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		Unk	Female	Unk	13	JUL	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
The patient ate something spoiled and became intoxicated [Food poisoning]
The patient ate something spoiled, which caused stomach discomfort [Abdominal discomfort]

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

15. DAILY DOSE(S)
#1) 1.8 mg, qd

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

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

18. THERAPY DATES(from/to)
#1) JUN-2025 / Ongoing

19. THERAPY DURATION
#1) Unknown

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

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

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

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.
1506482

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

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

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

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height, weight and body mass index (BMI) were not reported.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "The patient ate something spoiled and became intoxicated(Food poisoning)" beginning on 13-JUL-2025 , "The patient ate something spoiled, which caused stomach discomfort(Stomach discomfort)" beginning on 13-JUL-2025 and concerned a Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JUN-2025 and ongoing for "Weight loss",

Dosage Regimen of Saxenda: ??-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Medical history was not provided.

Treatment medications included - GRAVOL(DIMENHYDRINATE), BISMUTH SUBSALICYLATE., Nexium (esomeprazole)-(non-codable)

On 13-JUL-2025, The patient reports that the patient ate something spoiled, which caused stomach discomfort, and mentions that the patient became intoxicated (no further information provided).

The patient also indicates that the doctor agreed with the patient to remain on the dose of 1.8 mg and is currently at that dose, but does not specify how long they have been on that dose.

Batch Number of Saxenda has requested

Action taken to Saxenda was reported as No Change.

On 17-JUL-2025 the outcome for the event "The patient ate something spoiled and became intoxicated(Food poisoning)" was Recovered.
On 17-JUL-2025 the outcome for the event "The patient ate something spoiled, which caused stomach discomfort(Stomach discomfort)" was Recovered.

Reporter's causality (Saxenda) -
The patient ate something spoiled and became intoxicated(Food poisoning) : Unlikely
The patient ate something spoiled, which caused stomach discomfort(Stomach discomfort) : Unlikely

Company's causality (Saxenda) -
The patient ate something spoiled and became intoxicated(Food poisoning) : Unlikely
The patient ate something spoiled, which caused stomach discomfort(Stomach discomfort) : Possible

Company comment;

Food poisoning is assessed as an unlisted event; abdominal discomfort is assessed as listed event according to the Novo Nordisk company core data sheet (CCDS) for the Saxenda

A plausible explanation is that the food eaten was contaminated with pathogenic organisms that may have manifested as gastrointestinal discomfort.

Based on available information, the casual relationships between suspect product and adverse events are considered unlikely and related to other aetiologies.

This single case report is not considered to change the current knowledge of the safety profile of the product.