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		38 Years	Female	71.30 kg	02	JUN	2025

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

lack of energy [Asthenia]
vomiting [Vomiting]
nausea [Nausea]
Diarrhea [Diarrhoea]
gas [Flatulence]
abdominal bloating [Abdominal distension]

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 {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) UNK

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 For several previous years;Duration not reported	Irritable bowel syndrome (Irritable bowel syndrome)

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.
1453875

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

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

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1453875

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).

Patient's height: 159 cm.

Patient's weight: 71.3 kg.

Patient's BMI: 28.20299830.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "lack of energy(Loss of energy)" beginning on 02-JUN-2025 , "vomiting(Vomiting)" beginning on 02-JUN-2025 , "nausea(Nausea)" beginning on 02-JUN-2025 , "Diarrhea(Diarrhea)" beginning on 02-JUN-2025 , "gas(Gas)" beginning on 02-JUN-2025 , "abdominal bloating(Abdominal bloating)" beginning on 02-JUN-2025 and concerned a 38 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date to 04-JUN-2025 for "Obesity",

Dosage Regimens:
Saxenda: Not Reported to Not Reported, 02-JUN-2025 to 04-JUN-2025;

Current Condition: Obesity, Irritable bowel syndrome chronically.

Batch Numbers:
Saxenda: PP5M440, PP5M440;

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

On 04-JUN-2025 the outcome for the event "lack of energy(Loss of energy)" was Recovered.
On 04-JUN-2025 the outcome for the event "vomiting(Vomiting)" was Recovered.
On 04-JUN-2025 the outcome for the event "nausea(Nausea)" was Recovered.
On 04-JUN-2025 the outcome for the event "Diarrhea(Diarrhea)" was Recovered.
On 04-JUN-2025 the outcome for the event "gas(Gas)" was Recovered.
On 04-JUN-2025 the outcome for the event "abdominal bloating(Abdominal bloating)" was Recovered.

Reporter's causality (Saxenda) -
lack of energy(Loss of energy) : Possible
vomiting(Vomiting) : Possible
nausea(Nausea) : Possible
Diarrhea(Diarrhea) : Possible
gas(Gas) : Possible
abdominal bloating(Abdominal bloating) : Possible

Company's causality (Saxenda) -
lack of energy(Loss of energy) : Possible
vomiting(Vomiting) : Possible
nausea(Nausea) : Possible
Diarrhea(Diarrhea) : Possible
gas(Gas) : Possible
abdominal bloating(Abdominal bloating) : Possible

Reporter Comment: The patient indicated that when she is on the minimum dose, the symptoms no longer occur.

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	1.2 mg, qd; Subcutaneous	Obesity (Obesity)	02-JUN-2025 / 04-JUN-2025; 2 days