Diarrhoea]
Lack of muscle strength [Muscular weakness]

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 1.34 mg/mL) Solution for injection {Lot #
#2) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 **(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) 0.50 mg, qw(Every Monday)	#1) Subcutaneous
#2) 1 mg, qw(Ad (Continued on Additional Information Page)	#2) Subcutaneous

17. INDICATION(S) FOR USE
#1) Type 2 Diabetes Mellitus (Type 2 diabetes mellitus)
#2) 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) 17-FEB-2025 / Unknown	#1) Unknown
#2) 23-JUN-2025 / Ongoing	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) FELICITAT (ESCITALOPRAM OXALATE) ; 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 was not reported.	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition Increasing abdominal adiposity.	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.
1419427

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

24c. DATE RECEIVED BY MANUFACTURER
29-JUL-2025

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

DATE OF THIS REPORT
29-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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 "Intermittent diarrhea(Diarrhea)" with an unspecified onset date , "Excessive fatigue(Fatigue)" beginning on 30-JUN-2025 , "Diarrhea(Diarrhea)" beginning on 07-JUL-2025 , "Lack of muscle strength(Muscle weakness)" beginning on 30-JUN-2025 and concerned a 40 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 17-FEB-2025 for "Type 2 Diabetes Mellitus", , Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 23-JUN-2025 and ongoing for "Obesity", "Type 2 Diabetes mellitus",

Dosage Regimens:
Ozempic 0.25/0.50 mg: 17-FEB-2025 to Not Reported;
Ozempic 1.0 mg: 23-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 Diabetes Mellitus, Generalized Obesity, Anxiety disorder, Depression.

Concomitant medications included - FELICITAT(ESCITALOPRAM OXALATE).

Batch Numbers:
Ozempic 0.25/0.50 mg: PP5M906;
Ozempic 1.0 mg: PP5M708;

Action taken to Ozempic 0.25/0.50 mg was reported as No Change.
Action taken to Ozempic 1.0 mg was reported as No Change.

The outcome for the event "Intermittent diarrhea(Diarrhea)" was Recovered.
The outcome for the event "Excessive fatigue(Fatigue)" was Not recovered.
The outcome for the event "Diarrhea(Diarrhea)" was Not recovered.
The outcome for the event "Lack of muscle strength(Muscle weakness)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
Intermittent diarrhea(Diarrhea) : Unknown
Excessive fatigue(Fatigue) : Unknown
Diarrhea(Diarrhea) : Unknown
Lack of muscle strength(Muscle weakness) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
Intermittent diarrhea(Diarrhea) : Possible
Excessive fatigue(Fatigue) : Unlikely
Diarrhea(Diarrhea) : Unlikely
Lack of muscle strength(Muscle weakness) : Unlikely

Reporter's causality (Ozempic 1.0 mg) -
Intermittent diarrhea(Diarrhea) : Unknown
Excessive fatigue(Fatigue) : Unknown
Diarrhea(Diarrhea) : Unknown
Lack of muscle strength(Muscle weakness) : Unknown

Company's causality (Ozempic 1.0 mg) -
Intermittent diarrhea(Diarrhea) : Unlikely
Excessive fatigue(Fatigue) : Possible
Diarrhea(Diarrhea) : Possible
Lack of muscle strength(Muscle weakness) : Unlikely

Reporter Comment: Indications to improve the symptoms were provided to the patient by the PSP, as during the consultation, several factors in the diet were detected that are affecting and triggering adverse events.

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	0.50 mg, qw(Every	Type 2 Diabetes Mellitus	17-FEB-2025 /

Mfr. Control Number: 1419427

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
0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5M906; Exp.Dt. MAY-2027}; Regimen #1	Monday); Subcutaneous	(Type 2 diabetes mellitus)	Unknown; Unknown
#2) 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	1 mg, qw(Administered on 30-June and 07-July, 2025); Subcutaneous	Obesity (Obesity) Type 2 Diabetes mellitus (Type 2 diabetes mellitus)	23-JUN-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
19-DEC-2024 to Ongoing	Current Condition	Anxiety disorder (Anxiety disorder);
19-DEC-2024 to Ongoing	Current Condition	Depression (Depression);