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		Unk	Male	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
depression [Depression]
rebound effect [Rebound effect]
strong side effects [Adverse drug reaction]

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

15. DAILY DOSE(S)
#1) UNK

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

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

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

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 to Ongoing	Current Condition Duration not reported	Obesity (Obesity)

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.
1472355

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

24c. DATE RECEIVED BY MANUFACTURER
02-JUL-2025

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

DATE OF THIS REPORT
10-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This serious Solicited Report from COSTA RICA was reported by a Consumer as "depression(Depression)" with an unspecified onset date , "rebound effect(Rebound effect)" with an unspecified onset date , "strong side effects(Drug side effect)" with an unspecified onset date and concerned a Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date for "Obesity",

Patient height, weight and Body mass index (BMI) was Not reported

Dosage Regimen of Saxenda was Not reported

Current Condition: Obesity.

On an unknown date it was reported that patient had very strong side effects (unspecified). There was a tremendous rebound effect, and fell into depression because of the medication.

Batch Number of Saxenda was Unknown

Action taken to Saxenda was reported as Product discontinued due to AE.

The outcome for the event "depression(Depression)" was Unknown.
The outcome for the event "rebound effect(Rebound effect)" was Unknown.
The outcome for the event "strong side effects(Drug side effect)" was Unknown.

Reporter's causality (Saxenda) -
depression(Depression) : Possible
rebound effect(Rebound effect) : Possible
strong side effects(Drug side effect) : Unknown

Company's causality (Saxenda) -
depression(Depression) : Unlikely
rebound effect(Rebound effect) : Unlikely
strong side effects(Drug side effect) : Unlikely

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

company comment:
Depression, rebound effect, and drug side effect are assessed as unlisted events according to the current Novo Nordisk CCDS information for Saxenda.
Information regarding the patient's demographics, product and event onset dates (to assess temporal relationship), social and lifestyle factors (such as smoking and alcohol use), and stress levels is not available, limiting the ability to conduct a thorough medical evaluation. However, obesity may be a con-tributing factor to depression. It can influence mental health through biologi-cal mechanisms such as hormonal imbalances and systemic inflammation, as well as psychological impacts including negative body image and social stig-ma. Furthermore, a sedentary lifestyle and poor dietary habits commonly as-sociated with obesity can exacerbate depressive symptoms, potentially creat-ing a vicious cycle between the two conditions. Considering the nature of the events, the limited clinical information available, and the presence of con-founding factors, the causality is assessed as unlikely to be related to Saxen-da.
This single case report does not alter the current understanding of the safety profile of Saxenda.