CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		45 Years	Female	85.00 kg		AUG	2024	

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

weight increased to 90 Kg [Weight increased]
lot pain in her legs [Pain in extremity] ([Fluid retention])
Condition aggravated [Condition aggravated]

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

(Continued on Additional Information Page)

- ☐ 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

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

15. DAILY DOSE(S)
#1) UNK qd

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

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

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

18. THERAPY DATES(from/to)
#1) MAR-2024 / NOV-2024

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 to Ongoing	Current Condition	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Fluid retention (Fluid retention)

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.
1415758

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1415758

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 160 cm.

Patient's weight: 85 kg.

Patient's BMI: 33.203125.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "weight increased to 90 Kg(Weight increased)" beginning on AUG-2024 , "lot pain in her legs(Pains in legs)" beginning on AUG-2024 , "fluid retention increased(Fluid retention)" beginning on AUG-2024 , "Condition aggravated(Condition aggravated)" beginning on AUG-2024 and concerned a 45 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAR-2024 to NOV-2024 for "Obesity",

Dosage Regimens:
Saxenda: ??-MAR-2024 to ??-NOV-2024;

Current Condition: Obesity, Fluid retention.

Lab Data included:
Test Date: AUG-2024
Lab Data Test as Reported: weight
Test Name: Weight
Results: 90
Unit: kg
Comments:

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as Product discontinued.

On SEP-2024 the outcome for the event "weight increased to 90 Kg(Weight increased)" was Recovered.
On SEP-2024 the outcome for the event "lot pain in her legs(Pains in legs)" was Recovered.
On SEP-2024 the outcome for the event "fluid retention increased(Fluid retention)" was Recovered.
On SEP-2024 the outcome for the event "Condition aggravated(Condition aggravated)" was Recovered.

Reporter's causality (Saxenda) -
weight increased to 90 Kg(Weight increased) : Possible
lot pain in her legs(Pains in legs) : Possible
fluid retention increased(Fluid retention) : Possible
Condition aggravated(Condition aggravated) : Possible

Company's causality (Saxenda) -
weight increased to 90 Kg(Weight increased) : Unlikely
lot pain in her legs(Pains in legs) : Unlikely
fluid retention increased(Fluid retention) : Unlikely
Condition aggravated(Condition aggravated) : Unlikely

References included:
Reference Type: E2B Linked Report
Reference ID#: CR-NOVOPROD-1197635
Reference Notes: Same patient

Reporter Comment: Treatment for symptoms experienced: Medications for circulation and for fluid retention (does not remember the name)

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	AUG-2024	Weight	90 kg	