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		34 Years	Female	76.20 kg		Unk		☐ PATIENT DIED

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

dizziness [Dizziness]
Nausea [Nausea]
diarrhea [Diarrhoea]
Saxenda use for insulin resistance.

(Continued on Additional Information Page)

☐ 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) 1.2 mg, qd

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

17. INDICATION(S) FOR USE
#1) insulin resistance (Insulin resistance)

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

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

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	Hypertension (Hypertension)
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance)

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.
1438122

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

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

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

DATE OF THIS REPORT
01-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1438122

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Product use in unapproved indication]

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).

Patient's height: 157 cm.

Patient's weight: 76.2 kg.

Patient's BMI: 30.914033.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "dizziness(Dizziness)" with an unspecified onset date , "Nausea(Nausea)" with an unspecified onset date , "diarrhea(Diarrhea)" with an unspecified onset date , "Saxenda use for insulin resistance.(Product use in unapproved indication)" with an unspecified onset date and concerned a 34 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date and ongoing for "insulin resistance",

Dosage Regimens:
Saxenda:

Current Condition: Hypertension, Insulin resistance, Endometriosis, Overweight.

Treatment medications included - OSPASMOL(OTILONIUM BROMIDE), OMEPRAZOLE, FAMOTIDINE.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was Not reported.

The outcome for the event "dizziness(Dizziness)" was Recovered.
The outcome for the event "Nausea(Nausea)" was Recovered.
The outcome for the event "diarrhea(Diarrhea)" was Recovered.
The outcome for the event "Saxenda use for insulin resistance.(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Saxenda) -
dizziness(Dizziness) : Unknown
Nausea(Nausea) : Unknown
diarrhea(Diarrhea) : Unknown
Saxenda use for insulin resistance.(Product use in unapproved indication) : Unknown

Company's causality (Saxenda) -
dizziness(Dizziness) : Possible
Nausea(Nausea) : Possible
diarrhea(Diarrhea) : Possible
Saxenda use for insulin resistance.(Product use in unapproved indication) : Possible

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Endometriosis (Endometriosis);
Unknown to Ongoing	Current Condition	Overweight (Overweight);