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		48 Years	Female	99.00 kg		JUL	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
chronic granulomatous mastitis [Plasma cell mastitis]
rebound effect [Rebound effect]
nausea [Nausea]
stomach hurt a lot [Abdominal pain upper]
sensitivity in the area of application [Injection site discomfort]
disgust [Malaise]
Vomiting [Vomiting]

Case Description: Study ID: 828652-My Healthy Journey

(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

(Continued on Additional Information Page)

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

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

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

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

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) JUL-2024 / DEC-2024

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) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METF
#2) LEVOTHYROXINE (LEVOTHYROXINE) ; 2013 / 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	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
World Wide #: CR-NOVOPROD-1469082

24b. MFR CONTROL NO.
1469082

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

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

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

DATE OF THIS REPORT
01-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 159 cm.

Patient's weight: 99 kg.

Patient's BMI: 39.15984340.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "chronic granulomatous mastitis(Idiopathic granulomatous mastitis)" beginning on 07-APR-2025 , "rebound effect(Rebound effect)" beginning on DEC-2024 , "nausea(Nausea)" beginning on JUL-2024 , "stomach hurt a lot(Stomach pain)" beginning on JUL-2024 , "sensitivity in the area of application(Injection site discomfort)" beginning on JUL-2024 , "disgust(Feeling unwell)" beginning on JUL-2024 , "Vomiting(Vomiting)" with an unspecified onset date and concerned a 48 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JUL-2024 to DEC-2024 for "Obesity", "insulin resistance",

Dosage Regimens:
Saxenda: ??-JUL-2024 to ??-DEC-2024;

Current Condition: Obesity(Duration not reported), Insulin resistance, Hypothyroidism, Type 2 diabetes mellitus.

Concomitant medications included - XIGDUO(DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE), LEVOTHYROXINE.

Treatment medications included - CIPROFLOXACIN, IBUPROFEN.

Since an unknown date in JUL-2024 had a lot of disgust, too many nausea, stomach hurt a lot, and she had sensitivity in the area after a certain time of application in the abdomen.

Since an unknown date in DEC-2024 patient stopped consuming the medication and the rebound effect was terrible, its a dreadful thing. She really reconsidered whether or not she should continue with a medication that, at the moment she stopped using it, the rebound effect was too much
the rebound effect was brutal; from an unknown date in DEC or MAR (year unspecified), patient was at 103 kg, and was currently at 109 kg.

On 25-MAR-2025 patient felt her breast

Since 07-APR-2025 patient started having issues, developed an infection; on an unknown date underwent a biopsy (biopsy) (result unspecified)
On the same date a mammogram (mammogram) was done and , they told it was a tumor

Since 24-APR-2025 to 30-APR-2025 the patient was hospitalized due to the same

Patient already had the infection in her breast before, since her breast was so infected inside, they hospitalized.

On 24-APR-2025 , when they tried to perform the biopsy, but they could not do it because of the infection.

On 21-MAY-2025 They were able to perform the biopsy (result unspecified)

On 16-JUN-2025 the infected breast was diagnosed as benign, it was called chronic granulomatous mastitis.

Later on an unknown date it was reported that the patient suggested other things related to the use of saxenda that patient see align with the symptoms they have at a gastric level. the issue is that saxenda makes the digestion process slower, which means the body doesn't evacuate food quickly, and when one is eating, he/she feels like vomiting because the stomach is still full of food. he/she told me exactly the same thing i thought: that the rebound effect when one stops using the product is terrible, so it's not a medication that you can maintain for an extended period. when you stop using it, the rebound effect is quite aggressive.

The patient had been placed on a gluten-free diet and has managed to lose 2 kg after gaining all the weight back after stopping the use of saxenda.

Batch Numbers:
Saxenda: has been requested

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

The outcome for the event "chronic granulomatous mastitis(Idiopathic granulomatous mastitis)" was Not yet recovered.
The outcome for the event "rebound effect(Rebound effect)" was Not recovered.
On DEC-2024 the outcome for the event "nausea(Nausea)" was Recovered.
On DEC-2024 the outcome for the event "stomach hurt a lot(Stomach pain)" was Recovered.
On DEC-2024 the outcome for the event "sensitivity in the area of application(Injection site discomfort)" was Recovered.
On DEC-2024 the outcome for the event "disgust(Feeling unwell)" was Recovered.
The outcome for the event "Vomiting(Vomiting)" was Not Reported.

Reporter's causality (Saxenda) -
chronic granulomatous mastitis(Idiopathic granulomatous mastitis) : Possible
rebound effect(Rebound effect) : Possible
nausea(Nausea) : Possible
stomach hurt a lot(Stomach pain) : Possible
sensitivity in the area of application(Injection site discomfort) : Possible
disgust(Feeling unwell) : Possible
Vomiting(Vomiting) : Possible

Company's causality (Saxenda) -
chronic granulomatous mastitis(Idiopathic granulomatous mastitis) : Unlikely
rebound effect(Rebound effect) : Unlikely
nausea(Nausea) : Possible
stomach hurt a lot(Stomach pain) : Possible
sensitivity in the area of application(Injection site discomfort) : Possible
disgust(Feeling unwell) : Possible
Vomiting(Vomiting) : Possible

This case was re-classified from Priority 5 to Priority 3 on 24-JUL-2025 due to upgradation of reporter causality for event chronic granulomatous mastitis from Unknown /Unlikely to Possible/Unlikely.

Since last submission case was updated with following information:
-Medical history of diabetes mellitus was updated to Type 2 diabetes mellitus
-Suspect action taken was updated to Product discontinued due to AE and dechallenge was updated to N/A
-Conmed Xigduo start date and dose details was updated
-Event chronic granulomatous mastitis outcome was updated to Not yet recovered and reporter casuality was updated to possible
-Non serious event vomiting was added
-Narrative updated accordingly.

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1469082
Reference Notes:

Company comment:
Idiopathic granulomatous mastitis is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda
Information regarding circumstances leading to the reported event (such as autoimmune disorder, hormonal imbalance), social history (smoking) are unavailable which limits the medical assessment of the case. Recent infection of the breast can be considered as a risk factor for development of the reported event. Considering the pharmacological properties of the suspect product and nature of the event, idiopathic granulomatous mastitis is evaluated as unlikely related to the suspect product
This single case report is not considered to change the current knowledge of the safety profile of Saxenda

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Biopsy On an unknown date patient underwent a biopsy (result unspecified)		
2	21-MAY-2025	Biopsy On 21-MAY-2025 patient underwent a biopsy (result unspecified)		

Mfr. Control Number: 1469082

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
3	07-APR-2025	Mammogram On 07-APR-2025 patient had a mammogram and they told it was a tumor		
4		Weight	109 kg	
5		Weight	103 kg	

13. Relevant Tests

from December to March (year unspecified), patient was at 103 kg,
On an unknown date patient underwent a biopsy (result unspecified)
On 21-MAY-2025 patient underwent a biopsy (result unspecified)
On 07-APR-2025 patient had a mammogram and they told it was a tumor

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; Regimen #1	0.6 mg, qd; Subcutaneous	Obesity (Obesity) insulin resistance (Insulin resistance)	JUL-2024 / DEC-2024; Unknown

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

#1) XIGDUO (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE) ; 2018 / 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 Duration not reported	Type 2 diabetes mellitus (Type 2 diabetes mellitus);