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		54 Years	Female	76.70 kg		MAY	2025

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

terrible diarrhea [Diarrhoea]
Pain [Pain]
Candida infection [Candida infection]

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

(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

15. DAILY DOSE(S)
#1) 3 mg, qd

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

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

18. THERAPY DATES(from/to)
#1) NOV-2024 / Unknown

19. THERAPY DURATION
#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) IRBESARTAN (IRBESARTAN) ; Ongoing
#2) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) Tablet ; Ongoing
#3) LOVASTATIN (LOVASTATIN) ; Ongoing
#4) THYROXINE (LEVOTHYROXINE SODIUM) Tablet ; Ongoing
#5) GABAPENTIN (GABAPENTIN) Tablet ; Ongoing
#6) VENLAFAXINE (VENLAFAXINE) Tablet ; 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
Unknown to Ongoing	Current Condition Duration not reported.	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Glaucoma (Glaucoma)

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.
1460017

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

24c. DATE RECEIVED BY MANUFACTURER
12-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

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 157 cm.

Patient's weight: 76.7 kg.

Patient's BMI: 31.116881.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "terrible diarrhea(Diarrhea)" beginning on MAY-2025 , "Pain(Pain)" beginning on MAY-2025 , "Candida infection(Candida infection)" beginning on MAY-2025 and concerned a 54 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from NOV-2024 for "Obesity",

Dosage Regimens:
Saxenda: ??-NOV-2024 to Not Reported;

Current Condition: Obesity, Glaucoma in prevention, Hypertension, Insulin resistance, Menopause, Depression, knee pain, cramps, High cholesterol
Procedure: Arthroscopy.

Concomitant medications included - IRBESARTAN, HYDROCHLOROTHIAZIDE, LOVASTATIN, THYROXINE(LEVOTHYROXINE SODIUM), GABAPENTIN, VENLAFAXINE, ACETYLSALICYLIC ACID.

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as Drug discontinued temporarily.

The outcome for the event "terrible diarrhea(Diarrhea)" was Recovering/resolving.
The outcome for the event "Pain(Pain)" was Recovering/resolving.
The outcome for the event "Candida infection(Candida infection)" was Recovering/resolving.

Reporter's causality (Saxenda) -
terrible diarrhea(Diarrhea) : Unknown
Pain(Pain) : Unlikely
Candida infection(Candida infection) : Unlikely

Company's causality (Saxenda) -
terrible diarrhea(Diarrhea) : Possible
Pain(Pain) : Unlikely
Candida infection(Candida infection) : Unlikely

Reporter Comment: Patient was given NSAIDs (allergic to Non-Steroidal Anti-Inflammatory Drugs) for events pain and a Candida infection. (Non specified and non codable)
Saxenda was paused until the date: June 10, 2025.
Treatment: Ovals for Candida and Enterogermina for diarrhea. (Non codable and non specified)

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

#7) ACETYLSALICYLIC ACID (ACETYLSALICYLIC ACID) ; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Hypertension (Hypertension);
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance);
Unknown to Ongoing	Current Condition	Menopause (Menopause);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Depression (Depression);
Unknown to Ongoing	Current Condition	Knee pain (Arthralgia);
Unknown to Ongoing	Current Condition	Cramps (Muscle spasms);
Unknown to Ongoing	Current Condition	High cholesterol (Blood cholesterol increased);
Unknown to Ongoing	Procedure	Arthroscopic surgery (Arthroscopic surgery);