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		64 Years	Female	65.10 kg		APR	2025

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

Diarrhea [Diarrhoea]
Ozempic use for Obesity [Product use in unapproved indication]
ME:Ozempic applied with 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 **(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

15. DAILY DOSE(S)
#1) UNK (36 clicks)

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

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

18. THERAPY DATES(from/to)
#1) APR-2025 / Ongoing

19. THERAPY DURATION
#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) VITAMIN D3 (VITAMIN D3) Tablet ; SEP-2023 / Ongoing
#2) BILIVE [DROSPIRENONE;ESTRADIOL] (DROSPIRENONE, ESTRA
#3) TRIPLE OMEGA 3 6 9 (BORAGO OFFICINALIS OIL, FISH OIL, L

(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 Duration not reported.	Overweight (Overweight)
Unknown to Ongoing	Current Condition	Gastroesophageal reflux (Gastrooesophageal reflux disease)

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.
1443394

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

24c. DATE RECEIVED BY MANUFACTURER
23-MAY-2025

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 65.1 kg.

Patient's BMI: 25.75056370.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Diarrhea(Diarrhea)" beginning on MAY-2025 , "Ozempic use for Obesity(Product use in unapproved indication)" beginning on APR-2025 , "ME:Ozempic applied with clicks(Wrong technique in product usage process)" beginning on APR-2025 and concerned a 64 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "Obesity",

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

Current Condition: Overweight, Reflux, Knee issue (cartilage).

Concomitant medications included - VITAMIN D3, BILIVE [DROSPIRENONE;ESTRADIOL](DROSPIRENONE, ESTRADIOL), TRIPLE OMEGA 3 6 9(BORAGO OFFICINALIS OIL, FISH OIL, LINUM USITATISSIMUM OIL).

Batch Numbers:
Ozempic 1.0 mg: UNK;

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

The outcome for the event "Diarrhea(Diarrhea)" was Recovering/resolving.
The outcome for the event "Ozempic use for Obesity(Product use in unapproved indication)" was Not recovered.
The outcome for the event "ME:Ozempic applied with clicks(Wrong technique in product usage process)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
Diarrhea(Diarrhea) : Possible
Ozempic use for Obesity(Product use in unapproved indication) : Unknown
ME:Ozempic applied with clicks(Wrong technique in product usage process) : Unknown

Company's causality (Ozempic 1.0 mg) -
Diarrhea(Diarrhea) : Possible
Ozempic use for Obesity(Product use in unapproved indication) : Possible
ME:Ozempic applied with clicks(Wrong technique in product usage process) : Possible

References included:
Reference Type: E2B Linked Report
Reference ID#: CR-NOVOPROD-1221267
Reference Notes: Same patient

Reporter Comment: Concomitant drug: Tecta (Pantoprazole) or Zoltum (Pantoprazole), Formulation - Tablet, Indication - Gastric condition, Product Start Date - 2022, Product Ongoing - yes, Dose Frequency- qd, Route of Administration - Oral, Dose Description - 1 tablet (Non specified and non codable).
Concomitant drug: Gelicart (Collagen, proteins, sodium), Indication - Knee issue, Product Start Date - 2022, Product Ongoing - yes, Dose Frequency - qd, Route of Administration - Oral, Dose Description - 1 vial (Non codable).
Concomitant drug: Piascledine (Persea gratissima, glycine max), Formulation - Tablet, Indication - Knee issue, Product Start Date - 2022, Product Ongoing - Yes, Dose Frequency - qd, Route of Administration - Oral, Dose Description - 1 tablet. (Non codable)
-Patient reports that the event is intermittent because diarrhea occurs for 2-3 days and then subsides, but it reappears the following week. A definitive end date is not reported.

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

#2) BILIVE [DROSPIRENONE;ESTRADIOL] (DROSPIRENONE, ESTRADIOL) Capsule ; Ongoing

#3) TRIPLE OMEGA 3 6 9 (BORAGO OFFICINALIS OIL, FISH OIL, LINUM USITATISSIMUM OIL) ; 2021 / Ongoing

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

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