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		39 Years	Female	140.00 kg		FEB	2025

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

gaining weight with the dose of 1.2 mg [Weight increased]
lack of efficacy [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).

(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) UNK	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) OCT-2024 / 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 duration not reported	Obesity (Obesity)

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.
1476054

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

24c. DATE RECEIVED BY MANUFACTURER
04-JUL-2025

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 176 cm.

Patient's weight: 140 kg.

Patient's BMI: 45.196281.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "gaining weight with the dose of 1.2 mg(Weight gain)" beginning on FEB-2025 , "lack of efficacy(Lack of drug effect)" beginning on FEB-2025 and concerned a 39 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from OCT-2024 to MAR-2025 for "weight loss",

Dosage Regimens:
Saxenda: ??-OCT-2024 to Not Reported, Not Reported to Not Reported, Not Reported to ??-MAR-2025;

Current Condition: Obesity.

Lab Data included:
Lab Data Test as Reported: weight
Test Name: Weight
Comments: From an unknown date after patient began to notice that the patient was gaining weight with the dose of 1.2 mg.

Lab Data Test as Reported: weight
Test Name: Weight
Comments: On unknown date the patient has lost 3kg of weight

Batch Numbers:
Saxenda: ASKU, ASKU, ASKU;

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

On MAR-2025 the outcome for the event "gaining weight with the dose of 1.2 mg(Weight gain)" was Recovered.
On MAR-2025 the outcome for the event "lack of efficacy(Lack of drug effect)" was Recovered.

Reporter's causality (Saxenda) -
gaining weight with the dose of 1.2 mg(Weight gain) : Unknown
lack of efficacy(Lack of drug effect) : Unknown

Company's causality (Saxenda) -
gaining weight with the dose of 1.2 mg(Weight gain) : Possible
lack of efficacy(Lack of drug effect) : Possible

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight From an unknown date after patient began to notice that the patient was gaining weight with the dose of 1.2 mg.		
2		Weight On unknown date the patient has lost 3kg of weight		

13. Relevant Tests

On unknown date the patient has lost 3kg of weight
From an unknown date after patient began to notice that the patient was gaining weight with the dose of 1.2 mg.

Mfr. Control Number: 1476054

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
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	1.2 mg (increased dose); Subcutaneous	weight loss (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	3 mg, qd; Subcutaneous	weight loss (Weight control)	Unknown / MAR-2025; Unknown