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		34 Years	Female	117.00 kg		FEB	2024

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
suicidal thoughts [Suicidal ideation]
depression [Depression]
panic attacks [Panic attack]
anxiety increased [Anxiety]
abrupt weight loss [Weight decreased]
ozempic prescribed for weight loss [Off label use]

Case Description: Study ID: 199-NovoDia

(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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL {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 loss (Weight control)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) FEB-2024 / Unknown	#1) Unknown

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)
#1) ENALAPRIL (ENALAPRIL) Tablet ; 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	Anxiety (Anxiety)
Unknown to Ongoing	Current Condition	Blood pressure high (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
World Wide #: CR-NOVOPROD-1417202

24b. MFR CONTROL NO.
1417202

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
29-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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: 159 cm.

Patient's weight: 117 kg.

Patient's BMI: 46.27981490.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "suicidal thoughts(Suicidal ideation)" beginning on 2024 , "depression(Depression)" beginning on 2024 , "panic attacks(Panic attack)" beginning on 2024 , "anxiety increased(Anxiety aggravated)" beginning on 2024 , "abrupt weight loss(Weight loss)" beginning on 2024 , "ozempic prescribed for weight loss(Off label use)" beginning on FEB-2024 and concerned a 34 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from FEB-2024 to MAY-2024 for "weight loss",

Dosage Regimens:
Ozempic: ??-FEB-2024 to Not Reported, ??-???-2024 to ??-MAY-2024;

Current Condition: Anxiety, High blood pressure
Historical Drug: Phentermine.

Concomitant medications included - ENALAPRIL.

Treatment medications included - FLUOXETINE, VENLAFAXINE.

On an unknown date in FEB-2024 the ozempic was prescribed for weight loss.

On an unknown date in 2024 the patient experienced depression to the point that she had to seek psychological help and take medications because she was having too many panic attacks. It was after about a month of using the medication that she started experiencing those symptoms, and it got worse when the dose was increased, so she decided to stop because she was not men-tally well anymore.

The patient also mentions that although she had anxiety issues before, the use of Ozempic was a trigger (referring to the significant increase in anxiety). She stated that she already knew there were those risks, but she didn't think she would experience them. She continued taking it be-cause she thought it might be temporary, but she reached the dose of 0.5 mg, and that’s when she realized she was in a bad place because she literally had suicidal thoughts.

The patient reported that the Ozempic did work for her as she lost a lot of weight(Weight) but experienced a rebound effect afterward because of the depression. She started taking the medications, and they made her happy, and She started eating again’ (referring to the rebound effect). The patient was still in a recovery state. It was also a very abrupt weight loss, her food intake de-creased significantly.

It was reported that everything came back quadrupled, she don’t know why, but she feels that injection really worsened her condition. She always told her psychologist ‘The time she was thin-nest was the time she was saddest in her entire life,’ and she states that despite the effects, she continued the medication until she finished it.

On an unknown date, the patient stated that patient started everything using Ozempic the panic attacks appeared with the use of Ozempic. The product works, but at least I imagine I was predisposed to anxiety, and that predisposition also contributed to the medication harming me. Instead of being happy about the weight loss, it was the darkest, saddest moment I felt. It works, but the person must be very mentally strong to handle that medication because it is too strong and it destroys your mind. If you are going to use it for weight loss, it destroys your mind. Patient mentions that she feels mentally weak. Additionally, she states that she has not had any changes in her diet and is trying to stay calmer

Batch Numbers:
Ozempic: PP5K434, PP5K434;

Action taken to Ozempic was reported as Product discontinued.

The outcome for the event "suicidal thoughts(Suicidal ideation)" was Recovering/resolving.
The outcome for the event "depression(Depression)" was Recovering/resolving.
The outcome for the event "panic attacks(Panic attack)" was Recovering/resolving.
The outcome for the event "anxiety increased(Anxiety aggravated)" was Recovering/resolving.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The outcome for the event "abrupt weight loss(Weight loss)" was Recovering/resolving.
On MAY-2024 the outcome for the event "ozempic prescribed for weight loss(Off label use)" was Recovered.

Reporter's causality (Ozempic) -
suicidal thoughts(Suicidal ideation) : Possible
depression(Depression) : Possible
panic attacks(Panic attack) : Possible
anxiety increased(Anxiety aggravated) : Possible
abrupt weight loss(Weight loss) : Possible
ozempic prescribed for weight loss(Off label use) : Unknown

Company's causality (Ozempic) -
suicidal thoughts(Suicidal ideation) : Unlikely
depression(Depression) : Unlikely
panic attacks(Panic attack) : Unlikely
anxiety increased(Anxiety aggravated) : Unlikely
abrupt weight loss(Weight loss) : Possible
ozempic prescribed for weight loss(Off label use) : Possible

Since last submission case was updated with following information:
-Historical drug Phentermine was added
-Patient weight was updated from unk to 117kg
-Suspect dose 0.75mg was removed and 0.5 mg was updated with stop date.
-Suspect action taken was updated from No change to Product discontinued.
-Treatment drug Venlafaxine was added
-For event abrupt weight loss Treatmemt received was updated from UNK to No
-Medication error event "Ozempic dose administered as 0.75 mg" was removed
-Body of narrative was updated
-Narrative updated accordingly.

Company comment:
Suicidal ideation, depression, panic attack and anxiety are assessed as unlisted; weight decreased, off label use are assessed as listed events according to the Novo Nordisk current CCDS information on Ozempic. The information on relevant medical history (on traumatic or stressful events, substance abuse) are not available. However, a medical history of anxiety is a confounder in this case. Hence the causality is assessed as unlikely for the events Suicidal ideation, depression, panic attack and anxiety; possible for events weight decreased, off label use. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1417202
Reference Notes:

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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL {Lot # PP5K434; Exp.Dt. OCT-2026}; Regimen #1	0.25 mg, qw; Subcutaneous	weight loss (Weight control)	FEB-2024 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL {Lot # PP5K434; Exp.Dt. OCT-2026}; Regimen #2	0.5 mg, qw; Subcutaneous	weight loss (Weight control)	2024 / MAY-2024; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Drug	Phentermine (PHENTERMINE); Drug Indication: Product used for unknown indication (Product used for unknown indication), Drug Reaction: No adverse reaction (No adverse event)

Mfr. Control Number: 1417202

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description