CIOMS FORM

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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		62 Years	Male	68.00 kg		APR	2025	☐ PATIENT DIED

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

Severe constipation [Constipation]

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)

☐ 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)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.25 mg, qw	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) Type II diabetes (Type 2 diabetes mellitus)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) APR-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) PROZAC (FLUOXETINE HYDROCHLORIDE) Tablet ; 2024 / Ongoing
#2) CLONAZEPAM (CLONAZEPAM) ; Ongoing
#3) LAMICTAL (LAMOTRIGINE) Tablet ; 2015 / Ongoing
#4) QUETIAZIC (QUETIAPINE FUMARATE) ; 2020 / Ongoing
#5) LOVASTATIN (LOVASTATIN) ; 2023 / Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
2005 to Ongoing	Current Condition	Type II diabetes mellitus (Type 2 diabetes mellitus)
2005 to Ongoing	Current Condition	Hypertension (Hypertension)

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.
1443597

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

24c. DATE RECEIVED BY MANUFACTURER
20-MAY-2025

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

DATE OF THIS REPORT
03-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1443597

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

workshops and free A1c test.

Patient's height: 172 cm.

Patient's weight: 68 kg.

Patient's BMI: 22.98539750.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Severe constipation(Constipation)" beginning on APR-2025 and concerned a 62 Years old Male patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "Type II diabetes", "Hypertension",

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

Current Condition: Type II diabetes, Hypertension, Depression, Anxiety, High cholesterol, Insomnia
Historical Condition: Constipation
Procedure: Colonoscopy.

Concomitant medications included - PROZAC(FLUOXETINE HYDROCHLORIDE), CLONAZEPAM, LAMICTAL(LAMOTRIGINE), QUETIAZIC(QUETIAPINE FUMARATE), LOVASTATIN.

Treatment medications included - ALLULOSE(ALUMINIUM HYDROXIDE GEL).

Batch Numbers:
Ozempic 1.0 mg: PP5L760;

Action taken to Ozempic 1.0 mg was Not reported.

On 2025 the outcome for the event "Severe constipation(Constipation)" was Recovered.

Reporter's causality (Ozempic 1.0 mg) -
Severe constipation(Constipation) : Possible

Company's causality (Ozempic 1.0 mg) -
Severe constipation(Constipation) : Possible

Reporter Comment: Treatment for the event constipation : the doctor (endocrinologist) prescribed hifiber (fiber, fructooligosaccharides).

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 # PP5L760; Exp.Dt. JAN-2027}; Regimen #1	0.25 mg, qw; Subcutaneous	Type II diabetes (Type 2 diabetes mellitus) Hypertension (Hypertension)	APR-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Colonoscopy (Colonoscopy);
Unknown to Ongoing	Current Condition	Depression (Depression);
Unknown to Ongoing	Current Condition	Anxiety (Anxiety);
Unknown to Ongoing	Current Condition	High cholesterol (Blood cholesterol increased);
Unknown to Ongoing	Current Condition	Insomnia (Insomnia);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition before use of ozempic	Constipation (Constipation);