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		33 Years	Female	86.00 kg		Unk	

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

Other Serious Criteria: Medically Significant
affected the vision (the patient could not see) [Visual impairment]
vomiting [Vomiting]
migraines worsened [Migraine]

Case Description: 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).

(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) Weight loss (Weight control)

18. THERAPY DATES(from/to)
#1) JAN-2025 / 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 to Ongoing	Current Condition Duration not reported	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Migraine (Migraine)

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.
1467516

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

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

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

DATE OF THIS REPORT
03-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 163 cm.
Patient's weight: 86 kg.
Patient's BMI: 32.36854980.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "affected the vision (the patient could not see)(Visual impairment)" with an unspecified onset date , "vomiting(Vomiting)" with an unspecified onset date , "migraines worsened(Migraine aggravated)" with an unspecified onset date and concerned a 33 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JAN-2025 to 2025 for "Weight loss",

Dosage Regimens:
Saxenda: ??-JAN-2025 to ??-???-2025;

Current Condition: Obesity (Duration not reported), migraines.

Treatment medications included - MIGRADORIXINA(CLONIXIN LYSINATE, ERGOTAMINE TARTRATE), SALINE [SODIUM CHLORIDE].

On an unknown date patient experienced significant vomiting, worsened migraines and there were days when effects were so strong that it affected patient’s vision (patient could not see)

Batch Number of Saxenda was requested

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

The outcome for the event "affected the vision (the patient could not see)(Visual impairment)" was Recovered.
The outcome for the event "vomiting(Vomiting)" was Recovered.
The outcome for the event "migraines worsened(Migraine aggravated)" was Recovered.

Reporter's causality (Saxenda) -
affected the vision (the patient could not see)(Visual impairment) : Possible
vomiting(Vomiting) : Possible
migraines worsened(Migraine aggravated) : Possible

Company's causality (Saxenda) -
affected the vision (the patient could not see)(Visual impairment) : Unlikely
vomiting(Vomiting) : Possible
migraines worsened(Migraine aggravated) : Unlikely

COMPANY COMMENT -
Visual impairment is assessed as unlisted event according to the Novo Nordisk current CCDS information on Saxenda.
Medical history of migraine is considered confounding factor in the case, hence the causality is assessed as unlikely.
This single case report is not considered to change the current knowledge of the safety profile of Saxenda.