CIOMS FORM

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		31 Years	Female	77.10 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
colitis [Colitis]
sense of stomach inflammation [Gastritis]

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).

(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)
#1) unk

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) 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) METFORMIN (METFORMIN) ; 2024 / Ongoing
#2) MIA (DROSPIRENONE, ETHINYLESTRADIOL) ; 2024 / Ongoing
#3) FLUOXETINE (FLUOXETINE) ; 2022 / Ongoing
#4) SPIRONOLACTONE (SPIRONOLACTONE) ; 2021 / 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 duration not reported	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Prediabetes (Glucose tolerance impaired)

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.
1505058

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

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

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1505058

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 160 cm.

Patient's weight: 77.1 kg.

Patient's BMI: 30.11718750.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "colitis(Colitis)" beginning on AUG-2025 , "sense of stomach inflammation(Stomach inflammation)" beginning on AUG-2025 and concerned a 31 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from AUG-2024 and ongoing for "Obesity",

Dosage Regimens:
Saxenda: Not Reported to Not Reported, ??-AUG-2024 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity(duration not reported), prediabetes, Acne, Anxiety, insulin resistance.

Concomitant medications included - METFORMIN, MIA(DROSPIRENONE, ETHINYLESTRADIOL), FLUOXETINE, SPIRONOLACTONE.

Treatment medications included - BUSCAPINA [CAFFEINE;MEPYRAMINE MALEATE;PARACETAMOL](CAFFEINE, MEPYRAMINE MALEATE, PARACETAMOL).

On an unknown date in AUG-2025, patient experienced colitis and felt sense of stomach inflammation, similar to the sensations preceding her menstrual period.

The patient received Buscapina as treatment for the event.

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "colitis(Colitis)" was Recovering/resolving.
The outcome for the event "sense of stomach inflammation(Stomach inflammation)" was Recovering/resolving.

Reporter's causality (Saxenda) -
colitis(Colitis) : Possible
sense of stomach inflammation(Stomach inflammation) : Possible

Company's causality (Saxenda) -
colitis(Colitis) : Unlikely
sense of stomach inflammation(Stomach inflammation) : Possible

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

Company comment:
'Colitis' is assessed as unlisted; ‘Gastritis’ is assessed as listed according to Novo Nordisk current CCDS on Saxenda.
The information regarding detailed clinical course, complete medical history (including history of similar episodes, gastrointestinal disorder, 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 #2	1.8 mg, qd; Subcutaneous	Obesity (Obesity)	AUG-2024 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Acne (Acne);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Anxiety (Anxiety);
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance);