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		Unk	Male	110.00 kg		Unk	

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

only lost 1 kg after using the medication Saxenda [Weight loss poor]

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)

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

15. DAILY DOSE(S)
#1) UNK

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

17. INDICATION(S) FOR USE
#1) Product used for unknown indication (P
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 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)

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.
1476934

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

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1476934

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's weight: 110 kg.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "only lost 1 kg after using the medication Saxenda(Weight loss poor)" with an unspecified onset date and concerned a Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date for "Product used for unknown indication",

Dosage Regimens:
Saxenda:

Medical history was not provided.

Lab Data included:
Lab Data Test as Reported: Weight
Test Name: Weight
Results: 110
Unit: kg
Comments:

Lab Data Test as Reported: Weight
Test Name: Weight
Results: 111
Unit: kg
Comments:

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as Unknown.

The outcome for the event "only lost 1 kg after using the medication Saxenda(Weight loss poor)" was Not Reported.

Reporter's causality (Saxenda) -
only lost 1 kg after using the medication Saxenda(Weight loss poor) : Unknown

Company's causality (Saxenda) -
only lost 1 kg after using the medication Saxenda(Weight loss poor) : Unlikely

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight	110 kg	
2		Weight	111 kg	

13. Relevant Tests

On an unknown date patient lost only 1 kg from start weight 111 kg to current weight 110 kg.

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; Unknown	Product used for unknown indication (Product used for unknown indication)	Unknown; Unknown