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		41 Years	Female	80.00 kg	23	APR	2023

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

Nausea [Nausea]
Ozempic use for Weight loss [Product use in unapproved indication]
0.25 mg from Ozempic 1 mg pen [Wrong technique in product usage process]

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

This non-serious Spontaneous case from COSTA RICA was reported by a Physician as "Nausea(Nausea)" with an unspecified onset date, "Ozempic use for Weight loss(Product use in unapproved indication)" beginning on 23-APR-2023, "0.25 mg from Ozempic 1 mg pen(Wrong technique in product usage

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

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.25 mg from 1 mg pen

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

17. INDICATION(S) FOR USE
#1) Weight loss (Weight control)

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

18. THERAPY DATES(from/to)
#1) 23-APR-2023 / JUL-2023

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)
#1) SERTRALINE (SERTRALINE) ; Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

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: Yes

24b. MFR CONTROL NO.
1415641

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1415641

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

process)" beginning on 23-APR-2023, and concerned a 41 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 23-APR-2023 to 12-JAN-2025 for "Weight loss",

Patient's weight: 80 kg

Dosage Regimens:
Ozempic 1.0 mg: 23-APR-2023 to ??-JUL-2023, Not Reported to Not Reported, Not Reported to 12-JAN-2025;

Medical history was not provided.

Concomitant products included - SERTRALINE

Treatment included - FAMOTIDINE

Batch Numbers:
Ozempic 1.0 mg: ASKU, ASKU, ASKU

Action taken to Ozempic 1.0 mg was reported as Product discontinued due to AE.

The outcome for the event "Nausea(Nausea)" was Not Reported.
On 12-JAN-2025 the outcome for the event "Ozempic use for Weight loss(Product use in unapproved indication)" was Recovered.
On JUL-2023 the outcome for the event "0.25 mg from Ozempic 1 mg pen(Wrong technique in product usage process)" was Recovered.

Reporter Comment: The doctor changes the treatment from Ozempic to Saxenda.

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) Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #2	0.5 mg; Unknown	Weight loss (Weight control)	Unknown; Unknown
#1) Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #3	1 mg; Unknown	Weight loss (Weight control)	Unknown / 12-JAN-2025; Unknown