SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		46 Years	Female	68.00 kg	21	MAY	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
Erosive gastritis [Gastritis erosive]
Gained weight [Weight increased]

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 {Lot # PP5M440; Exp.Dt. AUG-2026}

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 0.60 mg, qd

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

17. INDICATION(S) FOR USE
#1) Weight loss (Weight control)

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

18. THERAPY DATES(from/to)
#1) 18-MAY-2025 / 23-MAY-2025

19. THERAPY DURATION
#1) 5 days

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	Procedure Duration not reported	Gallbladder removal (Cholecystectomy)

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
World Wide #: CR-NOVOPROD-1454139

24b. MFR CONTROL NO.
1454139

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

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

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

DATE OF THIS REPORT
24-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 163 cm.

Patient's weight: 68 kg.

Patient's BMI: 25.59373710.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "Erosive gastritis(Gastritis erosive)" beginning on 21-MAY-2025 , "Gained weight(Weight gain)" beginning on 21-MAY-2025 and concerned a 46 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 18-MAY-2025 to 23-MAY-2025 for "Weight loss",

Dosage Regimens:
Saxenda: 18-MAY-2025 to 23-MAY-2025;

Procedure: no longer has a gallbladder.

Treatment medications included - RILATEN(ROCIVERINE), NEXIUM ESOMEPRAZOLE SODIUM, NEWDISPET(LEVOSULPIRIDE), LISALGIL(METAMIZOLE MAGNESIUM), SERTAL COMPUESTO FORTE(CLONIXIN LYSINATE, PARGEVERINE HYDROCHLORIDE).

Patient had the first session with the nutritionist who told patient to start as she indicated, but patient felt fine on the first day, and by the third day body was different.
Patient used a syringe for 5 days and have no underlying conditions.

On 21-MAY-2025, Patient began to vomit day and night, diarrhea, constant burping; nothing would go away and was burping like rotting.
On 21-MAY-2025, Patient experienced erosive gastritis and patient felt like was going to die and stomach swelled so much, and patient also gained Weight (Weight)(values and units not reported).
The patient indicates: 'The day after I started taking it, I began to have pain, but by the fourth day, I started having pain in my stomach that was unmanageable, with terrible pain and my stomach being extremely bloated,' and they are still experiencing the pain.

It was also reported that the patient no longer have a gallbladder. They didn't explain to the patient that they couldn't take it. The strange thing is that it is available over the counter, and they don't explain anything at all before buying it.'

Patient went to observation as symptoms wouldn’t go away.
Patient took Rilaten and Lisalgil intravenously along with Sertal compuesto for pain. Patient took Nexium for gastritis and Newdispet for burping.

Batch Numbers:
Saxenda: PP5M440;

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

The outcome for the event "Erosive gastritis(Gastritis erosive)" was Not recovered.
The outcome for the event "Gained weight(Weight gain)" was Recovering/resolving.

Reporter's causality (Saxenda) -
Erosive gastritis(Gastritis erosive) : Possible
Gained weight(Weight gain) : Possible

Company's causality (Saxenda) -
Erosive gastritis(Gastritis erosive) : Possible
Gained weight(Weight gain) : Unlikely

Since last submission case has been updated with the following information:
-medical history updated
-outcome of the event 'Erosive gastritis' updated
-Narrative updated accordingly

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1454139
Reference Notes:

Mfr. Control Number: 1454139

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	21-MAY-2025	Weight		
		Gained(Values and units not reported)		

13. Relevant Tests

On an unknown date, Patient gained weight (Values and units not reported)