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		61 Years	Female	64.50 kg	07	FEB	2025

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

nausea [Nausea]
vomiting [Vomiting]
Dehydration [Dehydration]
fever [Pyrexia]

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 **(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) 1.8 mg, qd

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

17. INDICATION(S) FOR USE
#1) For weight loss (Weight control)

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

18. THERAPY DATES(from/to)
#1) JAN-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) Tresiba FlexTouch (Insulin Degludec) Solution for injection ; 2015 / Ongoing
#2) NovoRapid FlexPen (Insulin Aspart 100 U/mL) Solution for injection, 1
#3) FOLIC ACID (FOLIC ACID) ; 2020 / Ongoing
#4) JARDIANCE (EMPAGLIFLOZIN) ; 2021 / Ongoing
#5) VITAMIN D NOS (VITAMIN D NOS) ; 2020 / Ongoing
#6) ROSUVASTATIN (ROSUVASTATIN) ; 2015 / Ongoing **(Continued on Additional Information Page)**

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
2010 to Ongoing	Current Condition suffering from it for 15 years.	Type 1 diabetes mellitus (Type 1 diabetes mellitus)
2010 to Ongoing	Current Condition suffering from it for 15 years	Hypercholesterolemia (Hypercholesterolaemia)

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.
1409258

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

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

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 1409258

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

support program with focus on exercise, motivation, nutrition & maintaining strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 155 cm.

Patient's weight: 64.5 kg.

Patient's BMI: 26.84703430.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nausea(Nausea)" beginning on 07-FEB-2025 , "vomiting(Vomiting)" beginning on 07-FEB-2025 , "Dehydration(Dehydration)" beginning on 07-FEB-2025 , "fever(Fever)" beginning on 07-FEB-2025 and concerned a 61 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JAN-2025 and ongoing for "For weight loss",

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

Current Condition: Type 1 diabetes, Hypercholesterolaemia, dyslipidemia.

Concomitant medications included - Tresiba FlexTouch(Insulin Degludec), NovoRapid FlexPen(Insulin Aspart 100 U/mL), FOLIC ACID, JARDIANCE(EMPAGLIFLOZIN), VITAMIN D NOS, ROSUVASTATIN.

Batch Numbers:
Saxenda: PP5M440, PP5M440;

Action taken to Saxenda was reported as Dose Decreased.

On 10-FEB-2025 the outcome for the event "nausea(Nausea)" was Recovered.
On 10-FEB-2025 the outcome for the event "vomiting(Vomiting)" was Recovered.
On 10-FEB-2025 the outcome for the event "Dehydration(Dehydration)" was Recovered.
On 10-FEB-2025 the outcome for the event "fever(Fever)" was Recovered.

Reporter's causality (Saxenda) -
nausea(Nausea) : Unknown
vomiting(Vomiting) : Unknown
Dehydration(Dehydration) : Unknown
fever(Fever) : Unknown

Company's causality (Saxenda) -
nausea(Nausea) : Possible
vomiting(Vomiting) : Possible
Dehydration(Dehydration) : Possible
fever(Fever) : Unlikely

Reporter Comment: Treatment: oral rehydration solutions for Dehydration, nausea, vomiting and fever
Ezetin (active ingredient is not mentioned) (non codeable) has been used for 3 years for Hypercholesterolemia , at a dose of 10 mg per day.

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 #2	0.6 mg, qd; Subcutaneous	For weight loss (Weight control)	Ongoing; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) NovoRapid FlexPen (Insulin Aspart 100 U/mL) Solution for injection, 100 U/mL; 2015 / Ongoing

Mfr. Control Number: 1409258

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

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