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		58 Years	Female	75.00 kg		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
intestinal paralysis [Ileus paralytic]
feels quite confused [Confusional state]
vomits [Vomiting]
feel unwell [Malaise]
headaches [Headache]
did not decreased her appetite initially [Increased appetite]
treatment had no effect on patient initially [Drug ineffective]
Patient not following the physician's instructions [Treatment noncompliance]

(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)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) For weight loss (Weight control)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) MAY-2025 / Unknown	#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) LEVOTHYROXINE (LEVOTHYROXINE) ; MAY-2025 / Ongoing

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	Hypothyroidism (Hypothyroidism)

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-1456582

24b. MFR CONTROL NO.
1456582

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

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

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

DATE OF THIS REPORT
12-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

she decided to increase the dosage, essentially jumping ahead about 2 weeks [Inappropriate schedule of product administration]

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: 156 cm.

Patient's weight: 75 kg.

Patient's BMI: 30.81854040.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "intestinal paralysis(Paralysis intestinal)" beginning on 03-JUN-2025 , "feels quite confused(Confused)" beginning on 03-JUN-2025 , "vomits(Vomiting)" beginning on 03-JUN-2025 , "feel unwell(Feeling unwell)" beginning on 03-JUN-2025 , "headaches(Headache)" beginning on 03-JUN-2025 , "did not decreased her appetite initially(Increased appetite)" beginning on MAY-2025 , "treatment had no effect on patient initially(Lack of drug effect)" beginning on MAY-2025 , "Patient not following the physician's instructions(Treatment noncompliance)" beginning on JUN-2025 , "she decided to increase the dosage, essentially jumping ahead about 2 weeks(Inappropriate schedule of drug administration)" beginning on JUN-2025 and concerned a 58 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2025 to JUN-2025 for "For weight loss",

Dosage Regimens:
Saxenda: ??-MAY-2025 to Not Reported, Not Reported to Not Reported, ??-JUN-2025 to ??-JUN-2025, Not Reported to ??-JUN-2025;

Current Condition: Hypothyroidism.

Concomitant medications included - LEVOTHYROXINE.

Treatment medications included - ELECTROLYTE SOLUTIONS [ELECTROLYTES NOS], ALKA-SELTZER(ACETYLSALICYLIC ACID), and AVAMIGRAN(Non codable).

On an unspecified date in MAY 2025, The patient was using the treatment saxenda ,but initially it had no effect and did not decreased her appetite, so the patient increased the dosage a little, which caused very unpleasant side effects. Patient acknowledges that it was the patient's fault for not following the physician's instructions, and now the patient feels reluctant to continue.

On 03-JUN-2025 ,the patient experiences intestinal paralysis, vomits, and feels quite confused. The patient believes not use it anymore, as the patient also experiences symptoms like headaches. When the patient administers the medication, the patient starts vomiting 8 hours later, noting that this occurred with all dosages.

On an unknown date in JUN-2025, when the patient reached the 2.4 mg dosage, the patient could not tolerate the symptoms. The patient did this without the doctor's approval and mentions that after reaching the peak at 8 hours, all symptoms resolve. Additionally, the patient mentions that Saxenda did not decreased appetite initially, but after increasing the dose, it did decreased her appetite. However, the patient experienced symptoms such as vomiting and intestinal paralysis, so the patient reduced the dosage to 1.8 mg. the patient paused the treatment for approximately 4 days and resumed it the following week but could not tolerate the symptoms and discontinued it. The patient also indicates that increasing the dos-age was what made patient feel unwell; the patient was supposed to increase it gradually. Since it did not have much effect on the patient initially, the patient decided to increase the dosage and skipped the week that the doctor advised her to wait, essentially jumping ahead about 2 weeks.

Batch Numbers:
Saxenda: was requested

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

On 10-JUN-2025 the outcome for the event "intestinal paralysis(Paralysis intestinal)" was Recovered.
On 10-JUN-2025 the outcome for the event "feels quite confused(Confused)" was Recovered.
On 10-JUN-2025 the outcome for the event "vomits(Vomiting)" was Recovered.
On 10-JUN-2025 the outcome for the event "feel unwell(Feeling unwell)" was Recovered.
On 10-JUN-2025 the outcome for the event "headaches(Headache)" was Recovered.
On 2025 the outcome for the event "did not decreased her appetite initially(Increased appetite)" was Recovered.
On 2025 the outcome for the event "treatment had no effect on patient initially(Lack of drug effect)" was Recovered.
On JUN-2025 the outcome for the event "Patient not following the physician's instructions(Treatment noncompliance)" was Recovered.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

On JUN-2025 the outcome for the event "she decided to increase the dosage, essentially jumping ahead about 2 weeks(Inappropriate schedule of drug administration)" was Recovered.

Reporter's causality (Saxenda) -
intestinal paralysis(Paralysis intestinal) : Possible
feels quite confused(Confused) : Possible
vomits(Vomiting) : Possible
feel unwell(Feeling unwell) : Possible
headaches(Headache) : Possible
did not decreased her appetite initially(Increased appetite) : Possible
treatment had no effect on patient initially(Lack of drug effect) : Possible
Patient not following the physician's instructions(Treatment noncompliance) : Unknown
she decided to increase the dosage, essentially jumping ahead about 2 weeks(Inappropriate schedule of drug administration) : Unknown

Company's causality (Saxenda) -
intestinal paralysis(Paralysis intestinal) : Unlikely
feels quite confused(Confused) : Unlikely
vomits(Vomiting) : Possible
feel unwell(Feeling unwell) : Possible
headaches(Headache) : Possible
did not decreased her appetite initially(Increased appetite) : Unlikely
treatment had no effect on patient initially(Lack of drug effect) : Possible
Patient not following the physician's instructions(Treatment noncompliance) : Possible
she decided to increase the dosage, essentially jumping ahead about 2 weeks(Inappropriate schedule of drug administration) : Possible

Since last submission the case has been updated with the following:
- Saxenda 2.4 mg start date updated
- levothyroxine start date updated.
- Events Patient not following the physician's instructions and she decided to increase the dosage, essentially jumping ahead about 2 weeks: onset date updated.
-Narrative updated accordingly.

References included:
Reference Type: E2B Company Number
Reference ID#: CR-NOVOPROD-1456582
Reference Notes:

Company comment:
Ileus paralytic, confusional state, increased appetite are assessed as unlisted events and malaise, drug ineffective, headache, vomiting, treatment noncompliance are assessed as listed events ac-cording to NovoNordisk current reference safety information on Saxenda.
Medical history of hypothyroidism is a significant risk factor for the reported of ileus paralytic in the patient. Considering the safety profile of the suspect, details of treatment received and medical his-tory of hypothyroidism, ileus paralytic is assessed as unlikely related to the suspect.
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 #2	UNK; Subcutaneous	For weight loss (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	2.4 mg, qd; Subcutaneous	For weight loss (Weight control)	JUN-2025 / JUN-2025; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #4	1.8 mg, qd; Subcutaneous	For weight loss (Weight control)	Unknown / JUN-2025; Unknown