CIOMS FORM

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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		23 Years	Female	76.20 kg	22	MAY	2025	☐ PATIENT DIED

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

Diarrhea [Diarrhoea]
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)

☐ 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

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

15. DAILY DOSE(S)
#1) 1.20 mg, qd

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

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

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

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

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

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.
1443348

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

24c. DATE RECEIVED BY MANUFACTURER
23-MAY-2025

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 155 cm.

Patient's weight: 76.2 kg.

Patient's BMI: 31.71696150.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Diarrhea(Diarrhea)" beginning on 22-MAY-2025 , "Vomiting(Vomiting)" beginning on 22-MAY-2025 and concerned a 23 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2025 and ongoing for "For weight loss",

Dosage Regimens:
Saxenda: ??-MAY-2025 to Not Reported (Dosage Regimen Ongoing);

Medical history was not provided.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was Not reported.

On 23-MAY-2025 the outcome for the event "Diarrhea(Diarrhea)" was Recovered.
On 23-MAY-2025 the outcome for the event "Vomiting(Vomiting)" was Recovered.

Reporter's causality (Saxenda) -
  Diarrhea(Diarrhea) : Possible
  Vomiting(Vomiting) : Possible

Company's causality (Saxenda) -
  Diarrhea(Diarrhea) : Possible
  Vomiting(Vomiting) : Possible

Reporter Comment: The patient somewhat surprised and believes there may be interference from the foods thst they consumed, particularly fatty foods.