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)

Other Serious Criteria: Medically Significant
intoxicated and went to the emergency room.(The patient did not mention how long they stayed in the hospital). [Poisoning]

Case Description: 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).

(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) UNK

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

17. INDICATION(S) FOR USE
#1) Product used for unknown indication (P
(Continued on Additional Information Page)

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

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

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.
1470674

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

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

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

DATE OF THIS REPORT
04-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height, weight and body mass index was not reported.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "intoxicated and went to the emergency room.(The patient did not mention how long they stayed in the hospital).(Intoxication)" with an unspecified onset date and concerned a Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from APR-2024 for "Product used for unknown indication",

Dosage Regimens:
Saxenda: ??-APR-2024 to Not Reported;

Medical history was not provided.

On an unknown date patient discontinued Saxenda because the patient became intoxicated and went to the emergency room. Saxenda made the patient feel unwell (The patient did not mention how long they stayed in the hospital).

Batch Numbers:
Saxenda: was not reported

Action taken to Saxenda was reported as Product discont. not due to AE.

The outcome for the event "intoxicated and went to the emergency room.(The patient did not mention how long they stayed in the hospital).(Intoxication)" was Unknown.

Reporter's causality (Saxenda) -
intoxicated and went to the emergency room.(The patient did not mention how long they stayed in the hospital).(Intoxication) : Unknown

Company's causality (Saxenda) -
intoxicated and went to the emergency room.(The patient did not mention how long they stayed in the hospital).(Intoxication) : Unlikely

No further information available.

Company comment:
Poisoning is assessed as unlisted event according to the Novo Nordisk current CCDS information on Saxenda.
The limited information about relevant medical history, event onset date, details of intoxication, history of alcohol intake/substance use, product indication, diagnostic test reports, final diagnosis and concomitant medications interdict complete medical assessment of the case. With the available information, the causality for poisoning is assessed as unlikely related.
This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

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	UNK; Unknown	Product used for unknown indication (Product used for unknown indication)	APR-2024 / Unknown; Unknown