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		43 Years	Female	109.30 kg	07	APR	2025

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

Dizziness [Dizziness]
Nausea [Nausea]
dysgeusia [Dysgeusia]
dizziness [Dizziness]

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) 1.8 mg, qd

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

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

18. THERAPY DATES(from/to)
#1) 07-APR-2025 / Ongoing

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 to Ongoing	Current Condition Duration was not reported	Obesity (Obesity)
Unknown to Ongoing	Current Condition Duration not reported.	Insulin resistance (Insulin resistance)

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.
1412891

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

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

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1412891

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: 165 cm.

Patient's weight: 109.3 kg.

Patient's BMI: 40.14692380.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Dizziness(Dizziness)" beginning on 07-APR-2025 , "Nausea(Nausea)" with an unspecified onset date , "dysgeusia(Dysgeusia)" with an unspecified onset date , "dizziness(Dizziness)" with an unspecified onset date and concerned a 43 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 07-APR-2025 and ongoing for "Obesity",

Dosage Regimens:
Saxenda: 07-APR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Insulin resistance
Historical Condition: bulimia
Procedure: Sleeve gastrectomy.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as No Change.

The outcome for the event "Dizziness(Dizziness)" was Recovered.
The outcome for the event "Nausea(Nausea)" was Recovered.
The outcome for the event "dysgeusia(Dysgeusia)" was Recovered.
The outcome for the event "dizziness(Dizziness)" was Recovered.

Reporter's causality (Saxenda) -
Dizziness(Dizziness) : Unknown
Nausea(Nausea) : Unknown
dysgeusia(Dysgeusia) : Unknown
dizziness(Dizziness) : Unknown

Company's causality (Saxenda) -
Dizziness(Dizziness) : Possible
Nausea(Nausea) : Possible
dysgeusia(Dysgeusia) : Possible
dizziness(Dizziness) : Possible

Reporter Comment: Treatment Received: Reduce the 6 meals to 3-4 meals

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Procedure Duration not reported.	Sleeve gastrectomy (Sleeve gastrectomy);
Unknown	Historical Condition in adolescence	Bulimia (Bulimia nervosa);