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	104.00 kg		OCT	2024

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

headaches [Headache]
felt like nausea [Nausea]
vomiting [Vomiting]
feel very unwell [Malaise]
headaches [Headache]
felt a lot of sweating [Hyperhidrosis]

Case Description: ***This is an auto generated narrative***

Study ID: 828652-My Healthy Journey

(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

(Continued on Additional Information Page)

15. DAILY DOSE(S)
#1) UNK

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

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

(Continued on Additional Information Page)

18. THERAPY DATES(from/to)
#1) OCT-2024 / 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 not reported	Insulin resistance (Insulin resistance)
Unknown to Ongoing	Current Condition duration not reported	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.
1422570

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

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

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

DATE OF THIS REPORT
02-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1422570

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

Patient's height: 155 cm.

Patient's weight: 104 kg.

Patient's BMI: 43.28824140.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "headaches(Headache)" beginning on OCT-2024 , "felt like nausea(Nausea)" beginning on OCT-2024 , "vomiting(Vomiting)" with an unspecified onset date , "feel very unwell(Feeling unwell)" with an unspecified onset date , "headaches(Headache)" with an unspecified onset date , "felt a lot of sweating(Excess sweating)" 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 and ongoing for "Weight loss", "insulin resistance",

Dosage Regimens:
Saxenda: ??-OCT-2024 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Insulin Resistance, Migraine.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as No Change.

On 2024 the outcome for the event "headaches(Headache)" was Recovered.
On 2024 the outcome for the event "felt like nausea(Nausea)" was Recovered.
The outcome for the event "vomiting(Vomiting)" was Unknown.
The outcome for the event "feel very unwell(Feeling unwell)" was Unknown.
The outcome for the event "headaches(Headache)" was Unknown.
The outcome for the event "felt a lot of sweating(Excess sweating)" was Unknown.

Reporter's causality (Saxenda) -
headaches(Headache) : Possible
felt like nausea(Nausea) : Possible
vomiting(Vomiting) : Unknown
feel very unwell(Feeling unwell) : Unknown
headaches(Headache) : Unknown
felt a lot of sweating(Excess sweating) : Unknown

Company's causality (Saxenda) -
headaches(Headache) : Possible
felt like nausea(Nausea) : Possible
vomiting(Vomiting) : Possible
feel very unwell(Feeling unwell) : Possible
headaches(Headache) : Possible
felt a lot of sweating(Excess sweating) : Unlikely

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 #1	UNK; Unknown	Weight loss (Weight control) insulin resistance (Insulin resistance)	OCT-2024 / Ongoing; Unknown