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		60 Years	Female	Unk	21	MAY	2025

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

it felt very heavy (it didn't sit well with the patient) [Abdominal discomfort]
Nausea [Nausea]

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) 0.6 mg, qd

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

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

18. THERAPY DATES(from/to)
#1) 20-MAY-2025 / 21-MAY-2025

19. THERAPY DURATION
#1) 1 day

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: No

24b. MFR CONTROL NO.
1451607

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "it felt very heavy (it didn't sit well with the patient)(Stomach feeling heavy)" beginning on 21-MAY-2025 , "Nausea(Nausea)" beginning on 21-MAY-2025 and concerned a 60 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 20-MAY-2025 to 21-MAY-2025 for "For weight loss",

Dosage Regimens:
Saxenda: 20-MAY-2025 to 21-MAY-2025;

Medical history was not provided.

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as Drug discontinued temporarily.

On 29-MAY-2025 the outcome for the event "it felt very heavy (it didn't sit well with the patient)(Stomach feeling heavy)" was Recovered.
On 29-MAY-2025 the outcome for the event "Nausea(Nausea)" was Recovered.

Reporter's causality (Saxenda) -
it felt very heavy (it didn't sit well with the patient)(Stomach feeling heavy) : Possible
Nausea(Nausea) : Possible

Company's causality (Saxenda) -
it felt very heavy (it didn't sit well with the patient)(Stomach feeling heavy) : Possible
Nausea(Nausea) : Possible

Reporter Comment: the patient had nausea and spent 2 days resting, taking about a week to recover. The doctor recommended stopping it and resuming on June 2.