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		45 Years	Female	Unk	25	MAY	2025

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

Constipation [Constipation]
ME:Ozempic applied with clicks [Wrong technique in product usage process]
Ozempic use for obesity (unapproved indication) [Product use in unapproved indication]

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

This non-serious Spontaneous case from COSTA RICA was reported by a Consumer as "Constipation(Constipation)" beginning on 25-JUN-2025, "ME:Ozempic applied with clicks(Wrong technique in product usage process)"

(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 {Lot # PP5L760; Exp.Dt. JAN-2027}
(Continued on Additional Information Page)

15. DAILY DOSE(S)
#1) 18 clicks, qw

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

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

18. THERAPY DATES(from/to)
#1) 25-MAY-2025 / Unknown

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
Unknown to Ongoing	Current Condition duration not reported	Obesity (Obesity)

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.
1470757

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1470757

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

beginning on 25-MAY-2025, "Ozempic use for obesity (unapproved indication)(Product use in unapproved indication)" beginning on 25-MAY-2025, and concerned a 45 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 25-MAY-2025 and ongoing for "obesity",

Dosage Regimens:
Ozempic 1.0 mg: 25-MAY-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity.

Batch Numbers:
Ozempic 1.0 mg: PP5L760, PP5L760

Action taken to Ozempic 1.0 mg was reported as Dose Increased.

The outcome for the event "Constipation(Constipation)" was Not recovered.
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 (unapproved indication)(Product use in unapproved indication)" was Not recovered.

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 {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #2	26 clicks qw(dose increased); Subcutaneous	obesity (Obesity)	Ongoing; Unknown