

## SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>62</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>73.00</b> 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	
			<b>PRIVACY</b>					<b>26</b>	<b>MAY</b>	<b>2024</b>	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
migraines [Migraine]  
gas/flatulence [Flatulence]  
constipation [Constipation]  
belching [Eructation]  
nausea [Nausea]  
A lot of abdominal pain [Abdominal pain]  
a lot bloating [Abdominal distension]  
diarrhea [Diarrhoea]  
has plateaued in her weight [Weight loss poor]  
vomiting [Vomiting]

(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		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 ) 0.6 mg, qd	16. ROUTE(S) OF ADMINISTRATION #1 ) Subcutaneous	
17. INDICATION(S) FOR USE #1 ) Fatty liver (Hepatic steatosis)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 26-MAY-2024 / Ongoing	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 ) EUTIROX (LEVOTHYROXINE SODIUM) ; 2015 / Ongoing #2 ) CORTISONE (CORTISONE) ; Ongoing		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown to Ongoing	Type of History / Notes Current Condition 7 or 8 years ago	Description Fatty liver (Hepatic steatosis)
Unknown to Ongoing	Current Condition 20 years ago	Fibromyalgia (Fibromyalgia)

## 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. <b>1415617</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>21-MAY-2025</b>	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 <b>09-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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**ADDITIONAL INFORMATION****7+13. DESCRIBE REACTION(S) continued**

Hemorrhoids more frequently during the treatment [Haemorrhoids]  
Gastroenterologist prescribed the Saxenda for Lower fatty liver [Off label use]

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

Patient's height: 156 cm.

Patient's weight: 73 kg.

Patient's BMI: 29.99671270.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "migraines(Migraine)" beginning on 26-MAY-2024 , "gas/flatulence(Flatulence)" beginning on 26-MAY-2024 , "constipation(Constipation)" beginning on 26-MAY-2024 , "belching(Belching)" beginning on 26-MAY-2024 , "nausea(Nausea)" beginning on 26-MAY-2024 , "A lot of abdominal pain(Abdominal pain)" beginning on 26-MAY-2024 , "a lot bloating(Bloating)" beginning on 26-MAY-2024 , "diarrhea(Diarrhea)" beginning on 26-MAY-2024 , "has plateaued in her weight(Weight loss poor)" beginning on 26-MAY-2024 \*\*\*\*\* There are more than 9 events available in this case, The list of all the events - "Gastroenterologist prescribed the Saxenda for Lower fatty liver(Off label use in unapproved indication),constipation(Constipation),nausea(Nausea),A lot of abdominal pain(Abdominal pain),a lot bloating(Bloating),belching(Belching),migraines(Migraine),diarrhea(Diarrhea),has plateaued in her weight(Weight loss poor),Hemorrhoids more frequently during the treatment(Hemorrhoids aggravated),vomiting(Vomiting),gas/flatulence(Flatulence)" \*\*\*\*\* and concerned a 62 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 26-MAY-2024 and ongoing for "Fatty liver",

Dosage Regimens:

Saxenda: 26-MAY-2024 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Fatty liver, Fibromyalgia, Hypothyroidism, hemorrhoids.

Concomitant medications included - EUTIROX(LEVOTHYROXINE SODIUM), CORTISONE.

Treatment medications included - NEXIUM [ESOMEPRAZOLE SODIUM](ESOMEPRAZOLE SODIUM), MIGRADORIXINA(CLONIXIN LYSINATE, ERGOTAMINE TARTRATE), SOLUGASTRIL [SIMETICONE](SIMETICONE), RIOPAN [DIMETICONE;MAGALDRATE](DIMETICONE, MAGALDRATE).

Batch Numbers:

Saxenda: ASKU;

Action taken to Saxenda was reported as No Change.

On MAY-2025 the outcome for the event "migraines(Migraine)" was Recovered.  
The outcome for the event "gas/flatulence(Flatulence)" was Recovering/resolving.  
The outcome for the event "constipation(Constipation)" was Recovering/resolving.  
The outcome for the event "belching(Belching)" was Recovering/resolving.  
On MAY-2025 the outcome for the event "nausea(Nausea)" was Recovered.  
On FEB-2025 the outcome for the event "A lot of abdominal pain(Abdominal pain)" was Recovered.  
On FEB-2025 the outcome for the event "a lot bloating(Bloating)" was Recovered.  
On FEB-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.  
The outcome for the event "has plateaued in her weight(Weight loss poor)" was Recovering/resolving.  
\*\*\*\*\* There are more than 9 events available in this case \*\*\*\*\*

Reporter's causality (Saxenda) -

migraines(Migraine) : Possible

gas/flatulence(Flatulence) : Possible

constipation(Constipation) : Possible

belching(Belching) : Possible

nausea(Nausea) : Possible

A lot of abdominal pain(Abdominal pain) : Possible

a lot bloating(Bloating) : Possible

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**ADDITIONAL INFORMATION****7+13. DESCRIBE REACTION(S) continued**

diarrhea(Diarrhea) : Possible  
has plateaued in her weight(Weight loss poor) : Possible

Company's causality (Saxenda) -  
migraines(Migraine) : Unlikely  
gas/flatulence(Flatulence) : Possible  
constipation(Constipation) : Possible  
belching(Belching) : Possible  
nausea(Nausea) : Possible  
A lot of abdominal pain(Abdominal pain) : Possible  
a lot bloating(Bloating) : Possible  
diarrhea(Diarrhea) : Possible  
has plateaued in her weight(Weight loss poor) : Unlikely

Reporter Comment: Treatment: Alevian Duo 100 mg(pinaverium bromide) and intravenous fluids (does not provide further information) (non codable) for gas, belching, flatulence, constipation, plateaued in weight. Patients migraines has every two months for 4or5 days throughout head and pressure in eyes, experience during menstrual periods, relates it to digestive issues due to excess gas, constipation, and not sleeping well because of the vomiting.

**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition 35 years ago	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition	Hemorrhoids (Haemorrhoids);