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		42 Years	Female	86.50 kg	30	MAR	2025

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

Other Serious Criteria: Medically Significant
colon inflammation [Colitis]
constipation [Constipation]
Saxenda dosage: 1.8 mg + 3 clicks [Wrong technique in product usage process]

Case Description: Study ID: 828652-My Healthy Journey

Study description: Trial title: This is a 40 weeks digital patient support program with focus on exercise, motivation, nutrition & maintaining

(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) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5M440; Exp.Dt. AUG-2026}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.8 mg + 3 clicks, qd	#1) Subcutaneous

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 30-MAR-2025 / JUN-2025	#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
Unknown to Ongoing	Current Condition	Polycystic ovary (Polycystic ovaries)
Unknown to Ongoing	Current Condition	Metabolic syndrome (Metabolic syndrome)

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.
1455508

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

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

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

DATE OF THIS REPORT
18-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 156 cm.
Patient's weight: 86.5 kg.
Patient's BMI: 35.544050.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "colon inflammation(Colon inflammation)" beginning on 20-APR-2025 , "constipation(Constipation)" beginning on 20-APR-2025 , "Saxenda dosage: 1.8 mg + 3 clicks(Wrong technique in product usage process)" beginning on 30-MAR-2025 and concerned a 42 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 2025 for "weight loss",

Dosage Regimens:
Saxenda: 30-MAR-2025 to ??-JUN-2025;

Current Condition: Polycystic Ovary Syndrome, Metabolic syndrome, Insulin resistance, high blood pressure.

Treatment medication included Alivium Duo (NON-CODABLE), ginger with turmeric (Unspecified, NON-CODABLE), anti-inflammatory (Unspecified, NON-CODABLE), Hydroxal (NON-CODABLE).

On 30-MAR-2025 patient administered Saxenda 1.8 mg + 3 clicks.

On 20-APR-2025 the patient experienced constipation accompanied by colon inflammation.

The patient initially believed that it was due to certain foods she had eaten, but on 09-JUN-2025, she visited her doctor, who advised her to discontinue the medication, as it appeared to be a poor assimilation to the medication. The doctor prescribed a switch to Ozempic Dual Dose. The patient had not yet stopped taking Saxenda, as she has about two weeks remaining to complete it.

The Batch Numbers for Saxenda was PP5M440.

Action taken to Saxenda was reported as Product discontinued due to AE.

The outcome for the event "colon inflammation(Colon inflammation)" was Recovering/resolving.
The outcome for the event "constipation(Constipation)" was Recovering/resolving.
On JUN-2025 the outcome for the event "Saxenda dosage: 1.8 mg + 3 clicks(Wrong technique in product usage process)" was Recovered.

Reporter's causality (Saxenda) -
colon inflammation(Colon inflammation) : Possible
constipation(Constipation) : Possible
Saxenda dosage: 1.8 mg + 3 clicks(Wrong technique in product usage process) : Unknown

Company's causality (Saxenda) -
colon inflammation(Colon inflammation) : Unlikely
constipation(Constipation) : Possible
Saxenda dosage: 1.8 mg + 3 clicks(Wrong technique in product usage process) : Possible

No consent for safety follow-up questions, hence no further follow-up is possible.

Since last submission case has been updated with the following information(Not yet submitted):
-suspect product start date, stop date and action taken updated
-event 'Saxenda dosage: 1.8 mg + 3 clicks' start date, stop date and outcome updated
-dechallenge and rechallenge updated
-Narrative updated accordingly.

Company comment:
Colitis is assessed as unlisted event and constipation is assessed as listed event according to NovoNodisk current reference safety information on Saxenda.
Considering the nature of the event, safety profile and pharmacological properties of the suspect, colitis is assessed as unlikely related to the suspect. However, information on final diagnosis, relevant clinical and investigation results, concomitant medications, details of treatment received are unavailable for thorough medical assessment.
This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance);
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);