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		36 Years	Female	104.80 kg		MAY	2025

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

occasionally feels like vomiting [Nausea]
ME:Ozempic applied with clicks [Wrong technique in product usage process]
Ozempic use for obesity and insulin resistance (unapproved indication) [Product use in unapproved indication]

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 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg

15. DAILY DOSE(S)
#1) 37 clicks, qw

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

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

18. THERAPY DATES(from/to)
#1) MAY-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) ESOMEPRAZOLE (ESOMEPRAZOLE) ; 2025 / 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	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Gastritis (Gastritis)

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.
1468617

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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: 170 cm.

Patient's weight: 104.8 kg.

Patient's BMI: 36.26297580.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "occasionally feels like vomiting(Nausea)" beginning on JUN-2025 , "ME:Ozempic applied with clicks(Wrong technique in product usage process)" beginning on MAY-2025 , "Ozempic use for obesity and insulin resistance (unapproved indication)(Product use in unapproved indication)" beginning on MAY-2025 and concerned a 36 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from MAY-2025 and ongoing for "Obesity",

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

Current Condition: Obesity, Gastritis, Plantar fasciitis, calcification of the Achilles tendon, mixed dyslipidemia.

Concomitant medications included - ESOMEPRAZOLE.

Batch Numbers:
Ozempic 1.0 mg: UNK;

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

The outcome for the event "occasionally feels like vomiting(Nausea)" was Recovering/resolving.
The outcome for the event "ME:Ozempic applied with clicks(Wrong technique in product usage process)" was Not recovered.
The outcome for the event "Ozempic use for obesity and insulin resistance (unapproved indication)(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -
occasionally feels like vomiting(Nausea) : Possible
ME:Ozempic applied with clicks(Wrong technique in product usage process) : Unknown
Ozempic use for obesity and insulin resistance (unapproved indication)(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -
occasionally feels like vomiting(Nausea) : Possible
ME:Ozempic applied with clicks(Wrong technique in product usage process) : Possible
Ozempic use for obesity and insulin resistance (unapproved indication)(Product use in unapproved indication) : Possible

Reporter Comment: Concomitant drug: Nubelt (Darolutamide): Not codable.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Plantar fasciitis (Plantar fasciitis);
Unknown to Ongoing	Current Condition	Tendon calcification (Tendon calcification);
Unknown to Ongoing	Current Condition	Dyslipidemia (Dyslipidaemia);