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		36 Years	Female	Unk		Unk	

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

Nausea [Nausea]
The patient couldn't lose weight with Saxenda [Weight loss poor]
Discomfort [Discomfort]

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

(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) UNK (the minimum dose)

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

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

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

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: Yes

24b. MFR CONTROL NO.
1465432

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

24c. DATE RECEIVED BY MANUFACTURER
19-JUN-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

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 169 cm.

This non-serious Solicited Report from COSTA RICA was reported by a Other Health Care Professional as "Nausea(Nausea)" with an unspecified onset date , "The patient couldn't lose weight with Saxenda(Weight loss poor)" with an unspecified onset date , "Discomfort(Discomfort)" with an unspecified onset date and concerned a 36 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date to MAY-2025 for "weight loss",

Dosage Regimens:
Saxenda: Not Reported to ??-MAY-2025;

Medical history was not provided.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as Drug discontinued temporarily.

The outcome for the event "Nausea(Nausea)" was Recovered.
The outcome for the event "The patient couldn't lose weight with Saxenda(Weight loss poor)" was Unknown.
The outcome for the event "Discomfort(Discomfort)" was Recovered.

Reporter's causality (Saxenda) -
Nausea(Nausea) : Unknown
The patient couldn't lose weight with Saxenda(Weight loss poor) : Unknown
Discomfort(Discomfort) : Unknown

Company's causality (Saxenda) -
Nausea(Nausea) : Possible
The patient couldn't lose weight with Saxenda(Weight loss poor) : Unlikely
Discomfort(Discomfort) : Unlikely