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		46 Years	Female	57.00 kg		JUL	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
(unspecified) surgery [Surgery]
significant headaches It was noted that during the 3 or 4 days of consecutive use [Headache]
Nausea [Nausea]
The patient did not take it (the treatment saxenda) consistently [Inappropriate schedule of product administration]
The patient resumed the medication, but then had to stop again for a trip [Intentional dose omission]

(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) 1.80 mg, qd

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

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) JUL-2025 / 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 to Ongoing	Current Condition	Headache (Headache)

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.
1508039

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

24c. DATE RECEIVED BY MANUFACTURER
25-AUG-2025

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

DATE OF THIS REPORT
03-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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: 158 cm.

Patient's weight: 57 kg.

Patient's BMI: 22.83287930.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "(unspecified) surgery(Surgery)" beginning on AUG-2025 , "significant headaches It was noted that during the 3 or 4 days of consecutive use(Headache aggravated)" beginning on AUG-2025 , "Nausea(Nausea)" beginning on AUG-2025 , "The patient did not take it (the treatment saxenda) consistently(Inappropriate schedule of product administration)" beginning on JUL-2025 , "The patient resumed the medication, but then had to stop again for a trip(Intentionally missed dose)" beginning on AUG-2025 and concerned a 46 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JUL-2025 to 06-AUG-2025 for "Product used for unknown indication",

Dosage Regimens:
Saxenda: ??-JUL-2025 to Not Reported, Not Reported to Not Reported, Not Reported to 06-AUG-2025;

Current Condition: headaches.

Treatment medication: Migradorixine (Non codable)

On unknown date in JUL-2025, The patient did not take it (the treatment saxenda) consistently took it for a few consecutive days. then had to stop due to a surgery.
On an unknown date in AUG-2025, The patient indicates that the medication caused significant headaches and nausea. The patient had (unspecified) surgery and had to stop saxenda due to a surgery. After that, the patient resumed the medication, but then had to stop again for a trip, The headaches began. Previously, the patient experienced headaches, but they were more sporadic. It was noted that during the 3 or 4 days of consecutive use, the patient experienced headaches.

Batch Numbers:
Saxenda: Requested

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

On AUG-2025 the outcome for the event "(unspecified) surgery(Surgery)" was Recovered.
On AUG-2025 the outcome for the event "significant headaches It was noted that during the 3 or 4 days of consecutive use(Headache aggravated)" was Recovered.
On AUG-2025 the outcome for the event "Nausea(Nausea)" was Recovered.
On 06-AUG-2025 the outcome for the event "The patient did not take it (the treatment saxenda) consistently(Inappropriate schedule of product administration)" was Recovered.
On AUG-2025 the outcome for the event "The patient resumed the medication, but then had to stop again for a trip(Intentionally missed dose)" was Recovered.

Reporter's causality (Saxenda) -
(unspecified) surgery(Surgery) : Possible
significant headaches It was noted that during the 3 or 4 days of consecutive use(Headache aggravated) : Possible
Nausea(Nausea) : Possible
The patient did not take it (the treatment saxenda) consistently(Inappropriate schedule of product administration) : Possible
The patient resumed the medication, but then had to stop again for a trip(Intentionally missed dose) : Possible

Company's causality (Saxenda) -
(unspecified) surgery(Surgery) : Unlikely
significant headaches It was noted that during the 3 or 4 days of consecutive use(Headache aggravated) : Possible
Nausea(Nausea) : Possible
The patient did not take it (the treatment saxenda) consistently(Inappropriate schedule of product administration) : Possible
The patient resumed the medication, but then had to stop again for a trip(Intentionally missed dose) : Possible

Company comment:
Surgery is assessed as an unlisted event while headache, nausea, inappropriate schedule of product administration and intentional dose omission are assessed as listed events according to the Novo Nordisk current CCDS information on Saxenda.
Surgery could be elective or emergency and is done for many reasons as part of treatment or to further explore the condition for the

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

purpose of diagnosis. The limited information about relevant medical history, indication of surgery, diagnostic test reports and concomitant medications interdict complete medical assessment of the case. Considering the pharmacological profile of the suspect drug and with available information, the causality for surgery is assessed as unlikely related.
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	1.80 mg, qd; Subcutaneous	Product used for unknown indication (Product used for unknown indication)	JUL-2025 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	Unknown resumed dose; Subcutaneous	Product used for unknown indication (Product used for unknown indication)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	1.80 mg, qd; Subcutaneous	Product used for unknown indication (Product used for unknown indication)	Unknown / 06-AUG-2025; Unknown