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		30 Years	Female	97.00 kg		NOV	2024

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

A lot of stomach discomfort (indigestion) [Dyspepsia]
Ozempic use for lose weight, off label [Off label use]
The patient is a pharmacist and self-prescribed the treatment; it was not prescribed by any doctor [Prescription drug used without a prescription]

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

Study ID: 199-NovoDia

Study description: Trial Title: Patient support programme to support **(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
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) UNK

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

17. INDICATION(S) FOR USE
#1) overweight (Overweight)

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

18. THERAPY DATES(from/to)
#1) NOV-2024 / DEC-2024

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) BRUNELLE (CHLORMADINONE ACETATE, ETHINYLESTRADIOL) Tablet ; 2017 / 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.	Overweight (Overweight)
2017 to Ongoing	Procedure	Contraception (Contraception)

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: Yes

24b. MFR CONTROL NO.
1462204

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

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

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

DATE OF THIS REPORT
02-SEP-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 172 cm.

Patient's weight: 97 kg.

Patient's BMI: 32.78799350.

This non-serious Solicited Report from COSTA RICA was reported by a Pharmacist as "A lot of stomach discomfort (indigestion)(Indigestion)" beginning on NOV-2024 , "Ozempic use for lose weight, off label(Off label use in unapproved indication)" beginning on NOV-2024 , "The patient is a pharmacist and self-prescribed the treatment; it was not prescribed by any doctor(Prescription drug used without a prescription)" beginning on NOV-2024 and concerned a 30 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from NOV-2024 to JAN-2025 for "overweight",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-NOV-2024 to ??-DEC-2024, Not Reported to ??-JAN-2025;

Current Condition: Overweight
Procedure: contraception.

Concomitant medications included - BRUNELLE(CHLORMADINONE ACETATE, ETHINYLESTRADIOL).

Batch Numbers:
Ozempic 0.25/0.50 mg: ASKU, ASKU;

Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE.

On JAN-2025 the outcome for the event "A lot of stomach discomfort (indigestion)(Indigestion)" was Recovered.
On JAN-2025 the outcome for the event "Ozempic use for lose weight, off label(Off label use in unapproved indication)" was Recovered.
The outcome for the event "The patient is a pharmacist and self-prescribed the treatment; it was not prescribed by any doctor(Prescription drug used without a prescription)" was Not Reported.

Reporter's causality (Ozempic 0.25/0.50 mg) -
A lot of stomach discomfort (indigestion)(Indigestion) : Possible
Ozempic use for lose weight, off label(Off label use in unapproved indication) : Unknown
The patient is a pharmacist and self-prescribed the treatment; it was not prescribed by any doctor(Prescription drug used without a prescription) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
A lot of stomach discomfort (indigestion)(Indigestion) : Possible
Ozempic use for lose weight, off label(Off label use in unapproved indication) : Possible
The patient is a pharmacist and self-prescribed the treatment; it was not prescribed by any doctor(Prescription drug used without a prescription) : Possible

Reporter Comment: Batch number for Ozempic is not available.
Due to the discomfort experienced (a lot of stomach discomfort) the patient preferred not to use Ozempic in December because the stomach discomfort was intense at that time.
there was "a rebound in weight" (referring to the fact that the patient gained weight after stopping the medication).
The patient indicates that she has always suffered from being overweight.

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; Regimen #2	0.5 mg, qw(Restarted); Subcutaneous	overweight (Overweight)	Unknown / JAN-2025; Unknown

Mfr. Control Number: 1462204

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