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	73.00 kg		OCT	2024

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

Many gastrointestinal problems [Gastrointestinal disorder]
a lot of heartburn and a burning sensation in the stomach [Dyspepsia]
A lot headaches [Headache]
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 **(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) To lose weight. (Weight control)

18. THERAPY DATES(from/to)
#1) OCT-2024 / 26-DEC-2024

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: No

24b. MFR CONTROL NO.
1411327

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

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

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1411327

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

support program with focus on exercise, motivation, nutrition & maintaining strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 156 cm.

Patient's weight: 73 kg.

Patient's BMI: 29.99671270.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Many gastrointestinal problems(Gastrointestinal disorder)" beginning on OCT-2024 , "a lot of heartburn and a burning sensation in the stomach(Stomach burning sensation of)" beginning on OCT-2024 , "A lot headaches(Headache)" with an unspecified onset date , "Nausea(Nausea)" with an unspecified onset date and concerned a 38 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from OCT-2024 to 26-DEC-2024 for "To lose weight.",

Dosage Regimens:
Saxenda: ??-OCT-2024 to 26-DEC-2024;

Medical history was not provided.

Batch Numbers:
Saxenda: ASKU;

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

On DEC-2024 the outcome for the event "Many gastrointestinal problems(Gastrointestinal disorder)" was Recovered.
On DEC-2024 the outcome for the event "a lot of heartburn and a burning sensation in the stomach(Stomach burning sensation of)" was Recovered.
The outcome for the event "A lot headaches(Headache)" was Not Reported.
The outcome for the event "Nausea(Nausea)" was Not Reported.

Reporter's causality (Saxenda) -
Many gastrointestinal problems(Gastrointestinal disorder) : Possible
a lot of heartburn and a burning sensation in the stomach(Stomach burning sensation of) : Possible
A lot headaches(Headache) : Unknown
Nausea(Nausea) : Unknown

Company's causality (Saxenda) -
Many gastrointestinal problems(Gastrointestinal disorder) : Unlikely
a lot of heartburn and a burning sensation in the stomach(Stomach burning sensation of) : Possible
A lot headaches(Headache) : Possible
Nausea(Nausea) : Possible

Reporter Comment: -Treatment for symptoms experienced: Gastrointestinal protector
Treatment drug: Gastridex (omeprazole)(Non-codable)