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		29 Years	Female	95.00 kg			2023

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

Other Serious Criteria: Medically Significant
hypoglycemia that led her to faint with unconsciousness [Hypoglycaemic unconsciousness]
hypoglycemia that led her to faint with unconsciousness [Hypoglycaemic unconsciousness]
Saxenda for prediabetes and metabolic syndrome [Product use in unapproved indication]

Case Description: 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)

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

15. DAILY DOSE(S)
#1) 1.8 mg, qd

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

17. INDICATION(S) FOR USE
#1) prediabetes (Glucose tolerance impaired)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 2023 / 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 to Ongoing	Current Condition duration not reported	Prediabetes (Glucose tolerance impaired)
Unknown to Ongoing	Current Condition	Metabolic syndrome (Metabolic syndrome)

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.
1447750

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

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

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

DATE OF THIS REPORT
06-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1447750

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).

Patient's height: 167 cm.

Patient's weight: 95 kg.

Patient's BMI: 34.06360930.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness)" beginning on 01-DEC-2024 , "hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness)" beginning on 04-DEC-2024 , "Saxenda for prediabetes and metabolic syndrome(Product use in unapproved indication)" beginning on 2023 and concerned a 29 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 2023 for "prediabetes", "metabolic syndrome",

Dosage Regimens:
Saxenda: ??-???-2023 to Not Reported, Not Reported to ??-DEC-2024, ??-FEB-2025 to Not Reported;

Current Condition: prediabetes (duration not reported), Metabolic syndrome.

From an unknown date in 2023, patient has been using saxenda for prediabetes and metabolic syndrome

On 01-DEC-2024, the patient experienced hypoglycemia that led to fainting, and again on 04-DEC-2024 while using the medication. Although she typically stabilized and felt fine afterward, her doctor advised discontinuing the medication. Consequently, she stopped using Saxenda in DEC-2024 and resumed it in FEB-2025. Since resuming, she has not experienced any events.

Batch Number for Saxenda was not obtainable.

Action taken to Saxenda was reported as Drug discontinued temporarily.

The outcome for the event "hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness)" was Recovered.
The outcome for the event "hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness)" was Recovered.
The outcome for the event "Saxenda for prediabetes and metabolic syndrome(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Saxenda) -
hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness) : Unlikely
hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness) : Unlikely
Saxenda for prediabetes and metabolic syndrome(Product use in unapproved indication) : Unknown

Company's causality (Saxenda) -
hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness) : Unlikely
hypoglycemia that led her to faint with unconsciousness(Hypoglycemic unconsciousness) : Unlikely
Saxenda for prediabetes and metabolic syndrome(Product use in unapproved indication) : Possible

No consent for safety follow-up questions, hence no further follow-up is possible.

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	1.8 mg, qd; Subcutaneous	prediabetes (Glucose tolerance impaired) metabolic syndrome (Metabolic syndrome)	2023 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	UNK; Subcutaneous	prediabetes (Glucose tolerance impaired)	Unknown / DEC-2024; Unknown

Mfr. Control Number: 1447750

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
		metabolic syndrome (Metabolic syndrome)	
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	UNK; Subcutaneous	prediabetes (Glucose tolerance impaired) metabolic syndrome (Metabolic syndrome)	FEB-2025 / Unknown; Unknown