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		50 Years	Female	97.00 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 constipation [Constipation]
experiencing severe and frequent nausea [Nausea]
felt unwell [Malaise]

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) Unknown

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

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

18. THERAPY DATES(from/to)
#1) MAY-2024 / 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) LEVOTHYROXINE (LEVOTHYROXINE) ; Ongoing
#2) ACEPRESS [IRBESARTAN] (IRBESARTAN) ; Ongoing
#3) FAPRIS (DESVENLAFAXINE SUCCINATE) ; Ongoing
#4) ANSIOLIT (ALPRAZOLAM) ; Ongoing
#5) TESTOSTERONE (TESTOSTERONE) ; Ongoing
#6) MONTELUKAST (MONTELUKAST) ; Ongoing

(Continued on Additional Information Page)

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)
2022 to Unknown	Procedure	Bariatric surgery (Metabolic surgery)
	three years ago	

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.
1513105

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

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

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

DATE OF THIS REPORT
08-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 162 cm.

Patient's weight: 97 kg.

Patient's BMI: 36.96082910.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "severe constipation(Constipation)" beginning on AUG-2025 , "felt unwell(Feeling unwell)" beginning on AUG-2025 , "experiencing severe and frequent nausea(Nausea)" beginning on AUG-2025 and concerned a 50 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2024 for "obesity",

Dosage Regimens:
Saxenda: ??-MAY-2024 to Not Reported, Not Reported to Not Reported, Not Reported to Not Reported;

Current Condition: Obesity, high blood pressure, Depression, Hypothyroidism, Asthma, anemia, Low testosterone levels
Procedure: bariatric surgery.

Concomitant medications included - LEVOTHYROXINE, ACEPRESS IRBESARTAN, FAPRIS(DESVENLAFAXINE SUCCINATE), ANSIOLIT(ALPRAZOLAM), TESTOSTERONE, MONTELUKAST, LORATADINE, Multivitamins (non-codable)

On an unspecified date in AUG-2025, the patient experienced severe constipation, feeling as if it were a life-threatening situation, referring to it as intense and serious, and described a sensation of paralysis of intestine or something similar. The patient also felt unwell, experienced severe and frequent nausea and was unable to go to work.

Batch Numbers:
Saxenda: was not reported.

Action taken to Saxenda was reported as Dose Decreased.

The outcome for the event "severe constipation(Constipation)" was Recovering/resolving.
On AUG-2025 the outcome for the event "felt unwell(Feeling unwell)" was Recovered.
On AUG-2025 the outcome for the event "experiencing severe and frequent nausea(Nausea)" was Recovered.

Reporter's causality (Saxenda) -
severe constipation(Constipation) : Possible
felt unwell(Feeling unwell) : Possible
experiencing severe and frequent nausea(Nausea) : Possible

Company's causality (Saxenda) -
severe constipation(Constipation) : Possible
felt unwell(Feeling unwell) : Possible
experiencing severe and frequent nausea(Nausea) : Possible

No further information available.

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	2 mg, qd; Subcutaneous	obesity (Obesity)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	0.6 UNK, qd (dose decreased); Subcutaneous	obesity (Obesity)	Unknown; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#7) LORATADINE (LORATADINE) ; Ongoing

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);
Unknown to Ongoing	Current Condition	Depression (Depression);
Unknown to Ongoing	Current Condition	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition	Asthma (Asthma);
Unknown to Ongoing	Current Condition	Anemia (Anaemia);
Unknown to Ongoing	Current Condition	Blood testosterone decreased (Blood testosterone decreased);