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		33 Years	Male	116.00 kg	21	JUL	2025

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

Other Serious Criteria: Medically Significant
nearly caused kidney damage [Renal impairment]
lack of energy [Asthenia]
dehydration [Dehydration]
severe stomach pain [Abdominal pain upper]
administered 0.25 mg for 4 consecutive days(overdose) [Overdose]
dosing incorrectly due to a misunderstanding of the prescription (0.25 mg for 4 consecutive days) [Product communication issue]
Fatigue [Fatigue]
excessive sleepiness [Somnolence]

(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

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

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

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

17. INDICATION(S) FOR USE
#1) weight loss (Weight control)

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

18. THERAPY DATES(from/to)
#1) 21-JUL-2025 / 24-JUL-2025

19. THERAPY DURATION
#1) 3 days

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		

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.
1490393

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

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

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

DATE OF THIS REPORT
11-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Nausea [Nausea]
Constipation [Constipation]
Ozempic prescribed for weight loss [Off label use]

Case Description: 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 workshops and free A1c test.

Patient's height: 176 cm.

Patient's weight: 116 kg.

Patient's BMI: 37.44834710.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "nearly caused kidney damage(Renal impairment)" beginning on 21-JUL-2025 , "lack of energy(Feeling of total lack of energy)" beginning on 21-JUL-2025 , "dehydration(dehydration)" beginning on 21-JUL-2025 , "severe stomach pain(Stomach pain)" beginning on 21-JUL-2025 , "administered 0.25 mg for 4 consecutive days(overdose) (Overdose)" begin-ning on 21-JUL-2025 , dosing incorrectly due to a misunderstanding of the prescription (0.25 mg for 4 consecutive days) (Patient misunderstanding health care provider instructions for product use)" beginning on 21-JUL-2025, "excessive sleepiness(Sleepiness)" beginning on 21-JUL-2025 , "Nau-sea(Nausea)" beginning on 21-JUL-2025 , "Constipation(Constipation)" beginning on 21-JUL-2025 , "Fatigue(Fatigue)" beginning on 21-JUL-2025, ""Ozempic pre-scribed for weight loss(Off label use in unapproved indication)" beginning on 21-JUL-2025, and concerned a 33 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from 21-JUL-2025 to 24-JUL-2025 for "weight loss",

Dosage Regimens:
Ozempic: 21-JUL-2025 to 24-JUL-2025;

Medical history was not provided.

On 21-JUL-2025 patient experienced, Constipation, fatigue, excessive sleepiness, nausea.

Patient was prescribed Ozempic for weight loss and patient was dosing the medication incorrectly due to a misunderstanding of the prescription, having ad-ministered 0.25 mg for 4 consecutive days,

On 24-JUL-2025 it was recommended to discontinue its use until confirmed with the doctor re-garding the prescription and the correct administration.

On 30-JUL-2025, the patient ended up in the hospital over the weekend due to lack of energy, severe stomach pain, and dehydration. According to doctors, this overdose nearly caused kidney damage, and they recommend discontinuing the medication for at least one month. It was treated in the hospital, but the patient did not specify the treatment administered.

The patient reported that they had to go to the hospital; however, they did not indicate the duration of the visit .

Batch Numbers:
Ozempic: Requested

Action taken to Ozempic was reported as Product discontinued due to AE.

The outcome for the event "nearly caused kidney damage(Renal impairment)" was Not Reported.
The outcome for the event "lack of energy(Feeling of total lack of energy)" was Not recovered.
The outcome for the event "dehydration(dehydration)" was Not recovered.
The outcome for the event "severe stomach pain(Stomach pain)" was Not recovered.
On 24-JUL-2025 the outcome for the event "administered 0.25 mg for 4 consecutive days(overdose)(Overdose)" was Recovered.
On 24-JUL-2025 the outcome for the event " a dosing incorrectly due to a misunderstanding of the prescription (0.25 mg for 4 consecutive days) (Patient misunderstanding health care provider instructions for product use " was Recovered.
The outcome for the event "excessive sleepiness(Sleepiness)" was Not recovered.
The outcome for the event "Nausea(Nausea)" was Not recovered.
The outcome for the event "Constipation(Constipation)" was Not recovered.
The outcome for the event "Fatigue(Fatigue)" was Not recovered.
On 24-JUL-2025 the outcome for the event "Ozempic prescribed for weight loss(Off label use in unapproved indication)" was Recovered.

Mfr. Control Number: 1490393

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Reporter's causality (Ozempic) -
nearly caused kidney damage(Renal impairment) : possible
lack of energy(Feeling of total lack of energy) : Possible
dehydration(dehydration) : Possible
severe stomach pain(Stomach pain) : Possible
administered 0.25 mg for 4 consecutive days(overdose)(Overdose) : Unknown
dosing incorrectly due to a misunderstanding of the prescription (0.25 mg for 4 consecutive days) (Patient misunderstanding health care provider instructions for product use)": Unknown
excessive sleepiness(Sleepiness) : Possible
Nausea(Nausea) : Possible
Constipation(Constipation) : Possible
Fatigue(Fatigue) : Possible
Ozempic prescribed for weight loss(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic) -
nearly caused kidney damage(Renal impairment) : Unlikely
lack of energy(Feeling of total lack of energy) : Possible
dehydration(dehydration) : Unlikely
severe stomach pain(Stomach pain) : Possible
administered 0.25 mg for 4 consecutive days(overdose) (Overdose) : Possible
dosing incorrectly due to a misunderstanding of the prescription (0.25 mg for 4 consecutive days) (Patient misunderstanding health care provider instructions for product use)" : Possible
excessive sleepiness(Sleepiness) : Unlikely
Nausea(Nausea) : Possible
Constipation(Constipation) : Possible
Fatigue(Fatigue) : Possible
Ozempic prescribed for weight loss(Off label use in unapproved indication) : Possible

Company comment:
Renal impairment, Dehydration and Somnolence is assessed as unlisted : Asthenia, Abdominal pain upper, Overdose, Product communication issue, Fatigue, Nausea, Constipation are assessed as listed events according to the Novo Nordisk company core data sheet (CCDS) for Ozempic.
Patient’s misunderstanding of the prescription is considered as the possible factor causing the overdose and the associated events. Information on the use of any other concomitant medicines, any other signs/symptoms like vomiting or diarrhoea that could have caused dehydration and relevant clinical/diagnostic investigations is not available for assessment. Based on safety profile and considering the Product communication issue causing overdose, occurrence of Asthenia, Abdominal pain upper, cannot be denied, however causality for events, Renal impairment, and Dehydration is considered unlikely.
This single case report is not considered to change the current knowledge of the safety profile of Ozempic