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		53 Years	Female	103.00 kg		FEB	2025

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

did not help her lose weight [Weight loss poor]
She gained weight [Weight increased]
lack of efficacy in losing weight.

(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) UNK

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

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

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) NOV-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) IRBESARTAN (IRBESARTAN) ; 2015 / 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	Blood sugar abnormal (Blood glucose abnormal)
Unknown to Ongoing	Current Condition	Blood pressure abnormal (Blood pressure abnormal)

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.
1432669

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

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

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

DATE OF THIS REPORT
08-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Drug ineffective]

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 strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 160 cm.

Patient's weight: 103 kg.

Patient's BMI: 40.234375.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "did not help her lose weight(Weight loss poor)" beginning on FEB-2025 , "She gained weight(Weight gain)" with an unspecified onset date , "lack of efficacy in losing weight.(Lack of drug effect)" beginning on FEB-2025 and concerned a 53 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from NOV-2024 to FEB-2025 for "To Lose weight", "To control blood sugar.",

Dosage Regimens:
Saxenda: ??-NOV-2024 to Not Reported, Not Reported to ??-FEB-2025;

Current Condition: To control blood sugar, for blood pressure.

Concomitant medications included - IRBESARTAN.

Batch Numbers:
Saxenda: ASKU, ASKU;

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

On FEB-2025 the outcome for the event "did not help her lose weight(Weight loss poor)" was Recovered.
The outcome for the event "She gained weight(Weight gain)" was Not Reported.
On FEB-2025 the outcome for the event "lack of efficacy in losing weight.(Lack of drug effect)" was Recovered.

Reporter's causality (Saxenda) -
did not help her lose weight(Weight loss poor) : Possible
She gained weight(Weight gain) : Possible
lack of efficacy in losing weight.(Lack of drug effect) : Possible

Company's causality (Saxenda) -
did not help her lose weight(Weight loss poor) : Possible
She gained weight(Weight gain) : Possible
lack of efficacy in losing weight.(Lack of drug effect) : Possible

Reporter Comment: No medical history of endocrine disorder or no hospitalisation or stress, product appear normal at visual inspection.

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; Subcutaneous	To Lose weight (Weight control) To control blood sugar. (Blood glucose abnormal)	NOV-2024 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution	3 mg, qd; Subcutaneous	To Lose weight (Weight	Unknown / FEB-2025;

Mfr. Control Number: 1432669

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
for injection, 6 mg/mL; Regimen #2		control) To control blood sugar. (Blood glucose abnormal)	Unknown