CIOMS FORM

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		58 Years	Female	108.00 kg		MAR	2025

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

thyroid was very out of balance (Hypothyroidism aggrevated) [Hypothyroidism] ([Condition aggravated])
Gastritis (pain in the upper part of the stomach), bad-tasting belching,feel unwell [Gastritis]
Nausea [Nausea]
Vomiting [Vomiting]
A loss of appetite [Decreased appetite]
gas [Flatulence]
disgusted by food [Food aversion]
cramping [Muscle spasms]

(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 {Lot #
(Continued on Additional Information Page)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 18 clicks to get 0.5 mg	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) type 2 diabetes mellitus (Type 2 diabetes mellitus)
(Continued on Additional Information Page)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 26-MAR-2025 / 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) Novolin R Penfill (INSULIN HUMAN 100 IU/mL) Solution for injecti
#2) Novolin N (INSULIN ISOPHANE) Suspension for injection ; 2010 / Ongoing
#3) EUTIROX (LEVOTHYROXINE SODIUM) ; Ongoing
#4) NPH INSULIN (NPH INSULIN) ; Ongoing
#5) INSULIN NOS (INSULIN NOS) ; Ongoing
#6) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METF **(Continued on Additional Information Page)**

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	Obesity (Obesity)
Unknown to Ongoing	Current Condition duration not reported	Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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.
1400838

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Ozempic 0.5 mg applied in 18 clicks [Wrong technique in product usage process]

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

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: 159 cm.

Patient's weight: 108 kg.

Patient's BMI: 42.71982910.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "thyroid was very out of balance (Hypothyroidism aggrevated)(Hypothyroidism)" beginning on 09-MAY-2025 , "thyroid was very out of balance (Hypothyroidism aggrevated)(Condition aggravated)" beginning on 09-MAY-2025 , "Gastritis (pain in the upper part of the stomach), bad-tasting belching,feel unwell(Gastritis)" beginning on MAR-2025 , "Nausea(Nausea)" beginning on 26-MAR-2025 , "Vomiting(Vomiting)" beginning on 26-MAR-2025 , "A loss of appetite(Appetite lost)" beginning on 26-MAR-2025 , "gas(Gas)" beginning on 21-JUN-2025 , "disgusted by food(Food disgust)" beginning on 26-MAR-2025 , "cramping(Cramps)" beginning on 21-JUN-2025 ******* There are more than 9 events available in this case, The list of all the events - "Nausea(Nausea),Vomiting(Vomiting),A loss of appetite(Appetite lost),gas(Gas),cramping(Cramps),Gastritis (pain in the upper part of the stomach), bad-tasting belching,feel unwell(Gastritis),Ozempic 0.5 mg applied in 18 clicks and 36 clicks(Wrong technique in product usage process),thyroid was very out of balance (Hypothyroidism aggrevated)(Hypothyroidism),thyroid was very out of balance (Hypothyroidism aggrevated)(Condition aggravated),disgusted by food(Food disgust)" ******* and concerned a 58 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 26-MAR-2025 and ongoing for "type 2 diabetes mellitus", "Obesity",

Dosage Regimens:
Ozempic 1.0 mg: 26-MAR-2025 to Not Reported, 21-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Type 2 diabetes mellitus, Hypothyroidism, Depression, Anxiety, High blood presuure.

Concomitant medications included - Novolin R Penfill(INSULIN HUMAN 100 IU/mL), Novolin N(INSULIN ISOPHANE), EUTIROX(LEVOTHYROXINE SODIUM), NPH INSULIN, INSULIN NOS, XIGDUO(DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE), VENLAFAXINE, BIOSARTAN(LOSARTAN POTASSIUM).

Batch Numbers:
Ozempic 1.0 mg: PP5L760, PP5L760;

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

The outcome for the event "thyroid was very out of balance (Hypothyroidism aggrevated)(Hypothyroidism)" was Not recovered.
The outcome for the event "thyroid was very out of balance (Hypothyroidism aggrevated)(Condition aggravated)" was Not recovered.
The outcome for the event "Gastritis (pain in the upper part of the stomach), bad-tasting belching,feel unwell(Gastritis)" was Recovering/resolving.
The outcome for the event "Nausea(Nausea)" was Not recovered.
The outcome for the event "Vomiting(Vomiting)" was Not recovered.
The outcome for the event "A loss of appetite(Appetite lost)" was Not recovered.
The outcome for the event "gas(Gas)" was Not recovered.
The outcome for the event "disgusted by food(Food disgust)" was Not recovered.
The outcome for the event "cramping(Cramps)" was Not recovered.
******* There are more than 9 events available in this case *******

Reporter's causality (Ozempic 1.0 mg) -
thyroid was very out of balance (Hypothyroidism aggrevated)(Hypothyroidism) : Possible
thyroid was very out of balance (Hypothyroidism aggrevated)(Condition aggravated) : Possible
Gastritis (pain in the upper part of the stomach), bad-tasting belching,feel unwell(Gastritis) : Unknown
Nausea(Nausea) : Unknown
Vomiting(Vomiting) : Unknown
A loss of appetite(Appetite lost) : Unknown

Mfr. Control Number: 1400838

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

gas(Gas) : Unknown
disgusted by food(Food disgust) : Unknown
cramping(Cramps) : Unknown

Company's causality (Ozempic 1.0 mg) -
thyroid was very out of balance (Hypothyroidism aggrevated)(Hypothyroidism) : Unlikely
thyroid was very out of balance (Hypothyroidism aggrevated)(Condition aggravated) : Unlikely
Gastritis (pain in the upper part of the stomach), bad-tasting belching,feel unwell(Gastritis) : Possible
Nausea(Nausea) : Possible
Vomiting(Vomiting) : Possible
A loss of appetite(Appetite lost) : Possible
gas(Gas) : Possible
disgusted by food(Food disgust) : Unlikely
cramping(Cramps) : Unlikely

Reporter Comment: Patient suspended the suspect product as not losing weight and restarted the product on 07-JUN-2025 or 08-JUN-2025

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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #1	18 clicks to get 0.5 mg; Subcutaneous	type 2 diabetes mellitus (Type 2 diabetes mellitus) Obesity (Obesity)	26-MAR-2025 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #2	36 clicks; Subcutaneous	type 2 diabetes mellitus (Type 2 diabetes mellitus) Obesity (Obesity)	21-JUN-2025 / Ongoing; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#1) Novolin R Penfill (INSULIN HUMAN 100 IU/mL) Solution for injection, 100 IU/mL; 2010 / Ongoing

#6) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE) Tablet ; MAY-2025 / Ongoing

#7) VENLAFAXINE (VENLAFAXINE) Tablet ; 2023 / Ongoing

#8) BIOSARTAN (LOSARTAN POTASSIUM) ; 2015 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition	Depression (Depression);
Unknown to Ongoing	Current Condition	Anxiety (Anxiety);
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);