SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		43 Years	Female	76.10 kg	04	MAR	2025

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

Constipation increased [Constipation]
occasional headaches [Headache]
Reflux [Gastrooesophageal reflux disease]

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 support program with focus on exercise, motivation, nutrition & maintaining

(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)

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

15. DAILY DOSE(S)
#1) 3 mg, qd (In the evening)

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

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

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 04-MAR-2025 / Ongoing

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)

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 was 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.
1455949

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

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1455949

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 159 cm.

Patient's weight: 76.1 kg.

Patient's BMI: 30.10165740.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Constipation increased(Constipation aggravated)" beginning on 04-MAR-2025 , "occasional headaches(Headache transient)" beginning on 04-MAR-2025 , "Reflux(Gastroesophageal reflux)" beginning on 04-MAR-2025 and concerned a 43 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 04-MAR-2025 and ongoing for "Obesity", "insulin resistance.",

Dosage Regimens:
Saxenda: 04-MAR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Insulin resistance, Constipation.

Treatment medications included - MAGNESIUM CITRATE.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as No Change.

The outcome for the event "Constipation increased(Constipation aggravated)" was Not recovered.
The outcome for the event "occasional headaches(Headache transient)" was Not recovered.
The outcome for the event "Reflux(Gastroesophageal reflux)" was Not recovered.

Reporter's causality (Saxenda) -
Constipation increased(Constipation aggravated) : Unknown
occasional headaches(Headache transient) : Unknown
Reflux(Gastroesophageal reflux) : Unknown

Company's causality (Saxenda) -
Constipation increased(Constipation aggravated) : Possible
occasional headaches(Headache transient) : Possible
Reflux(Gastroesophageal reflux) : Possible

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	3 mg, qd (In the evening); Subcutaneous	Obesity (Obesity) insulin resistance. (Insulin resistance)	04-MAR-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
03-MAR-2025 to Ongoing	Current Condition	Constipation (Constipation);