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	120.00 kg		JUN	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
Hypothyroidism [Hypothyroidism]
Iron taste [Dysgeusia]
nausea [Nausea]
vomiting [Vomiting]
Stomach Pain [Abdominal pain upper]
Stomach discomfort [Abdominal discomfort]
Headache [Headache]
couldn't sleep [Insomnia]
Saxenda was not prescribed by a physician [Prescription drug used without a

(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)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.8 mg, qd	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) overweight (Overweight)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JUN-2025 / Unknown	#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
2021 to Ongoing	Current Condition	Overweight (Overweight)
Unknown to Ongoing	Current Condition	Migraine (Migraine)
	since more than 20 years ago	

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.
1472780

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

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

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

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

a prescription]

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: 160 cm.
Patient's weight: 120 kg.
Patient's BMI: 46.8750.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "Hypothyroidism(Hypothyroidism)" beginning on JUN-2025 , "Iron taste(Taste metallic)" beginning on 15-JUL-2025 , "nausea(Nausea)" beginning on 15-JUL-2025 , "vomiting(Vomiting)" beginning on 15-JUL-2025 , "Stomach Pain(Stomach Pain)" beginning on 15-JUL-2025 , "Stomach discomfort(Stomach discomfort)" beginning on 15-JUL-2025 , "Headache(Headache)" beginning on JUN-2025 , "couldn't sleep(Sleep difficult)" beginning on 15-JUL-2025 , "Saxenda was not prescribed by a physician(Prescription drug used without a prescription)" beginning on JUN-2025 and concerned a 45 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JUN-2025 and ongoing for "overweight",

Dosage Regimens:
Saxenda: ??-JUN-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Overweight, Migraine
Historical Condition: obesity.

Treatment medications included - GRAVOL(DIMENHYDRINATE).

On an unknown date in JUN-2025, patient started using Saxenda (not prescribed by physician), experienced hypothyroidism and headache, patient reported that symptom has decreased. Frequency of headache was every day, and it lasted all day, on both sides of the head.

Patient did not have any family history of headache. Headache has not been triggered by specific factors like light, noise, food, etc.

On 15-JUL-2025, patient experienced nausea, iron taste, could not sleep and eat due to nausea, stomach discomfort and experienced intense stomach pain, one occasion when it caused vomiting in the early morning. Patient refers that this occurred when started with the 3.0 mg dose. Patient reported that on that night, couldn't sleep due to significant Stomach discomfort, and in the morning, vomited. That day, Patient couldn't eat anything at all because the nausea and stomach pain were significant.

Patient also mentioned that no matter how much brushes the teeth, the iron taste doesn't disappear. Patient reported the use of GRAVOL (Dimenhydrinate) for treating the adverse events.

Batch Number for Saxenda was requested.

Action taken to Saxenda was reported as No Change.

The outcome for the event "Hypothyroidism(Hypothyroidism)" was Not recovered.
The outcome for the event "Iron taste(Taste metallic)" was Not yet recovered.
On AUG-2025 the outcome for the event "nausea(Nausea)" was Recovered.
On 12-AUG-2025 the outcome for the event "vomiting(Vomiting)" was Recovered.
On 12-AUG-2025 the outcome for the event "Stomach Pain(Stomach Pain)" was Recovered.
On 12-AUG-2025 the outcome for the event "Stomach discomfort(Stomach discomfort)" was Recovered.
The outcome for the event "Headache(Headache)" was Not yet recovered.
The outcome for the event "couldn't sleep(Sleep difficult)" was Not yet recovered.
The outcome for the event "Saxenda was not prescribed by a physician(Prescription drug used without a prescription)" was Not recovered.

Reporter's causality (Saxenda) -
Hypothyroidism(Hypothyroidism) : Unknown
Iron taste(Taste metallic) : Possible
nausea(Nausea) : Possible
vomiting(Vomiting) : Possible
Stomach Pain(Stomach Pain) : Possible
Stomach discomfort(Stomach discomfort) : Possible
Headache(Headache) : Unknown

Mfr. Control Number: 1472780

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

couldn't sleep(Sleep difficult) : Possible
Saxenda was not prescribed by a physician(Prescription drug used without a prescription) : Unknown

Company's causality (Saxenda) -
Hypothyroidism(Hypothyroidism) : Unlikely
Iron taste(Taste metallic) : Possible
nausea(Nausea) : Possible
vomiting(Vomiting) : Possible
Stomach Pain(Stomach Pain) : Possible
Stomach discomfort(Stomach discomfort) : Possible
Headache(Headache) : Possible
couldn't sleep(Sleep difficult) : Possible
Saxenda was not prescribed by a physician(Prescription drug used without a prescription) : Possible

This case was re-classified from non-serious to serious on 18-AUG-2025 due to addition of an event for hypothyroidism with medically significant marked as seriousness criterion.

Since last submission the case has been updated with the following:
Obesity added in patient's medical history, hypothyroidism removed from patient's medical history
Relevant history notes updated for migrain, medical history start date removed, history start date for overweight added
Indication for Saxenda updated
Hypothyroidism and couldn't sleep added as an event
Event outcome and treatment received updated for the event headache
Event outcome updated for the event Iron taste
Event stop date for nausea, vomiting, stomach pain, stomach discomfort added, outcome updated to recovered
Narrative updated accordingly

company comment:
Hypothyroidism is assessed as an unlisted event, while nausea, me-tallic taste, vomiting, stomach pain, stomach discomfort, headache, and difficulty sleeping are assessed as listed events according to the current Novo Nordisk CCDS information on Saxenda.
Information on any autoimmune conditions, exposure to radiation, family history, or surgical history is not available, which limits a thorough medi-cal evaluation. Considering the nature of the event and the pharmacologi-cal properties of the drug, causality for hypothyroidism is assessed as unlikely related to the drug.
This single case report is not considered to change the current knowledge of the safety profile of the product.

Reporter Comment: patient does not have any family history of headache, headache has not been triggered by specific factors like light, noise, food, etc.
Patient does not use Concomitant Medications.
Patient also mentions that no matter how much brushes the teeth, the iron taste doesn't dissapear.

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 #2	3 mg, qd; Subcutaneous	overweight (Overweight)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Obesity (Obesity);