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		56 Years	Female	56.10 kg		APR	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
Seizure [Seizure]
feel very unwell [Malaise]
aversions to food (feels that can't even look at it) and eats very little. [Food aversion]
slowness in thinking [Bradyphrenia]
forgetting things [Memory impairment]
not being able to concentrate. [Disturbance in attention]
Ozempic applied with clicks [Wrong technique in product usage process]

(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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg
#2) IDeg PDS290 (Insulin Degludec 100 U/mL) Solution for injection, 100 U/mL

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 37 clicks qw	#1) Subcutaneous
#2) 10 IU, qd	#2) Subcutaneous

17. INDICATION(S) FOR USE
#1) Type 2 diabetes mellitus (Type 2 diabetes mellitus)
#2) Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) APR-2025 / Ongoing	#1) Unknown
#2) Ongoing	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) FORXIGA (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE) ; APR-2025 / 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	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Current Condition	Seizures (Seizure)

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.
1463263

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

24c. DATE RECEIVED BY MANUFACTURER
18-JUN-2025

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 160 cm.
Patient's weight: 56.1 kg.
Patient's BMI: 21.91406250.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "Seizure(Seizure)" beginning on 18-JUN-2025 , "feel very unwell(Feeling unwell)" beginning on APR-2025 , "The patient has aversions to food (feels that can't even look at it) and eats very little.(Food aversion)" beginning on APR-2025 , "slowness in thinking(Slowed thinking)" beginning on 18-JUN-2025 , "forgetting things(Forgetfulness)" beginning on 18-JUN-2025 , "not being able to concentrate.(Concentration loss)" beginning on 18-JUN-2025 , "Ozempic applied with clicks(Wrong technique in product usage process)" beginning on APR-2025 and concerned a 56 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "Type 2 diabetes mellitus", , IDeg PDS290 (Insulin Degludec 100 U/mL) from unknown start date and ongoing for "Type 2 diabetes mellitus",

Dosage Regimens:
Ozempic 1.0 mg: ??-APR-2025 to Not Reported (Dosage Regimen Ongoing);
IDeg PDS290:

Current Condition: Type 2 diabetes mellitus(Duration not reported), frequent seizures, Epilepsy.

Concomitant medications included - FORXIGA(DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE).

On an unspecified date in APR-2025, the patient applied Ozempic with clicks and felt very unwell. The patient has aversions to food (feels that can't even look at it) and eats very little.
On 18-JUN-2025, the patient had an episode of seizure, but the patient is not sure; the patient also reports slowness in thinking, forgetting things, and not being able to concentrate.

Batch Numbers:
Ozempic 1.0 mg: Not available
IDeg PDS290: Not available

Action taken to Ozempic 1.0 mg was reported as No Change.
Action taken to IDeg PDS290 was reported as No Change.

The outcome for the event "Seizure(Seizure)" was Recovering/resolving.
The outcome for the event "feel very unwell(Feeling unwell)" was Recovering/resolving.
The outcome for the event "The patient has aversions to food (feels that can't even look at it) and eats very little.(Food aversion)" was Recovering/resolving.
The outcome for the event "slowness in thinking(Slowed thinking)" was Recovering/resolving.
The outcome for the event "forgetting things(Forgetfulness)" was Recovering/resolving.
The outcome for the event "not being able to concentrate.(Concentration loss)" was Recovering/resolving.
The outcome for the event "Ozempic applied with clicks(Wrong technique in product usage process)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
Seizure(Seizure) : Unlikely
feel very unwell(Feeling unwell) : Possible
The patient has aversions to food (feels that can't even look at it) and eats very little.(Food aversion) : Possible
slowness in thinking(Slowed thinking) : Unlikely
forgetting things(Forgetfulness) : Unlikely
not being able to concentrate.(Concentration loss) : Unlikely
Ozempic applied with clicks(Wrong technique in product usage process) : Unknown

Company's causality (Ozempic 1.0 mg) -
Seizure(Seizure) : Unlikely
feel very unwell(Feeling unwell) : Unlikely
The patient has aversions to food (feels that can't even look at it) and eats very little.(Food aversion) : Unlikely
slowness in thinking(Slowed thinking) : Unlikely
forgetting things(Forgetfulness) : Unlikely
not being able to concentrate.(Concentration loss) : Unlikely
Ozempic applied with clicks(Wrong technique in product usage process) : Possible

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Reporter's causality (IDeg PDS290) -
Seizure(Seizure) : Unknown
feel very unwell(Feeling unwell) : Unknown
The patient has aversions to food (feels that can't even look at it) and eats very little.(Food aversion) : Unknown
slowness in thinking(Slowed thinking) : Unlikely
forgetting things(Forgetfulness) : Unlikely
not being able to concentrate.(Concentration loss) : Unlikely
Ozempic applied with clicks(Wrong technique in product usage process) : Unknown

Company's causality (IDeg PDS290) -
Seizure(Seizure) : Unlikely
feel very unwell(Feeling unwell) : Unlikely
The patient has aversions to food (feels that can't even look at it) and eats very little.(Food aversion) : Unlikely
slowness in thinking(Slowed thinking) : Unlikely
forgetting things(Forgetfulness) : Unlikely
not being able to concentrate.(Concentration loss) : Unlikely
Ozempic applied with clicks(Wrong technique in product usage process) : Possible

The reporter could not be reached. Hence, no further information was available.

company comment:
Seizure, feeling unwell, Food aversion, slowed thinking, Forgetfulness, concentration loss are assessed as unlisted event according to Novo Nordisk current CCDS information on Ozempic and insulin degludec.
Medical history of epilepsy is a confounding factor . Information on product start dates to as-sess temporal relationship, concomitant medications, clinical/ diagnostic investigations are not available limiting thorough medical evaluation. However, considering the nature of event and pharmacological properties of the drug, the causality is assessed as unlikely related to the drug.
This single case report is not considered to change the current knowledge of the safety profile of Ozempic and insulin degludec.

23. OTHER RELEVANT HISTORY continued

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