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		40 Years	Female	88.00 kg	14	APR	2025

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
was unable to control vomiting [Vomiting]
severe nausea [Nausea]
Dizziness [Dizziness]
fatigued [Fatigue]
nauseous [Nausea]
diarrhea [Diarrhoea]
stomach pain [Abdominal pain upper]
for 3 months and has only lost 6 kg / does not feel any difference in weight [Weight loss poor]

(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 {Lot # PP5M440; Exp.Dt. AUG-2026}

(Continued on Additional Information Page)

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) weight loss (Weight control)

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 07-APR-2025 / 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)
#1) APOZEMIA (METFORMIN HYDROCHLORIDE) ; APR-2025 / Ongoing
#2) ENANTYUM (DEXKETOPROFEN TROMETAMOL) ; Unknown

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 was not reported	Insulin resistance (Insulin resistance)
Unknown to Ongoing	Current Condition	Fatty liver (Hepatic steatosis)

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
World Wide #: CR-NOVOPROD-1417200

24b. MFR CONTROL NO.
1417200

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

24c. DATE RECEIVED BY MANUFACTURER
13-AUG-2025

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

DATE OF THIS REPORT
21-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

Patient's height: 165 cm.

Patient's weight: 88 kg.

Patient's BMI: 32.32323230.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "was unable to control vomiting(Vomiting)" beginning on AUG-2025 , "severe nausea(Nausea)" beginning on AUG-2025 , "Dizziness(Dizziness)" beginning on 14-APR-2025 , "fatigued(Fatigue)" beginning on 14-APR-2025 , "nauseous(Nauseous)" beginning on 14-APR-2025 , "diarrhea(Diarrhea)" beginning on 14-APR-2025 , "stomach pain(Stomach pain)" beginning on 14-APR-2025 , "for 3 months and has only lost 6 kg / does not feel any difference in weight(Weight loss poor)" beginning on MAY-2025 and concerned a 40 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 07-APR-2025 and ongoing for "weight loss", "insulin resistance", "glucose control",

Dosage Regimens:
Saxenda: 07-APR-2025 to Not Reported, Not Reported to Not Reported, ??-AUG-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Insulin resistance, fatty liver, thyroid issues, glucose control, Headaches.

Concomitant medications included - APOZEMIA(METFORMIN HYDROCHLORIDE), ENANTYUM(DEXKETOPROFEN TROMETAMOL).

On 14-APR-2025, patient experienced dizziness, fatigued, nauseous, significant stomach pain, and diarrhea. No treatment was received. The patient believed that during the first few weeks of using the medication, there is significant stomach discomfort and nausea, which was causing weight loss because the patient can hardly eat due to the level of nausea and ends up vomiting everything consumed.

On an unknown date in APR-2025 (first month of treatment), patient lost 5 kg weight (Weight). Then in MAY-2025, patient lost 3 kg-6 kg weight (Weight). Currently, the patient continued using the medication but did not feel any difference in weight.

Patient indicated that they spent the entire Holy Week in bed due to the effects. The patient didn't increased to 1.8 mg as prescribed.

On an unknown date in AUG-2025, the patient experienced severe nausea and was unable to control vomiting, which led the patient to visit the emergency room, where intravenous fluids were administered.

Despite starting exercise routines that the patient had not been doing and controlling his/her diet, the patient had only lost 2 kg in 2 months.

Batch Numbers:
Saxenda: PP5M440, PP5M440, PP5M440;

Action taken to Saxenda was reported as Dose Decreased.

The outcome for the event "was unable to control vomiting(Vomiting)" was Recovered.
The outcome for the event "severe nausea(Nausea)" was Recovered.
The outcome for the event "Dizziness(Dizziness)" was Not recovered.
The outcome for the event "fatigued(Fatigue)" was Not recovered.
The outcome for the event "nauseous(Nauseous)" was Not recovered.
The outcome for the event "diarrhea(Diarrhea)" was Not recovered.
The outcome for the event "stomach pain(Stomach pain)" was Not recovered.
The outcome for the event "for 3 months and has only lost 6 kg / does not feel any difference in weight(Weight loss poor)" was Not recovered.

Reporter's causality (Saxenda) -
was unable to control vomiting(Vomiting) : Possible
severe nausea(Nausea) : Possible
Dizziness(Dizziness) : Unlikely
fatigued(Fatigue) : Unlikely
nauseous(Nauseous) : Possible

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

diarrhea(Diarrhea) : Unlikely
stomach pain(Stomach pain) : Possible
for 3 months and has only lost 6 kg / does not feel any difference in weight(Weight loss poor) : Possible

Company's causality (Saxenda) -
was unable to control vomiting(Vomiting) : Possible
severe nausea(Nausea) : Possible
Dizziness(Dizziness) : Possible
fatigued(Fatigue) : Possible
nauseous(Nauseous) : Possible
diarrhea(Diarrhea) : Possible
stomach pain(Stomach pain) : Possible
for 3 months and has only lost 6 kg / does not feel any difference in weight(Weight loss poor) : Unlikely

Since last submission case has been updated with the following information:
-Patient weight updated
-Medical history glucose control, Headaches added
-Lab data added
-Suspected product indication and dosage details updated
-Concomitant medications APOZEMIA, ENANTYUM added
-Event Saxenda prescribed for insulin resistance removed
-New events severe nausea, was unable to control vomiting, for 3 months and has only lost 6 kg / does not feel any difference in weight added
-Reporter causality for the events nauseous, stomach pain updated from Unlikely to Possible
-Updated narrative accordingly

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1417200
Reference Notes:

Company comment:
Vomiting, nausea (2 events), dizziness, fatigue, Diarrhoea, Abdominal pain upper are assessed as listed events according to the Novo Nordisk current reference safety information on Saxenda.
Based on the safety profile and pharmacological properties of the suspect product (GLP-1 analogue), possible causality cannot be denied in this case.
Considering the nature of the event with the pharmacological properties of the suspect product, causality is assessed as possibly related.
This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight On an unknown date, patient had only lost 2 kg weight (Weight) in 2 months.		
2	APR-2025	Weight On an unknown date in APR-2025, patient lost 5 kg weight (Weight).		
3	MAY-2025	Weight On an unknown date in MAY-2025, patient lost 3-6 kg weight (Weight).		

13. Relevant Tests

On an unknown date, patient had only lost 2 kg weight (Weight) in 2 months.
On an unknown date in MAY-2025, patient lost 3-6 kg weight (Weight).
On an unknown date in APR-2025, patient lost 5 kg weight (Weight).

Mfr. Control Number: 1417200

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 {Lot # PP5M440; Exp.Dt. AUG-2026}; Regimen #1	1.2 mg, qd; Subcutaneous	weight loss (Weight control) insulin resistance (Insulin resistance) glucose control (Blood glucose abnormal)	07-APR-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5M440; Exp.Dt. AUG-2026}; Regimen #2	UNK(Dose decreased); Subcutaneous	weight loss (Weight control) insulin resistance (Insulin resistance) glucose control (Blood glucose abnormal)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5M440; Exp.Dt. AUG-2026}; Regimen #3	3 mg; Subcutaneous	weight loss (Weight control) insulin resistance (Insulin resistance) glucose control (Blood glucose abnormal)	AUG-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Thyroid disorder (Thyroid disorder);
Unknown to Ongoing	Current Condition	Glucose abnormal (Blood glucose abnormal);
Unknown to Ongoing	Current Condition	Headache (Headache);