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		55 Years	Female	96.00 kg		DEC	2024

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

diarrhea [Diarrhoea]
strong sulfur taste in the mouth [Dysgeusia]
A lot of gas [Flatulence]
diarrhea [Diarrhoea]
Hives on her back for three days [Urticaria]
Digestive problems [Dyspepsia]
Itching in the arms [Pruritus]
Tongue with white spots [Tongue coated]
ME: Initial dose of 3 mg (Saxenda) [Off label use]

(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) 3 mg, qd

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

17. INDICATION(S) FOR USE
#1) metabolic syndrome (Metabolic syndrome)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) DEC-2024 / 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) LEVOTHYROXINE (LEVOTHYROXINE) ; 2025 / Ongoing
#2) IRBESARTAN (IRBESARTAN) ; 2020 / Ongoing
#3) PREBICTAL (PREGABALIN) ; MAR-2025 / Ongoing
#4) BETADUO (BETAMETHASONE DIPROPIONATE, BETAMETHASONE
#5) XUMER (ETORICOXIB) ; 12-FEB-2025 / 18-FEB-2025
#6) CHLORPHENIRAMINE [CHLORPHENAMINE MALEATE] (CHLORPHE **(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 15 years ago	Metabolic syndrome (Metabolic syndrome)
2005 to Ongoing	Current Condition Glucose intolerance - more than 20 years	Prediabetes (Glucose tolerance impaired)

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.
1434961

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

24c. DATE RECEIVED BY MANUFACTURER
09-JUN-2025

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 157 cm.

Patient's weight: 96 kg.

Patient's BMI: 38.94681330.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "diarrhea(Diarrhea)" beginning on FEB-2025 , "strong sulfur taste in the mouth(Taste pungent)" beginning on 18-MAY-2025 , "A lot of gas(Gas)" beginning on 18-MAY-2025 , "diarrhea(Diarrhea)" beginning on 18-MAY-2025 , "Hives on her back for three days(Hives)" beginning on DEC-2024 , "Digestive problems(Digestion impaired)" beginning on FEB-2025 , "Itching in the arms(Itching-generalised)" with an unspecified onset date , "Tongue with white spots(Coated tongue)" with an unspecified onset date , "ME: Initial dose of 3 mg (Saxenda)(Off label dosing)" beginning on JUN-2025 and concerned a 55 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from DEC-2024 and ongoing for "metabolic syndrome", "prediabetes", "weight loss",

Dosage Regimens:
Saxenda: ??-DEC-2024 to Not Reported, Not Reported to Not Reported, Not Reported to Not Reported, 18-MAY-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Metabolic syndrome, Prediabetes, Hypothyroidism, Hypertension, Skin allergies, Back injury, Obesity.

Concomitant medications included - LEVOTHYROXINE, IRBESARTAN, PREBICTAL(PREGABALIN), BETADUO(BETAMETHASONE DIPROPIONATE, BETAMETHASONE SODIUM PHOSPHATE), XUMER(ETORICOXIB), CHLORPHENIRAMINE CHLORPHENAMINE MALEATE.

Batch Numbers:
Saxenda: PP5M440, PP5M440, PP5M440, PP5M440;

Action taken to Saxenda was reported as Drug discontinued temporarily.

On FEB-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.
The outcome for the event "strong sulfur taste in the mouth(Taste pungent)" was Not recovered.
The outcome for the event "A lot of gas(Gas)" was Not recovered.
The outcome for the event "diarrhea(Diarrhea)" was Not recovered.
On DEC-2024 the outcome for the event "Hives on her back for three days(Hives)" was Recovered.
On FEB-2025 the outcome for the event "Digestive problems(Digestion impaired)" was Recovered.
The outcome for the event "Itching in the arms(Itching-generalised)" was Not recovered.
The outcome for the event "Tongue with white spots(Coated tongue)" was Not recovered.
The outcome for the event "ME: Initial dose of 3 mg (Saxenda)(Off label dosing)" was Not recovered.

Reporter's causality (Saxenda) -
diarrhea(Diarrhea) : Probable
strong sulfur taste in the mouth(Taste pungent) : Possible
A lot of gas(Gas) : Possible
diarrhea(Diarrhea) : Possible
Hives on her back for three days(Hives) : Possible
Digestive problems(Digestion impaired) : Probable
Itching in the arms(Itching-generalised) : Unknown
Tongue with white spots(Coated tongue) : Unknown
ME: Initial dose of 3 mg (Saxenda)(Off label dosing) : Unknown

Company's causality (Saxenda) -
diarrhea(Diarrhea) : Possible
strong sulfur taste in the mouth(Taste pungent) : Possible
A lot of gas(Gas) : Possible
diarrhea(Diarrhea) : Possible
Hives on her back for three days(Hives) : Possible

Mfr. Control Number: 1434961

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Digestive problems(Digestion impaired) : Possible
Itching in the arms(Itching-generalised) : Unlikely
Tongue with white spots(Coated tongue) : Unlikely
ME: Initial dose of 3 mg (Saxenda)(Off label dosing) : Possible

Reporter Comment: Patient taking Chlorpheniramine: started 3 years ago currently ongoing dosage one tablet daily oral indication skin allergies (Non-codable).
on JUN-2025, patient experienced the symptoms of diarrhea and gas with a sulfur taste after administering the dose of 2.4 mg. The symptoms are different from those previously reported (a lot of gas, diarrhea, and a strong sulfur taste in the mouth).

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	3 mg, qd; Subcutaneous	metabolic syndrome (Metabolic syndrome) prediabetes (Glucose tolerance impaired) weight loss (Weight control)	DEC-2024 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5M440; Exp.Dt. AUG-2026}; Regimen #2	2.4 mg, qd (dose reduced); Subcutaneous	metabolic syndrome (Metabolic syndrome) prediabetes (Glucose tolerance impaired) weight loss (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5M440; Exp.Dt. AUG-2026}; Regimen #3	3 mg, qd; Subcutaneous	metabolic syndrome (Metabolic syndrome) prediabetes (Glucose tolerance impaired) weight loss (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL {Lot # PP5M440; Exp.Dt. AUG-2026}; Regimen #4	0.6 mg, qd (restart); Subcutaneous	metabolic syndrome (Metabolic syndrome) prediabetes (Glucose tolerance impaired) weight loss (Weight control)	18-MAY-2025 / Ongoing; Unknown

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

#4) BETADUO (BETAMETHASONE DIPROPIONATE, BETAMETHASONE SODIUM PHOSPHATE) ; FEB-2025 / 2025

#6) CHLORPHENIRAMINE [CHLORPHENAMINE MALEATE] (CHLORPHENAMINE MALEATE) ; 2022 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Hypothyroidism (Hypothyroidism);
Unknown to Ongoing	Current Condition	Hypertension (Hypertension);
Unknown to Ongoing	Current Condition	Allergic skin reaction (Dermatitis allergic);
Unknown to Ongoing	Current Condition	Back injury (Back injury);
Unknown to Ongoing	Current Condition	Obesity (Obesity);