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		50 Years	Male	123.50 kg		MAY	2025

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

Patient became pale [Pallor]
feel very unwell [Malaise]
significant stomach heaviness [Abdominal discomfort]
diarrhea [Diarrhoea]
abdominal pain [Abdominal pain]
gastritis [Gastritis]
foul-smelling burps (excessive belching) [Eructation]
nausea [Nausea]
stomach cramps [Abdominal pain upper]
delayed digestion [Dyspepsia]

(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 # PP5L468; Exp.Dt. JUN-2026}

15. DAILY DOSE(S)
#1) 0.6 mg, qd

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

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

18. THERAPY DATES(from/to)
#1) MAY-2025 / JUN-2025

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)

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	Fatty liver (Hepatic steatosis)

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.
1481833

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

24c. DATE RECEIVED BY MANUFACTURER
11-JUL-2025

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

DATE OF THIS REPORT
28-AUG-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: 186 cm.

Patient's weight: 123.5 kg.

Patient's BMI: 35.69776850.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Patient became pale(Pale)" beginning on MAY-2025 , "feel very unwell(Feeling unwell)" beginning on MAY-2025 , "significant stomach heaviness(Stomach heaviness)" beginning on MAY-2025 , "diarrhea(Diarrhea)" beginning on MAY-2025 , "abdominal pain(Abdominal pain)" beginning on MAY-2025 , "gastritis(Gastritis)" beginning on MAY-2025 , "foul-smelling burps (excessive belching)(Malodorous burping)" beginning on MAY-2025 , "nausea(Nausea)" beginning on MAY-2025 , "stomach cramps(Stomach cramps)" beginning on MAY-2025 ******* There are more than 9 events available in this case, The list of all the events - "feel very unwell(Feeling unwell),foul-smelling burps (excessive belching)(Malodorous burping),significant stomach heaviness(Stomach heaviness),diarrhea(Diarrhea),abdominal pain(Abdominal pain),gastritis(Gastritis),nausea(Nausea),stomach cramps(Stomach cramps),delayed digestion(Digestion impaired),Patient became pale(Pale)" ******* and concerned a 50 Years old Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2025 to JUN-2025 for "Obesity",

Dosage Regimens:
Saxenda: ??-MAY-2025 to ??-JUN-2025;

Current Condition: Obesity, Fatty liver.

Lab Data included:
Lab Data Test as Reported: Weight
Test Name: Weight
Comments: On an unknown date, patient lost 10 kg.

Batch Numbers:
Saxenda: PP5L468;

Action taken to Saxenda was reported as Product discontinued due to AE.

On JUN-2025 the outcome for the event "Patient became pale(Pale)" was Recovered.
On JUN-2025 the outcome for the event "feel very unwell(Feeling unwell)" was Recovered.
On JUN-2025 the outcome for the event "significant stomach heaviness(Stomach heaviness)" was Recovered.
On JUN-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.
On JUN-2025 the outcome for the event "abdominal pain(Abdominal pain)" was Recovered.
On JUN-2025 the outcome for the event "gastritis(Gastritis)" was Recovered.
On JUN-2025 the outcome for the event "foul-smelling burps (excessive belching)(Malodorous burping)" was Recovered.
On JUN-2025 the outcome for the event "nausea(Nausea)" was Recovered.
On JUN-2025 the outcome for the event "stomach cramps(Stomach cramps)" was Recovered.
******* There are more than 9 events available in this case *******

Reporter's causality (Saxenda) -
Patient became pale(Pale) : Possible
feel very unwell(Feeling unwell) : Possible
significant stomach heaviness(Stomach heaviness) : Possible
diarrhea(Diarrhea) : Possible
abdominal pain(Abdominal pain) : Possible
gastritis(Gastritis) : Possible
foul-smelling burps (excessive belching)(Malodorous burping) : Possible
nausea(Nausea) : Possible
stomach cramps(Stomach cramps) : Possible

Company's causality (Saxenda) -

Mfr. Control Number: 1481833

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient became pale(Pale) : Unlikely
feel very unwell(Feeling unwell) : Possible
significant stomach heaviness(Stomach heaviness) : Possible
diarrhea(Diarrhea) : Possible
abdominal pain(Abdominal pain) : Possible
gastritis(Gastritis) : Possible
foul-smelling burps (excessive belching)(Malodorous burping) : Possible
nausea(Nausea) : Possible
stomach cramps(Stomach cramps) : Possible

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Weight On an unknown date, patient lost 10 kg.		

13. Relevant Tests

On an unknown date, patient lost 10 kg.