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		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		43 Years	Female	Unk	23	JUN	2025

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

cramping, spasms [Muscle spasms]
gagging [Retching]
Metallic taste [Dysgeusia]
Nausea [Nausea]
dizziness [Dizziness]
Heartburn [Dyspepsia]
bloating [Abdominal distension]

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

(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)

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

15. DAILY DOSE(S)
#1) 0.6 mg, qd

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) 23-JUN-2025 / 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)

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.
1468400

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1468400

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "cramping, spasms(Muscle spasms)" beginning on 30-JUN-2025 , "gagging(Gagging)" beginning on 23-JUN-2025 , "Metallic taste(Taste metallic)" beginning on 23-JUN-2025 , "Nausea(Nausea)" beginning on 23-JUN-2025 , "dizziness(Dizziness)" beginning on 23-JUN-2025 , "Heartburn(Heartburn)" beginning on 30-JUN-2025 , "bloating(Bloating)" beginning on 30-JUN-2025 and concerned a 43 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 23-JUN-2025 and ongoing for "Obesity",

Dosage Regimens:
Saxenda: 23-JUN-2025 to Not Reported, 30-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity.

Batch Numbers:
Saxenda: ASKU, ASKU;

Action taken to Saxenda was reported as No Change.

The outcome for the event "cramping, spasms(Muscle spasms)" was Not recovered.
The outcome for the event "gagging(Gagging)" was Not recovered.
The outcome for the event "Metallic taste(Taste metallic)" was Not recovered.
The outcome for the event "Nausea(Nausea)" was Not recovered.
The outcome for the event "dizziness(Dizziness)" was Not recovered.
The outcome for the event "Heartburn(Heartburn)" was Not recovered.
The outcome for the event "bloating(Bloating)" was Not recovered.

Reporter's causality (Saxenda) -
cramping, spasms(Muscle spasms) : Possible
gagging(Gagging) : Possible
Metallic taste(Taste metallic) : Possible
Nausea(Nausea) : Possible
dizziness(Dizziness) : Possible
Heartburn(Heartburn) : Possible
bloating(Bloating) : Possible

Company's causality (Saxenda) -
cramping, spasms(Muscle spasms) : Unlikely
gagging(Gagging) : Possible
Metallic taste(Taste metallic) : Possible
Nausea(Nausea) : Possible
dizziness(Dizziness) : Possible
Heartburn(Heartburn) : Possible
bloating(Bloating) : 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; Subcutaneous	Obesity (Obesity)	30-JUN-2025 / Ongoing; Unknown