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		43 Years	Female	88.40 kg		APR	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
colitis [Colitis]

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 strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 159 cm.

(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 # PP5L468; Exp.Dt. JUN-2026}

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.6 mg, qd

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

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

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

18. THERAPY DATES(from/to)
#1) 15-MAR-2025 / Unknown

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) FAMOTIDINE (FAMOTIDINE) ; 2023 / 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	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Hyperacidity (Hyperchlorhydria)

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
World Wide #: CR-NOVOPROD-1432756

24b. MFR CONTROL NO.
1432756

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

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's weight: 88.4 kg.

Patient's BMI: 34.96697120.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "colitis(Colitis)" beginning on APR-2025 and concerned a 43 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 15-MAR-2025 and ongoing for "obesity",

Dosage Regimens:
Saxenda: 15-MAR-2025 to Not Reported, 22-MAR-2025 to Not Reported, 29-MAR-2025 to Not Reported, 05-APR-2025 to Not Reported, 12-APR-2025 to ??-APR-2025, ??-APR-2025 to Not Reported, ??-???-2025 to Not Reported, ??-???-2025 to Not Reported, ??-???-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Acidity.

Concomitant medications included - FAMOTIDINE.

On an unspecified date in APR-2025, the patient experienced severe diarrhea, stomach ache and colitis. It was the third box; she increased the dose to 3 mg but experienced very intense colitis-like pain and severe diarrhea. She lowered it to 2.4 mg, went to the doctor, and was advised to reduce it to 1.8 mg, and she has felt improvement. She tried to return to the 2.4 mg dose, but the stomach ache returned, used the 2.4 mg for three days. Then she went back to 1.8 mg because of stomach hurts too much. With 1.8 mg, she don’t have stomach pain. The patient comments that they feel unwell from the stomachache with the doses of 2.4 mg and 3.0 mg.

The patient indicates: 'she had been told not to consume fat, and was given a corresponding diet.'

Batch Numbers:
Saxenda: PP5L468, PP5L468, PP5L468, PP5L468, PP5L468, PP5L468, PP5L468, PP5L468, PP5L468;

Action taken to Saxenda was reported as Dose Decreased.

On 17-MAY-2025 the outcome for the event "colitis(Colitis)" was Recovered.

Reporter's causality (Saxenda) -
  colitis(Colitis) : Unknown

Company's causality (Saxenda) -
  colitis(Colitis) : Unlikely

Since last submission, the case was updated with the following:
Medical history acidity added
Dosage regimen added
Concomitant Famotidine added
Narrative generated accordingly

Company comment:
Colitis is assessed as unlisted event according to the Novo Nordisk current Company Core Data Sheet information on Saxenda.
Colitis is defined as inflammation of the colon which is part of the large intestine and it can be temporary or chronic. This inflammation can cause a variety of symptoms, including abdominal pain, diarrhoea, and bloody stools.
The concomitant use of Famotidine is an important confounding factor, given its potential to induce colitis.
Although the temporal relationship appears plausible and dechallenge is positive, limited information on complete medical history, relevant laboratory investigation reports and treatment received precludes thorough medical assessment of the case.
With the available information and considering the nature of the event and known safety profile of suspect, the causality for the event colitis is assessed as unlikely related to the suspect product.
This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1432756
Reference Notes:

Mfr. Control Number: 1432756

ADDITIONAL INFORMATION

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) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #2	1.2 mg, qd; Subcutaneous	obesity (Obesity)	22-MAR-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #3	1.8 mg, qd; Subcutaneous	obesity (Obesity)	29-MAR-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #4	2.4 mg, qd; Subcutaneous	obesity (Obesity)	05-APR-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #5	3 mg, qd (remained for 2 weeks); Subcutaneous	obesity (Obesity)	12-APR-2025 / APR-2025; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #6	2.4 mg, qd(dose decreased); Subcutaneous	obesity (Obesity)	APR-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #7	1.8 mg, qd(dose decreased further); Subcutaneous	obesity (Obesity)	2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #8	2.4 mg, qd (for 3 days); Subcutaneous	obesity (Obesity)	2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #9	1.8 mg, qd; Subcutaneous	obesity (Obesity)	2025 / Ongoing; Unknown