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		42 Years	Female	81.60 kg		MAR	2025

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

Constipation [Constipation]
Vomiting [Vomiting]
Nausea [Nausea]
Fullness [Abdominal distension]
pain when defecating or passing gas [Gastrointestinal pain]
internal pain in the intestine that radiates down to the rib [Pain]

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

Study ID: 828652-My Healthy Journey

(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}

(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) Unknown

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)

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	Rheumatoid arthritis (Rheumatoid arthritis)

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.
1413224

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

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

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

DATE OF THIS REPORT
29-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 168 cm.

Patient's weight: 81.6 kg.

Patient's BMI: 28.91156460.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Constipation(Constipation)" beginning on MAR-2025 , "Vomiting(Vomiting)" beginning on MAR-2025 , "Nausea(Nausea)" beginning on MAR-2025 , "Fullness(Abdominal fullness)" beginning on MAR-2025 , "pain when defecating or passing gas(Gastrointestinal pain)" beginning on JUN-2025 , "internal pain in the intestine that radiates down to the rib(Radiating pain)" beginning on JUN-2025 and concerned a 42 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date and ongoing for "Obesity",

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

Current Condition: Obesity, Rheumatoid arthritis, Fatty liver.

Treatment medications included - OMEPRAZOLE.

Batch Numbers:
Saxenda: PP5M440, PP5M440, ASKU;

Action taken to Saxenda was reported as No Change.

The outcome for the event "Constipation(Constipation)" was Not recovered.
The outcome for the event "Vomiting(Vomiting)" was Not recovered.
The outcome for the event "Nausea(Nausea)" was Not recovered.
The outcome for the event "Fullness(Abdominal fullness)" was Not recovered.
The outcome for the event "pain when defecating or passing gas(Gastrointestinal pain)" was Not recovered.
The outcome for the event "internal pain in the intestine that radiates down to the rib(Radiating pain)" was Not recovered.

Reporter's causality (Saxenda) -
Constipation(Constipation) : Unknown
Vomiting(Vomiting) : Unknown
Nausea(Nausea) : Unknown
Fullness(Abdominal fullness) : Unknown
pain when defecating or passing gas(Gastrointestinal pain) : Unknown
internal pain in the intestine that radiates down to the rib(Radiating pain) : Unknown

Company's causality (Saxenda) -
Constipation(Constipation) : Possible
Vomiting(Vomiting) : Possible
Nausea(Nausea) : Possible
Fullness(Abdominal fullness) : Possible
pain when defecating or passing gas(Gastrointestinal pain) : Unlikely
internal pain in the intestine that radiates down to the rib(Radiating pain) : Unlikely

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 # PP5M440; Exp.Dt. AUG-2026}; Regimen #2	2.40 mg, qd; Subcutaneous	Obesity (Obesity)	MAR-2025 / Unknown; Unknown

Mfr. Control Number: 1413224

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; Regimen #3	3 mg, qd; Subcutaneous	Obesity (Obesity)	JUN-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Fatty liver (Hepatic steatosis);