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		44 Years	Female	52.00 kg		Unk	

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

Stomach discomfort, a lot dizziness, and severe nausea, an endoscopy with result was "gastritis." [Gastritis]
The patient sometimes wakes up feeling nauseous [Nausea]

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

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

(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) 1.2 mg, qd

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

17. INDICATION(S) FOR USE
#1) Lose weight (Weight control)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) MAR-2025 / 16-MAY-2025

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) BERIOLI (ORLISTAT) ; MAR-2025 / MAY-2025

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 was not reported.	Gastric disorder (Gastrointestinal disorder)
Unknown to Ongoing	Current Condition	Anxiety (Anxiety)

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.
1477509

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

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1477509

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's weight: 52 kg.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Stomach discomfort, a lot dizziness, and severe nausea, an endoscopy with result was "gastritis."(Gastritis)" with an unspecified onset date , "The patient sometimes wakes up feeling nauseous(Nauseous)" with an unspecified onset date and concerned a 44 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAR-2025 to 16-MAY-2025 for "Lose weight", "Control satiety", "Anxiety related to eating",

Dosage Regimens:
Saxenda: ??-MAR-2025 to 16-MAY-2025;

Current Condition: Stomach problems normally, Anxiety related to eating, Obesity, control satiety.

Concomitant medications included - BERIOLI(ORLISTAT).

Lab Data included:
Lab Data Test as Reported: Endoscopy
Test Name: Endoscopy
Comments: On an unknown date, the patient underwent an endoscopy and the result was "gastritis."

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as Product discontinued due to AE.

On MAY-2025 the outcome for the event "Stomach discomfort, a lot dizziness, and severe nausea, an endoscopy with result was "gastritis."(Gastritis)" was Recovered.
The outcome for the event "The patient sometimes wakes up feeling nauseous(Nauseous)" was Not Reported.

Reporter's causality (Saxenda) -
Stomach discomfort, a lot dizziness, and severe nausea, an endoscopy with result was "gastritis."(Gastritis) : Unlikely
The patient sometimes wakes up feeling nauseous(Nauseous) : Unlikely

Company's causality (Saxenda) -
Stomach discomfort, a lot dizziness, and severe nausea, an endoscopy with result was "gastritis."(Gastritis) : Possible
The patient sometimes wakes up feeling nauseous(Nauseous) : Possible

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Endoscopy On an unknown date, the patient underwent an endoscopy and the result was "gastritis."		

13. Relevant Tests

On an unknown date,the patient underwent an endoscopy and the result was "gastritis."

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	1.2 mg, qd; Subcutaneous	Lose weight (Weight control) Control satiety (Early satiety) Anxiety related to eating	MAR-2025 / 16-MAY-2025; Unknown

Mfr. Control Number: 1477509

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
		(Anxiety)	

23. OTHER RELEVANT HISTORY continued

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