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		Unk	Female	Unk		MAY	2025

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
very ill in the mouth [Oral disorder]

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 height, weight and body mass index(BMI) was not reported

(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 / APR-2025

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

24b. MFR CONTROL NO.
1476076

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1476076

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This serious Solicited Report from COSTA RICA was reported by a Consumer as "very ill in the mouth(Oral disorder)" beginning on MAY-2025 and concerned a Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date to APR-2025 for "Product used for unknown indication",

Dosage Regimens:
Saxenda: Not Reported to ??-APR-2025;

Medical history was not provided.

On an unspecified date in MAY 2025, the patient was very ill in the mouth and underwent major surgery about two months ago. The patient discontinued using Saxenda approximately three months ago

Batch Numbers:
Saxenda:was not reported

Action taken to Saxenda was reported as Product discont. not due to AE.

The outcome for the event "very ill in the mouth(Oral disorder)" was Unknown.

Reporter's causality (Saxenda) -
very ill in the mouth(Oral disorder) : Unknown

Company's causality (Saxenda) -
very ill in the mouth(Oral disorder) : Unlikely

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

Company comment:
Oral disorder is assessed as unlisted event according to the Novo Nordisk current Company Core Data Sheet information on Saxenda.
Limited information on suspect product indication, complete medical history, final diagnosis, details of surgery, relevant laboratory test reports, and concomitant medications precludes thorough medical evaluation of the case.
Considering the nature of event and known safety profile of suspect product, the causality for the event oral disorder is assessed 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.

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	UNK; Unknown	Product used for unknown indication (Product used for unknown indication)	Unknown / APR-2025; Unknown