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		45 Years	Female	112.00 kg	20	APR	2024

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

Other Serious Criteria: Medically Significant
inflammation in pancreas [Pancreatitis]

Case Description: 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: 167 cm.

(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) 0.6 mg, qd

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

17. INDICATION(S) FOR USE
#1) weight loss (Weight control)

18. THERAPY DATES(from/to)
#1) 18-APR-2024 / 21-APR-2024

19. THERAPY DURATION
#1) 3 days

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
2005 to Unknown	Current Condition	Gallstones (Cholelithiasis)
	which caused a pancreatitis attack	
2005 to Unknown	Current Condition	Pancreatitis (Pancreatitis)
	after that, the patient had surgery	

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
World Wide #: CR-NOVOPROD-1450823

24b. MFR CONTROL NO.
1450823

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

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's weight: 112 kg.
Patient's BMI: 40.15920260.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "inflammation in pancreas(Pancreatic inflammation)" beginning on 20-APR-2024 and concerned a 45 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 18-APR-2024 to 21-APR-2024 for "weight loss",

Dosage Regimens:
Saxenda: 18-APR-2024 to 21-APR-2024;

Current Condition: don't drink alcohol, gallstones, pancreatitis attack.

Treatment medications included - FAMOTIDINE.

On an unknown date, the patient’s leukocyte count (White blood cell count) was found to be 5 (units not reported). Liver enzyme levels (Hepatic enzyme) were recorded as 0.572 (units not reported). C-reactive protein (C-reactive protein) was reported as positive, and the amylase level (Amylase)was 46 (units not reported).

On 20-APR-2024, the patient experienced very severe pancreatic inflammation and nausea and the stomach became very swollen. This required discontinuation of the medication and hospital visits. The reaction was identified as a side effect since the patient has no underlying conditions

On an unknown date in FEB-2025, the patient underwent an ultrasound(Ultrasound scan)for which result was not provided.

Batch Number of Saxenda was requested

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

On OCT-2024 the outcome for the event "inflammation in pancreas(Pancreatic inflammation)" was Recovered.

Reporter's causality (Saxenda) -
  inflammation in pancreas(Pancreatic inflammation) : Possible

Company's causality (Saxenda) -
  inflammation in pancreas(Pancreatic inflammation) : Possible

Since last submission the case has been updated with the following:
- Medical history updated
- Lab data updated
- Rechallenge updated
- Narrative updated accordingly.

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1450823
Reference Notes:

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Amylase 46 (units were not reported)		
2		C-reactive protein Positive		
3		Hepatic enzyme 0.572 (units were not reported)		

Mfr. Control Number: 1450823

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
4	FEB-2025	Ultrasound scan On an unknown date in ??-FEB-2025, the patient underwent Ultrasound (result not reported)		
5		White blood cell count 5 (units were not reported)		

13. Relevant Tests

On an unknown date in ??-FEB-2025, the patient underwent Ultrasound (result not reported)
On an unknown date, the patient’s leukocyte count (White blood cell count) was found to be 5 (units not reported). Liver enzyme levels (Hepatic enzyme) were recorded as 0.572 (units not reported). C-reactive protein (C-reactive protein) was reported as positive, and the amylase level (Amylase)was 46 (units not reported).

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Abstains from alcohol (Abstains from alcohol);