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		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		26 Years	Male	109.00 kg	03	MAY	2025

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

diarrhea [Diarrhoea]
Ozempic prescribed for weight reduction and treatment of kidney-related conditions (the patient does not have diabetes) [Off label use]

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

(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 #
(Continued on Additional Information Page)

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

17. INDICATION(S) FOR USE
#1) weight reduction (Weight control)
(Continued on Additional Information Page)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 03-MAY-2025 / 26-MAY-2025	#1) 23 days

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	Nephrotic syndrome (Nephrotic syndrome)
Unknown to Ongoing	Current Condition	

(Continued on Additional Information Page)

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.
1457162

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

24c. DATE RECEIVED BY MANUFACTURER
10-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: 1457162

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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 weight: 109 kg.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "diarrhea(Diarrhea)" beginning on 26-MAY-2025 , "Ozempic prescribed for weight reduction and treatment of kidney-related conditions (the patient does not have diabetes)(Off label use in unapproved indication)" beginning on 03-MAY-2025 and concerned a 26 Years old Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 03-MAY-2025 to 26-MAY-2025 for "weight reduction", "nephrotic syndrome", "focal segmental glomerulosclerosis",

Dosage Regimens:
Ozempic 0.25/0.50 mg: 03-MAY-2025 to 26-MAY-2025;

Current Condition: nephrotic syndrome, focal segmental glomerulosclerosis.

Batch Numbers:
Ozempic 0.25/0.50 mg: PP5N237;

Action taken to Ozempic 0.25/0.50 mg was reported as Drug discontinued temporarily.

On 01-JUN-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.
On 26-MAY-2025 the outcome for the event "Ozempic prescribed for weight reduction and treatment of kidney-related conditions (the patient does not have diabetes)(Off label use in unapproved indication)" was Recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
diarrhea(Diarrhea) : Possible
Ozempic prescribed for weight reduction and treatment of kidney-related conditions (the patient does not have diabetes)(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
diarrhea(Diarrhea) : Possible
Ozempic prescribed for weight reduction and treatment of kidney-related conditions (the patient does not have diabetes)(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 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5N237; Exp.Dt. MAY-2027}; Regimen #1	0.25 mg, qw; Subcutaneous	weight reduction (Weight control) nephrotic syndrome (Nephrotic syndrome) focal segmental glomerulosclerosis (Focal segmental glomerulosclerosis)	03-MAY-2025 / 26-MAY-2025; 23 days

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Focal segmental glomerulosclerosis (Focal segmental glomerulosclerosis);