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		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Female	Unk		Unk	

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

nausea [Nausea]
insomnia [Insomnia]
Blood pressure slightly increased [Blood pressure increased]
aversion to eating [Food aversion]
loss of appetite (no longer has the desire to eat.) [Decreased appetite]

Case Description: ***This is an auto generated narrative***

Study ID: 828652-My Healthy Journey

(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)
#1) 1.2 mg, qd

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

17. INDICATION(S) FOR USE
#1) Product used for unknown indication (P

(Continued on Additional Information Page)

18. THERAPY DATES(from/to)
#1) APR-2025 / Ongoing

19. THERAPY DURATION
#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

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.
1452180

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

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

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

DATE OF THIS REPORT
26-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nausea(Nausea)" with an unspecified onset date , "insomnia(Insomnia)" with an unspecified onset date , "Blood pressure slightly increased(Blood pressure increased)" with an unspecified onset date , "aversion to eating(Food aversion)" with an unspecified onset date , "loss of appetite (no longer has the desire to eat.)(Appetite lost)" with an unspecified onset date and concerned a Adult Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from APR-2025 and ongoing for "Product used for unknown indication",

Dosage Regimens:
Saxenda: ??-APR-2025 to Not Reported (Dosage Regimen Ongoing);

Medical history was not provided.

Lab Data included:
Lab Data Test as Reported: blood pressure
Test Name: Blood pressure measurement
Comments: on an unknown date patients blood pressure slightly increased (units and values not reported)

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "nausea(Nausea)" was Unknown.
The outcome for the event "insomnia(Insomnia)" was Unknown.
The outcome for the event "Blood pressure slightly increased(Blood pressure increased)" was Unknown.
The outcome for the event "aversion to eating(Food aversion)" was Unknown.
The outcome for the event "loss of appetite (no longer has the desire to eat.)(Appetite lost)" was Unknown.

Reporter's causality (Saxenda) -
nausea(Nausea) : Unknown
insomnia(Insomnia) : Unknown
Blood pressure slightly increased(Blood pressure increased) : Unknown
aversion to eating(Food aversion) : Unknown
loss of appetite (no longer has the desire to eat.)(Appetite lost) : Unknown

Company's causality (Saxenda) -
nausea(Nausea) : Possible
insomnia(Insomnia) : Possible
Blood pressure slightly increased(Blood pressure increased) : Unlikely
aversion to eating(Food aversion) : Unlikely
loss of appetite (no longer has the desire to eat.)(Appetite lost) : Unlikely

Reporter Comment: The patient reports that she is in the emergency room (she does not mention how long she has been there) for the assessment of her blood pressure.
The nutritionist is evaluating whether the patient should decrease the dose.
no longer has the desire to eat.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement on an unknown date patients blood pressure slightly increased (units and values not reported)		

13. Relevant Tests

on an unknown date patients blood pressure slightly increased (units and values not reported)

Mfr. Control Number: 1452180

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 #1	1.2 mg, qd; Subcutaneous	Product used for unknown indication (Product used for unknown indication)	APR-2025 / Ongoing; Unknown