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		57 Years	Male	120.00 kg		Unk	

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

constipation [Constipation]
Ozempic prescribed for weight loss [Off label use]

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

This non-serious Spontaneous case from COSTA RICA was reported by a Consumer as "constipation(Constipation)" with an unspecified onset date, "Ozempic prescribed for weight loss(Off label use in unapproved indication)" with an unspecified onset date, and concerned a 57 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from unknown

(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

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

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

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

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) VASSLUTEN H (HYDROCHLOROTHIAZIDE, IRBESARTAN) ; 2023 / Ongoing
#2) JARDIANZ DUO (EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE) ; Ongoing
#3) EUTIROX (LEVOTHYROXINE SODIUM) ; 2017 / 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 Approximately 20 years ago	Blood pressure high (Hypertension)
Unknown to Ongoing	Current Condition for approximately 8 to 10 years	Thyroid disorder (Thyroid disorder)

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.
1446404

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

24c. DATE RECEIVED BY MANUFACTURER
03-JUL-2025

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1446404

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

start date to 2025 for "for weight loss",

Patient's height: 171 cm

Patient's weight: 120 kg

Patient's BMI: 41.03826820.

Dosage Regimens:
Ozempic: Not Reported to ??-???-2025;

Current Condition: High blood pressure, thyroid disorder.

Concomitant products included - VASSLUTEN H(HYDROCHLOROTHIAZIDE, IRBESARTAN), JARDIANZ DUO(EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE), EUTIROX(LEVOTHYROXINE SODIUM)

Batch Numbers:
Ozempic: ASKU

Action taken to Ozempic was reported as Product discontinued.

The outcome for the event "constipation(Constipation)" was Not Reported.
On 2025 the outcome for the event "Ozempic prescribed for weight loss(Off label use in unapproved indication)" was Recovered.

References included:
Reference Type: E2B Linked Report
Reference ID#: CR-NOVOPROD-1416625
Reference Notes: same patient

On 03-JUL-2025, the case has re-classified from Non-expedited to Expedited due to the addition of the adverse event Constipation

Reporter Comment: the doctor switched him to Saxenda
The patient switched to Trulicity (dulaglutide) approximately a month ago.