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		72 Years	Male	103.40 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)

feeling "dazed" [Feeling abnormal]
reflux has returned [Gastrooesophageal reflux disease]
weak [Asthenia]
Ozempic used in 18 clicks [Wrong technique in product usage process]
Ozempic prescribed for obesity and prediabetes [Off label use]

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

Study ID: 199-NovoDia

(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
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 18 clicks qw

16. ROUTE(S) OF ADMINISTRATION
#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)
#1) APR-2025 / Ongoing

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ATROLIP PLUS (ATORVASTATIN CALCIUM, EZETIMIBE) ; Ongoing
#2) APROVASC (AMLODIPINE BESILATE, IRBESARTAN) ; Ongoing
#3) BOLARIA (BETAHISTINE HYDROCHLORIDE) ; Ongoing
#4) LYRICA (PREGABALIN) ; Ongoing
#5) DUTAFLOX DUO (DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE) ; 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	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Prediabetes (Glucose tolerance impaired)

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.
1455920

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

24c. DATE RECEIVED BY MANUFACTURER
06-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: 1455920

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: 183 cm.

Patient's weight: 103.4 kg.

Patient's BMI: 30.875810.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "feeling "dazed"(Feeling dazed)" beginning on MAY-2025 , "reflux has returned(Gastrooesophageal reflux disease)" beginning on MAY-2025 , "weak(Weakness)" beginning on MAY-2025 , "Ozempic used in 18 clicks(Wrong technique in product usage process)" beginning on APR-2025 , "Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication)" beginning on APR-2025 and concerned a 72 Years old Male patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "Obesity", "prediabetes",

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

Current Condition: Obesity, Prediabetes, Sciatic pain, High cholesterol, High blood pressure
Historical Condition: Reflux.

Concomitant medications included - ATROLIP PLUS(ATORVASTATIN CALCIUM, EZETIMIBE), APROVASC(AMLODIPINE BESILATE, IRBESARTAN), BOLARIA(BETAHISTINE HYDROCHLORIDE), LYRICA(PREGABALIN), DUTAFLOX DUO(DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE).

Batch Numbers:
Ozempic 1.0 mg: UNK;

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

The outcome for the event "feeling "dazed"(Feeling dazed)" was Recovering/resolving.
The outcome for the event "reflux has returned(Gastrooesophageal reflux disease)" was Recovering/resolving.
The outcome for the event "weak(Weakness)" was Recovering/resolving.
The outcome for the event "Ozempic used in 18 clicks(Wrong technique in product usage process)" was Not recovered.
The outcome for the event "Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
feeling "dazed"(Feeling dazed) : Possible
reflux has returned(Gastrooesophageal reflux disease) : Possible
weak(Weakness) : Possible
Ozempic used in 18 clicks(Wrong technique in product usage process) : Unknown
Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -
feeling "dazed"(Feeling dazed) : Unlikely
reflux has returned(Gastrooesophageal reflux disease) : Possible
weak(Weakness) : Possible
Ozempic used in 18 clicks(Wrong technique in product usage process) : Possible
Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication) : Possible

Reporter Comment: Treatment for reflux: Probiotics(unspecified), digestive enzymes(non codeable)

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	18 clicks qw;	Obesity (Obesity)	APR-2025 / Ongoing;

Mfr. Control Number: 1455920

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
mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #1	Subcutaneous	prediabetes (Glucose tolerance impaired)	Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Sciatica (Sciatica);
Unknown	Historical Condition	Gastrooesophageal reflux disease (Gastrooesophageal reflux disease);
Unknown to Ongoing	Current Condition	High cholesterol (Blood cholesterol increased);
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);