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		59 Years	Female	Unk		NOV	2024

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

nausea [Nausea]
She has not lost much weight [Weight loss poor]
treatment was not effective [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

(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	#1) Subcutaneous

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) NOV-2024 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) CODIOVAN (HYDROCHLOROTHIAZIDE, VALSARTAN) ; Ongoing
#2) CLIMABEL (TIBOLONE) ; 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 pressure high (Hypertension)
Unknown to Ongoing	Current Condition	Menopause (Menopause)

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.
1412243

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

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

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

DATE OF THIS REPORT
02-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1412243

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 164 cm.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nausea(Nausea)" beginning on NOV-2024 , "She has not lost much weight(Weight loss poor)" beginning on NOV-2024 , "treatment was not effective(Drug ineffective)" beginning on NOV-2024 and concerned a 59 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from NOV-2024 and ongoing for "weight loss",

Dosage Regimens:
Saxenda: ??-NOV-2024 to Not Reported, Not Reported to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: High blood pressure, menopause.

Concomitant medications included - CODIOVAN(HYDROCHLOROTHIAZIDE, VALSARTAN), CLIMABEL(TIBOLONE).

Lab Data included:
Test Date: NOV-2024
Lab Data Test as Reported: Weight
Test Name: Weight
Comments: On an unknown date in NOV-2024 patient noticed she has not lost much weight (only about 2 or 3 kg).

Batch Numbers:
Saxenda: ASKU, ASKU, ASKU;

Action taken to Saxenda was reported as Dose Decreased.

The outcome for the event "nausea(Nausea)" was Not recovered.
The outcome for the event "She has not lost much weight(Weight loss poor)" was Not recovered.
The outcome for the event "treatment was not effective(Drug ineffective)" was Not recovered.

Reporter's causality (Saxenda) -
nausea(Nausea) : Possible
She has not lost much weight(Weight loss poor) : Possible
treatment was not effective(Drug ineffective) : Possible

Company's causality (Saxenda) -
nausea(Nausea) : Possible
She has not lost much weight(Weight loss poor) : Possible
treatment was not effective(Drug ineffective) : Possible

Reporter Comment: Concomitant medication: Isobloc (Hidroclorotiazida)(non codeable) since 2015 ongoing at 5 mg ,qd dose orally.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	NOV-2024	Weight On an unknown date in NOV-2024 patient noticed she has not lost much weight (only about 2 or 3 kg).		

13. Relevant Tests

On an unknown date in NOV-2024 patient noticed she has not lost much weight (only about 2 or 3 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

Mfr. Control Number: 1412243

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	2.4 mg, qd; Subcutaneous	weight loss (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	1.8 mg, qd; Subcutaneous	weight loss (Weight control)	Ongoing; Unknown