

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 61 Years	3. SEX Female	3a. WEIGHT 64.50 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year			Day	Month	Year		
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)

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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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.) <table border="0"> <tr> <td>From/To Dates</td> <td>Type of History / Notes</td> <td>Description</td> </tr> <tr> <td>2010 to Ongoing</td> <td>Current Condition</td> <td>Type 1 diabetes mellitus (Type 1 diabetes mellitus) suffering from it for 15 years.</td> </tr> <tr> <td>2010 to Ongoing</td> <td>Current Condition</td> <td>Hypercholesterolemia (Hypercholesterolaemia) suffering from it for 15 years</td> </tr> </table>		From/To Dates	Type of History / Notes	Description	2010 to Ongoing	Current Condition	Type 1 diabetes mellitus (Type 1 diabetes mellitus) suffering from it for 15 years.	2010 to Ongoing	Current Condition	Hypercholesterolemia (Hypercholesterolaemia) suffering from it for 15 years
From/To Dates	Type of History / Notes	Description								
2010 to Ongoing	Current Condition	Type 1 diabetes mellitus (Type 1 diabetes mellitus) suffering from it for 15 years.								
2010 to Ongoing	Current Condition	Hypercholesterolemia (Hypercholesterolaemia) suffering from it for 15 years								

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 05-MAY-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 19-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

19-May-2025 09:33

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 (Simvastatin and Ezetimibe) (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

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

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