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		51 Years	Female	74.00 kg		JUN	2025

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

gained 6 kg a month ago [Weight increased]
Symptoms of excessive sleepiness [Hypersomnia]
high stress [Stress]
depression [Depression]
Saxenda has not had an effect [Drug ineffective]

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)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.8 mg, qd	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) MAY-2022 / Unknown	#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	Hip deformity (Hip deformity)
Unknown to Ongoing	Current Condition	Hunger (Hunger)

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.
1472119

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

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

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

DATE OF THIS REPORT
02-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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: 160 cm.

Patient's weight: 74 kg.

Patient's BMI: 28.906250.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "gained 6 kg a month ago(Weight gain)" beginning on JUN-2025 , "Symptoms of excessive sleepiness(Sleep excessive)" with an unspecified onset date , "high stress(Stress)" with an unspecified onset date , "depression(Depression)" with an unspecified onset date , "Saxenda has not had an effect(Lack of drug effect)" beginning on JUN-2025 and concerned a 51 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2022 to JUN-2025 for "for weight loss",

Dosage Regimens:
Saxenda: ??-MAY-2022 to Not Reported, Not Reported to ??-JUN-2025;

Current Condition: Problem in the hip, hunger, anxiety.

Lab Data included:
Test Date: 2023
Lab Data Test as Reported: weight
Test Name: Weight
Comments: On an unspecified date in 2023 patient reported to have lost approximately 15kg with saxenda.

Test Date: OCT-2024
Lab Data Test as Reported: weight
Test Name: Weight
Comments: On an unknown date in Oct-2024, the patient gained weight

Test Date: 2025
Lab Data Test as Reported: weight
Test Name: Weight
Comments: On an unspecified date in 2025 patient reported to have gained 6kg weight.

Batch Numbers:
Saxenda: ASKU, ASKU;

Action taken to Saxenda was reported as Product discontinued.

The outcome for the event "gained 6 kg a month ago(Weight gain)" was Not recovered.
The outcome for the event "Symptoms of excessive sleepiness(Sleep excessive)" was Not Reported.
The outcome for the event "high stress(Stress)" was Not Reported.
The outcome for the event "depression(Depression)" was Not Reported.
The outcome for the event "Saxenda has not had an effect(Lack of drug effect)" was Not recovered.

Reporter's causality (Saxenda) -
gained 6 kg a month ago(Weight gain) : Possible
Symptoms of excessive sleepiness(Sleep excessive) : Unknown
high stress(Stress) : Unlikely
depression(Depression) : Unlikely
Saxenda has not had an effect(Lack of drug effect) : Possible

Company's causality (Saxenda) -
gained 6 kg a month ago(Weight gain) : Possible
Symptoms of excessive sleepiness(Sleep excessive) : Unlikely
high stress(Stress) : Unlikely
depression(Depression) : Unlikely
Saxenda has not had an effect(Lack of drug effect) : Possible

Reporter Comment: The patient started using Saxenda in 2022, and in 2023, mentions that the experience was "super good" as approximately 15 kg were lost.

02-Sep-2025 11:29

Mfr. Control Number: 1472119

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	2023	Weight On an unspecified date in 2023 patient reported to have lost approximately 15kg with saxenda.		
2	OCT-2024	Weight On an unknown date in Oct-2024, the patient gained weight		
3	2025	Weight On an unspecified date in 2025 patient reported to have gained 6kg weight.		

13. Relevant Tests

On an unspecified date in 2023 patient reported to have lost approximately 15kg weight with saxenda.
On an unspecified date in 2025 patient reported to have gained 6kg weight.
On an unknown date in Oct-2024, the patient gained weight

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 #2	UNK(resumed in March or April 2025); Subcutaneous	for weight loss (Weight control)	Unknown / JUN-2025; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Anxiety (Anxiety);