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		32 Years	Male	86.10 kg	20	MAY	2025

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

felt very tired [Fatigue]
lacks the energy [Asthenia]
feels dizzy [Dizziness]
headache [Headache]

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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.25 mg, qw

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

17. INDICATION(S) FOR USE
#1) Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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

18. THERAPY DATES(from/to)
#1) 20-MAY-2025 / Unknown

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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
2020 to Ongoing	Current Condition	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.
1463273

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

24c. DATE RECEIVED BY MANUFACTURER
18-JUN-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

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: 177 cm.

Patient's weight: 86.1 kg.

Patient's BMI: 27.48252420.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "felt very tired(Tiredness)" beginning on 20-MAY-2025 , "lacks the energy(Loss of energy)" beginning on 20-MAY-2025 , "feels dizzy(Dizzy)" beginning on 20-MAY-2025 , "headache(Headache)" beginning on 20-MAY-2025 and concerned a 32 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from 20-MAY-2025 and ongoing for "Type 2 diabetes mellitus",

Dosage Regimens:
Ozempic: 20-MAY-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 2 diabetes mellitus.

Batch Numbers:
Ozempic: UNK, UNK;

Action taken to Ozempic was reported as No Change.

The outcome for the event "felt very tired(Tiredness)" was Not recovered.
The outcome for the event "lacks the energy(Loss of energy)" was Not recovered.
The outcome for the event "feels dizzy(Dizzy)" was Not recovered.
The outcome for the event "headache(Headache)" was Not recovered.

Reporter's causality (Ozempic) -
felt very tired(Tiredness) : Unknown
lacks the energy(Loss of energy) : Unknown
feels dizzy(Dizzy) : Unknown
headache(Headache) : Unknown

Company's causality (Ozempic) -
felt very tired(Tiredness) : Possible
lacks the energy(Loss of energy) : Possible
feels dizzy(Dizzy) : Possible
headache(Headache) : Possible

Reporter Comment: The patient has reduced his physical activity by at least half

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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL; Regimen #2	0.5 mg, qw; Subcutaneous	Type 2 diabetes mellitus (Type 2 diabetes mellitus)	Ongoing; Unknown