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		67 Years	Female	Unk	26	JUN	2025

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

Reflux [Gastrooesophageal reflux disease]
vomiting [Vomiting]

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 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 {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) 3 mg, qd (approximately 2 years)

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)

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	Gastritis (Gastritis)

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.
1471435

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

24c. DATE RECEIVED BY MANUFACTURER
27-JUN-2025

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1471435

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Reflux(Gastroesophageal reflux)" beginning on 26-JUN-2025 , "vomiting(Vomiting)" beginning on 26-JUN-2025 and concerned a 67 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, 26-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, gastritis.

Batch Numbers:
Saxenda: PP5M440, PP5M440;

Action taken to Saxenda was reported as No Change.

The outcome for the event "Reflux(Gastroesophageal reflux)" was Not recovered.
The outcome for the event "vomiting(Vomiting)" was Not recovered.

Reporter's causality (Saxenda) -
Reflux(Gastroesophageal reflux) : Possible
vomiting(Vomiting) : Possible

Company's causality (Saxenda) -
Reflux(Gastroesophageal reflux) : Possible
vomiting(Vomiting) : Possible

Reporter Comment: -Treatment Received for Reflux and vomiting: Nexium (Esomeprazole) (Non codable)

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	3 mg, qd (Resumed dose); Subcutaneous	Obesity (Obesity)	26-JUN-2025 / Ongoing; Unknown