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		42 Years	Female	89.40 kg			2024

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

losing a lot of muscle [Muscle atrophy]
gained a lot of weight [Weight increased]
nausea [Nausea]
Constipation [Constipation]
very bloated [Abdominal distension]
Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use [Off label use]

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

(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) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1 mg	#1) Unknown
#2) 0.25 mg, qw	#2) Subcutaneous

17. INDICATION(S) FOR USE
#1) weight loss (Weight control)
#2) Insulin resistance (Insulin resistance) **(Continued on Additional Information Page)**

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2024 / DEC-2024	#1) Unknown
#2) 28-JUL-2024 / Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) PREGABALIN (PREGABALIN) ; JUN-2024 / Unknown
#2) EUTIROX (LEVOTHYROXINE SODIUM) ; 2007 / Unknown
#3) DULOXETINE (DULOXETINE) ; JUN-2024 / Unknown

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 since always	Overweight (Overweight)
2007 to Ongoing	Current Condition	Insulin resistance (Insulin resistance)

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.
1269921

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

24c. DATE RECEIVED BY MANUFACTURER
25-APR-2025

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 154 cm.

Patient's weight: 89.4 kg.

Patient's BMI: 37.69607020.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "losing a lot of muscle(Muscle atrophy)" beginning on 2024 , "gained a lot of weight(Weight gain)" beginning on 2024 , "nausea(Nausea)" with an unspecified onset date , "Constipation(Constipation)" beginning on 2024 , "very bloated(Bloating)" with an unspecified onset date , "Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use(Off label use)" beginning on 2024 and concerned a 42 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 2024 to DEC-2024 for "weight loss", , Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from 28-JUL-2024 to DEC-2024 for "Insulin resistance", "weight loss",

Dosage Regimens:
Ozempic 1.0 mg: ??-???-2024 to ??-DEC-2024;
Ozempic 0.25/0.50 mg: 28-JUL-2024 to Not Reported, ??-???-2024 to ??-DEC-2024;

Current Condition: Overweight, Insulin resistance, Hashimoto disease, Fibromyalgia, hypothyroidism, neuropathic pain
Historical Drug: METFORMIN, METFORMIN.

Concomitant medications included - PREGABALIN, EUTIROX(LEVOTHYROXINE SODIUM), DULOXETINE.

Lab Data included:
Test Date: 2024
Lab Data Test as Reported: Weight
Test Name: Weight
Comments: On an unspecified date in 2024, Patient gained a lot of body weight (unit and value not reported)

Lab Data Test as Reported: Weight
Test Name: Weight
Results: 82
Unit: kg
Comments:

Lab Data Test as Reported: Weight
Test Name: Weight
Results: 83
Unit: kg
Comments:

Lab Data Test as Reported: weight
Test Name: Weight
Comments: On an unknown date patient had lost weight Approximately 1.5 to 2 kg.

Batch Numbers:
Ozempic 1.0 mg: ASKU;
Ozempic 0.25/0.50 mg: PP5M019, PP5M019;

Action taken to Ozempic 1.0 mg was reported as Product discontinued due to AE.
Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued.

The outcome for the event "losing a lot of muscle(Muscle atrophy)" was Not recovered.
The outcome for the event "gained a lot of weight(Weight gain)" was Not recovered.
The outcome for the event "nausea(Nausea)" was Recovering/resolving.
The outcome for the event "Constipation(Constipation)" was Recovering/resolving.

Mfr. Control Number: 1269921

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The outcome for the event "very bloated(Bloating)" was Not Reported.
On DEC-2024 the outcome for the event "Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use(Off label use)" was Recovered.

Reporter's causality (Ozempic 1.0 mg) -
losing a lot of muscle(Muscle atrophy) : Possible
gained a lot of weight(Weight gain) : Possible
nausea(Nausea) : Unknown
Constipation(Constipation) : Possible
very bloated(Bloating) : Unknown
Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use(Off label use) : Unknown

Company's causality (Ozempic 1.0 mg) -
losing a lot of muscle(Muscle atrophy) : Unlikely
gained a lot of weight(Weight gain) : Unlikely
nausea(Nausea) : Possible
Constipation(Constipation) : Possible
very bloated(Bloating) : Possible
Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use(Off label use) : Possible

Reporter's causality (Ozempic 0.25/0.50 mg) -
losing a lot of muscle(Muscle atrophy) : Unknown
gained a lot of weight(Weight gain) : Unknown
nausea(Nausea) : Possible
Constipation(Constipation) : Possible
very bloated(Bloating) : Unknown
Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use(Off label use) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
losing a lot of muscle(Muscle atrophy) : Unlikely
gained a lot of weight(Weight gain) : Unlikely
nausea(Nausea) : Possible
Constipation(Constipation) : Possible
very bloated(Bloating) : Possible
Physician prescribed Ozempic use for Insulin resistance and weight loss and indicates Spent 2 weeks on 0.25 mg and started 0.50 mg from the third week: Off label use(Off label use) : Possible

Reporter Comment: The nutritionist sent patient shakes to help a bit for Nausea and Constipation
New Weight(kg): 82 a 83 kg

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight On an unknown date patient had lost weight Approximately 1.5 to 2 kg.		
2		Weight	82 kg	
3		Weight	83 kg	
4	2024	Weight On an unspecified date in 2024, Patient gained a lot of body weight (unit and value not reported)		

13. Relevant Tests

On an unknown date patient had lost weight Approximately 1.5 to 2 kg.
On an unspecified date, Patient weight was reported as 82 kg
On an unspecified date, Patient weight was reported as 83 kg

Mfr. Control Number: 1269921

ADDITIONAL INFORMATION

13. Relevant Tests

On an unspecified date in 2024, Patient gained a lot of body weight (unit and value not reported)

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
#2) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5M019; Exp.Dt. FEB-2027}; Regimen #1	0.25 mg, qw; Subcutaneous	Insulin resistance (Insulin resistance) weight loss (Weight control)	28-JUL-2024 / Unknown; Unknown
#2) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5M019; Exp.Dt. FEB-2027}; Regimen #2	0.50 mg, qw; Subcutaneous	Insulin resistance (Insulin resistance) weight loss (Weight control)	2024 / DEC-2024; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2007 to Ongoing	Current Condition	Hashimoto's disease (Autoimmune thyroiditis);
2014 to Ongoing	Current Condition	Fibromyalgia (Fibromyalgia);
2023 to Unknown	Historical Drug	METFORMIN (METFORMIN); Drug Indication: Insulin resistance (Insulin resistance), Drug Reaction: Feeling bad (Feeling abnormal)
	November or december , was in treatment for approximately 2 months	
2023 to Unknown	Historical Drug	METFORMIN (METFORMIN); Drug Indication: Overweight (Overweight), Drug Reaction: Drug side effect (Adverse drug reaction)
	November or december , was in treatment for approximately 2 months	
2007 to Ongoing	Current Condition	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition	Neuropathic pain (Neuralgia);