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		66 Years	Female	80.00 kg		AUG	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
severe 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: 152 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

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 2.4 mg, qd	#1) Subcutaneous

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

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) APR-2025 / Unknown	#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 Duration not reported	Hepatic steatosis (Hepatic steatosis)

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.
1503525

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

24c. DATE RECEIVED BY MANUFACTURER
18-AUG-2025

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

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1503525

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's weight: 80 kg.

Patient's BMI: 34.62603880.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "severe colitis(Colitis)" beginning on AUG-2025 and concerned a 66 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from APR-2025 and ongoing for "control weight", "hepatic steatosis",

Dosage Regimens:
Saxenda: ??-APR-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Hepatic steatosis.

Treatment medications included - PROBIOTICS NOS, NORMALIP [CLOFIBRATE;INOSITOL NICOTINATE](CLOFIBRATE, INOSITOL NICOTINATE).

On an unspecified date in AUG-2025 , The patient reports experiencing a severe colitis two weeks ago, accompanied by significant constipation. She was using 2.4 mg of medication, but the doctor reduced the dose to 1.8 mg until September, when she will be re-evaluated. The doctor prescribed probiotics, which she started taking a week ago, and she has been taking Normalips. She was also given intravenous fluids due to vomiting and abdominal pain on the left side.

Batch Numbers:
Saxenda: not available

Action taken to Saxenda was reported as Dose Decreased.

On AUG-2025 the outcome for the event "severe colitis(Colitis)" was Recovered.

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

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

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

Company comment:
'Colitis' is assessed as unlisted according to Novo Nordisk current CCDS on Saxenda.
The information regarding other concomitant medications, detailed clinical course, complete medical history (including history of similar episodes, autoimmune conditions, food allergies, etc.), relevant investigations such as imaging, C-reactive protein, fecal routine test, fecal calprotectin, etc., and final diagnosis is not available. Considering the available information, causality 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.

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; Regimen #1	2.4 mg, qd; Subcutaneous	control weight (Weight control) hepatic steatosis (Hepatic steatosis)	APR-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	1.8 mg, qd(dose decreased); Subcutaneous	control weight (Weight control) hepatic steatosis (Hepatic steatosis)	Ongoing; Unknown