# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year |
| PRIVACY | COSTA RICA | | PRIVACY | | Unk | Male | Unk | | Unk | |

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
cataract surgery on one eye [Cataract operation]
pain referring to the area where the surgery took place [Procedural pain]

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).

**(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 ) UNK

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

17. INDICATION(S) FOR USE
#1 ) Product used for unknown indication (P

**(Continued on Additional Information Page)**

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

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

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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | | |

## 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-1466276

24b. MFR CONTROL NO.
**1466276**

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

24c. DATE RECEIVED BY MANUFACTURER
28-JUN-2025

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

DATE OF THIS REPORT
07-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

Patient's weight, height and body mass index were not reported

This serious Solicited Report from COSTA RICA was reported by a Consumer as "cataract surgery on one eye(Cataract operation)" with an unspecified onset date , "pain referring to the area where the surgery took place(Postoperative pain)" with an unspecified onset date and concerned a Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date for "Product used for unknown indication",

Dosage Regimens:
Saxenda:

Medical history was not provided.

On an unknown date, the patient underwent cataract surgery on one eye and experienced a lot of pain in the area where the surgery took place.

Batch Numbers:
Saxenda: not reported

Action taken to Saxenda was Not reported.

The outcome for the event "cataract surgery on one eye(Cataract operation)" was Not recovered.
The outcome for the event "pain referring to the area where the surgery took place(Postoperative pain)" was Not recovered.

Reporter's causality (Saxenda) -
cataract surgery on one eye(Cataract operation) : Unknown
pain referring to the area where the surgery took place(Postoperative pain) : Unknown

Company's causality (Saxenda) -
cataract surgery on one eye(Cataract operation) : Unlikely
pain referring to the area where the surgery took place(Postoperative pain) : Unlikely

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1466276
Reference Notes:

No consent for safety follow-up questions, hence no further follow-up was possible.

Since last submission the case has been updated with the following:
Event tab updated (pain updated to postoperation pain)
Narrative updated accordingly

Company comment
Cataract operation and procedural pain are assessed as unlisted events according to the Novo Nordisk current CCDS information on Saxenda.
Information on event onset date and product start date (to assess the temporal relationship), age of the patient, product indication, relevant medical history on diabetes mellitus, underlying cause/indication for the reported procedure, relevant laboratory/diagnostic evaluation are unavailable for medical evaluation. It is difficult to perform thorough medical evaluation. Considering the safety profile of the suspect product, the reported events are assessed unlikely related to the suspect product.
This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #1 | UNK; Unknown | Product used for unknown indication (Product used for unknown indication) | Unknown; Unknown |