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		37 Years	Female	Unk		JUN	2024

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

She did not see results (stuck at her weight). [Weight loss poor]
potential weight gain [Weight increased]
Patient felt that it completely took away her hunger; at lunchtime, she did not want to eat anything. [Decreased appetite]
LACK OF EFFICACY OF SAXENDA [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)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK, qd	#1) Subcutaneous

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) DEC-2023 / Unknown	#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) ; 2022 / Ongoing
#2) BROMAZEPAM (BROMAZEPAM) ; 2021 / Ongoing
#3) NEOGAIVAL (ESZOPICLONE) ; 2021 / Ongoing
#4) PREGABALIN (PREGABALIN) ; Ongoing
#5) QUETIAPINE (QUETIAPINE) ; Ongoing
#6) NEOGAIVAL (ESZOPICLONE) ; 2021 / 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

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.
1448141

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

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

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

DATE OF THIS REPORT
02-JUL-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: 156 cm.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "She did not see results (stuck at her weight).(Weight loss poor)" beginning on JUN-2024 , "potential weight gain(Weight gain)" with an unspecified onset date , "Patient felt that it completely took away her hunger; at lunchtime, she did not want to eat anything.(Appetite lost)" with an unspecified onset date , "LACK OF EFFICACY OF SAXENDA(Lack of drug effect)" beginning on JUN-2024 and concerned a 37 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from DEC-2023 for "lose weight",

Dosage Regimens:
Saxenda: ??-DEC-2023 to Not Reported, Not Reported to Not Reported;

Medical history was not provided.

Concomitant medications included - VENLAFAXINE, BROMAZEPAM, NEOGAIVAL(ESZOPICLONE), PREGABALIN, QUETIAPINE, NEOGAIVAL(ESZOPICLONE).

Batch Numbers:
Saxenda: ASKU, ASKU;

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

The outcome for the event "She did not see results (stuck at her weight).(Weight loss poor)" was Unknown.
The outcome for the event "potential weight gain(Weight gain)" was Not Reported.
The outcome for the event "Patient felt that it completely took away her hunger; at lunchtime, she did not want to eat anything.(Appetite lost)" was Not Reported.
The outcome for the event "LACK OF EFFICACY OF SAXENDA(Lack of drug effect)" was Not Reported.

Reporter's causality (Saxenda) -
She did not see results (stuck at her weight).(Weight loss poor) : Possible
potential weight gain(Weight gain) : Unknown
Patient felt that it completely took away her hunger; at lunchtime, she did not want to eat anything.(Appetite lost) : Unknown
LACK OF EFFICACY OF SAXENDA(Lack of drug effect) : Unknown

Company's causality (Saxenda) -
She did not see results (stuck at her weight).(Weight loss poor) : Possible
potential weight gain(Weight gain) : Possible
Patient felt that it completely took away her hunger; at lunchtime, she did not want to eat anything.(Appetite lost) : Unlikely
LACK OF EFFICACY OF SAXENDA(Lack of drug effect) : Possible

References included:
Reference Type: E2B Linked Report
Reference ID#: CR-NOVOPROD-1448155
Reference Notes: Same patient

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, qd (lower dose); Subcutaneous	lose weight (Weight control)	Unknown; Unknown