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		55 Years	Female	Unk	03	JUN	2025

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

vomiting [Vomiting]
stomach pain [Abdominal pain upper]
diarrhea [Diarrhoea]
belching with a sulfurous taste [Eructation]
reflux [Gastrooesophageal reflux disease]

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

Study ID: 828652-My Healthy Journey

(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)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#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 to Ongoing	Current Condition Duration not reported	Obesity (Obesity)

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.
1454963

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

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

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

DATE OF THIS REPORT
25-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1454963

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "vomiting(Vomiting)" beginning on 03-JUN-2025 , "stomach pain(Stomach pain)" beginning on 03-JUN-2025 , "diarrhea(Diarrhea)" beginning on 03-JUN-2025 , "belching with a sulfurous taste(Malodorous burping)" beginning on 03-JUN-2025 , "reflux(Gastroesophageal reflux)" beginning on 03-JUN-2025 and concerned a 55 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, 03-JUN-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity.

Treatment medications included - GRAVOL(DIMENHYDRINATE).

Batch Numbers:
Saxenda: ASKU, ASKU, ASKU;

Action taken to Saxenda was reported as Dose Decreased.

The outcome for the event "vomiting(Vomiting)" was Not recovered.
The outcome for the event "stomach pain(Stomach pain)" was Not recovered.
The outcome for the event "diarrhea(Diarrhea)" was Not recovered.
The outcome for the event "belching with a sulfurous taste(Malodorous burping)" was Not recovered.
The outcome for the event "reflux(Gastroesophageal reflux)" was Not recovered.

Reporter's causality (Saxenda) -
vomiting(Vomiting) : Unknown
stomach pain(Stomach pain) : Unknown
diarrhea(Diarrhea) : Unknown
belching with a sulfurous taste(Malodorous burping) : Unknown
reflux(Gastroesophageal reflux) : Unknown

Company's causality (Saxenda) -
vomiting(Vomiting) : Possible
stomach pain(Stomach pain) : Possible
diarrhea(Diarrhea) : Possible
belching with a sulfurous taste(Malodorous burping) : Possible
reflux(Gastroesophageal reflux) : Possible

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	1.2 mg, qd at night (resumed); Subcutaneous	Obesity (Obesity)	03-JUN-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	0.6 mg (dose decreased); Subcutaneous	Obesity (Obesity)	Ongoing; Unknown