CIOMS FORM

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		42 Years	Female	97.00 kg	01	DEC	2023

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

strong stomach ache [Abdominal pain upper]
acute diarrhoea [Diarrhoea]
unable to go to the bathroom for several days (understood as constipated) [Constipation]
Strong diarrhea [Diarrhoea]
dryness in her mouth [Dry mouth]
occasionally has gas [Flatulence]
foul-smelling burps [Eructation]

Case Description: ***This is an auto generated narrative***

(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) Solution for injection, 6 mg/mL

(Continued on Additional Information Page)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) AUG-2023 / NOV-2023	#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)

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	Insulin resistance (Insulin resistance)

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.
1150727

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

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

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

DATE OF THIS REPORT
26-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 162 cm.

Patient's weight: 97 kg.

Patient's BMI: 36.96082910.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "strong stomach ache(Stomach ache)" beginning on 01-DEC-2023 , "acute diarrhoea(Acute diarrhoea)" beginning on 01-DEC-2023 , "unable to go to the bathroom for several days (understood as constipated)(Constipation)" beginning on 06-MAY-2025 , "Strong diarrhea(Diarrhea)" beginning on 06-MAY-2025 , "dryness in her mouth(Dry mouth)" beginning on MAY-2025 , "occasionally has gas(Gas)" beginning on MAY-2025 , "foul-smelling burps(Malodorous burping)" beginning on MAY-2025 and concerned a 42 Years old Female patient who was treated with Saxenda (liraglutide) from AUG-2023 and ongoing for "Obesity",

Dosage Regimens:
Saxenda: ??-AUG-2023 to ??-NOV-2023, ??-DEC-2023 to Not Reported, 04-MAY-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Insulin resistance.

Treatment medications included - DUSPATALIN MEBEVERINE HYDROCHLORIDE.

Batch Numbers:
Saxenda: UNK, UNK, UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "strong stomach ache(Stomach ache)" was Not recovered.
The outcome for the event "acute diarrhoea(Acute diarrhoea)" was Recovered.
On 08-MAY-2025 the outcome for the event "unable to go to the bathroom for several days (understood as constipated)(Constipation)" was Recovered.
On 08-MAY-2025 the outcome for the event "Strong diarrhea(Diarrhea)" was Recovered.
The outcome for the event "dryness in her mouth(Dry mouth)" was Recovering/resolving.
The outcome for the event "occasionally has gas(Gas)" was Recovering/resolving.
The outcome for the event "foul-smelling burps(Malodorous burping)" was Recovering/resolving.

Reporter's causality (Saxenda) -
strong stomach ache(Stomach ache) : Possible
acute diarrhoea(Acute diarrhoea) : Possible
unable to go to the bathroom for several days (understood as constipated)(Constipation) : Possible
Strong diarrhea(Diarrhea) : Possible
dryness in her mouth(Dry mouth) : Possible
occasionally has gas(Gas) : Possible
foul-smelling burps(Malodorous burping) : Possible

Company's causality (Saxenda) -
strong stomach ache(Stomach ache) : Possible
acute diarrhoea(Acute diarrhoea) : Possible
unable to go to the bathroom for several days (understood as constipated)(Constipation) : Possible
Strong diarrhea(Diarrhea) : Possible
dryness in her mouth(Dry mouth) : Possible
occasionally has gas(Gas) : Possible
foul-smelling burps(Malodorous burping) : Possible

Reporter Comment: had to go to the physician because of the symptoms. Patient received treatment but does not specify

Mfr. Control Number: 1150727

ADDITIONAL INFORMATION

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) Solution for injection, 6 mg/mL; Regimen #2	0.6 mg, qd; Subcutaneous	Obesity (Obesity)	DEC-2023 / Unknown; Unknown
#1) Saxenda (liraglutide) Solution for injection, 6 mg/mL; Regimen #3	UNK(resumed dose); Subcutaneous	Obesity (Obesity)	04-MAY-2025 / Ongoing; Unknown