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		34 Years	Female	84.00 kg		AUG	2024

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

severe headaches [Headache]
reflux [Gastrooesophageal reflux disease]
vomiting, [Vomiting]
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 {Lot # NP5K115; Exp.Dt. MAR-2026}
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☒ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1) 0.6 mg, qd

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

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

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)
#1) JUL-2024 / Unknown

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) VENLAFAXINE (VENLAFAXINE) ; Ongoing
#2) ENALAPRIL (ENALAPRIL) ; Ongoing
#3) FUROSEMIDE (FUROSEMIDE) ; Ongoing
#4) LOVASTATIN (LOVASTATIN) ; Ongoing
#5) CARBAMAZEPINE (CARBAMAZEPINE) ; Ongoing

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	Hypertension (Hypertension)
Unknown to Ongoing	Current Condition	Mental disorder (Mental disorder)

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.
1468525

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1468525

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: 168 cm.

Patient's weight: 84 kg.

Patient's BMI: 29.76190480.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "severe headaches(Headache)" beginning on AUG-2024 , "reflux(Gastroesophageal reflux)" beginning on AUG-2024 , "vomiting,(Vomiting)" beginning on AUG-2024 , "dizziness(Dizziness)" beginning on AUG-2024 and concerned a 34 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JUL-2024 and ongoing for "Weight control",

Dosage Regimens:
Saxenda: ??-JUL-2024 to Not Reported, Not Reported to Not Reported, Not Reported to ??-DEC-2024, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Hypertension, Psychiatric disorders, Cholesterol, triglycerides, Sciatic nerve condition.

Concomitant medications included - VENLAFAXINE, ENALAPRIL, FUROSEMIDE, LOVASTATIN, CARBAMAZEPINE.

Batch Numbers:
Saxenda: NP5K115, NP5K115, NP5K115, ASKU;

Action taken to Saxenda was reported as Drug discontinued temporarily.

The outcome for the event "severe headaches(Headache)" was Recovering/resolving.
The outcome for the event "reflux(Gastroesophageal reflux)" was Recovering/resolving.
The outcome for the event "vomiting,(Vomiting)" was Recovering/resolving.
The outcome for the event "dizziness(Dizziness)" was Recovering/resolving.

Reporter's causality (Saxenda) -
severe headaches(Headache) : Possible
reflux(Gastroesophageal reflux) : Possible
vomiting,(Vomiting) : Possible
dizziness(Dizziness) : Possible

Company's causality (Saxenda) -
severe headaches(Headache) : Possible
reflux(Gastroesophageal reflux) : Possible
vomiting,(Vomiting) : Possible
dizziness(Dizziness) : Possible

Reporter Comment: The treatment was paused in December 2024 and the patient resumed the application of Saxenda approximately 3 months ago.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # NP5K115; Exp.Dt. MAR-2026}; Regimen #2	1.2 mg, qd; Subcutaneous	Weight control (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # NP5K115; Exp.Dt. MAR-2026}; Regimen #3	1.8 mg, qd; Subcutaneous	Weight control (Weight control)	Unknown / DEC-2024; Unknown

Mfr. Control Number: 1468525

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #4	UNK (resumed); Subcutaneous	Weight control (Weight control)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Blood cholesterol abnormal (Blood cholesterol abnormal);
Unknown to Ongoing	Current Condition	Triglycerides abnormal (Blood triglycerides abnormal);
Unknown to Ongoing	Current Condition	Sciatica (Sciatica);