CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		40 Years	Male	Unk		FEB	2025

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

nausea [Nausea]
Vomiting [Vomiting]
Ozempic prescribed for Type 1 diabetes mellitus.

(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) Ozempic (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL

15. DAILY DOSE(S)
#1) UNK, qw (highest dose)

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

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

18. THERAPY DATES(from/to)
#1) FEB-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)

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

From/To Dates	Type of History / Notes	Description
FEB-2025 to Ongoing	Current Condition	Type 1 diabetes mellitus (Type 1 diabetes mellitus)
Unknown to Ongoing	Current Condition	Overweight (Overweight)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Novo Nordisk A/S
Lise Grimmeshave
Vandtaarnsvej 114
Soeborg, DK-2860 DENMARK
Phone: +45 44448888

24b. MFR CONTROL NO.
1457521

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

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

26. REMARKS
Medically Confirmed: Yes

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 1457521

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Off label use]

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

This non-serious Spontaneous case from COSTA RICA was reported by a Pharmacist as "nausea(Nausea)" beginning on FEB-2025, "Vomiting(Vomiting)" beginning on FEB-2025, "Ozempic prescribed for Type 1 diabetes mellitus.(Off label use in unapproved indication)" beginning on FEB-2025, and concerned a 40 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from FEB-2025 and ongoing for "Type 1 diabetes mellitus",

Dosage Regimens:
Ozempic: ??-FEB-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Type 1 diabetes mellitus, Overweight, snores a lot at night., Sleep apnoea, Uses a machine to avoid sleep apnea, Condition in the nose and trachea.

Batch Numbers:
Ozempic: ASKU

Action taken to Ozempic was reported as No Change.

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 "Ozempic prescribed for Type 1 diabetes mellitus.(Off label use in unapproved indication)" was Not recovered.

Reporter Comment: The patient does not want to eat to avoid the event.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Snoring (Snoring);
Unknown to Ongoing	Current Condition	Sleep apnoea (Sleep apnoea syndrome);
Unknown to Ongoing	Current Condition	Device dependence (Device dependence);
Unknown to Ongoing	Current Condition Causing weak breathing.	Upper respiratory disorder (Respiratory disorder);