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	Male	Unk		MAR	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Nausea [Nausea]
the patient cannot eat (loss of appetite) [Decreased appetite]
Saxenda prescribed for type 2 diabetes [Off label use]

Case Description: ***This is an auto generated narrative***

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 **(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) 0.6 mg, qd

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

17. INDICATION(S) FOR USE
#1) type 2 diabetes (Type 2 diabetes mellitus)

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

18. THERAPY DATES(from/to)
#1) MAR-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 Duration not reported	Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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.
1479218

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

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

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1479218

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Nausea(Nausea)" with an unspecified onset date , "the patient cannot eat (loss of appetite)(Appetite lost)" with an unspecified onset date , "Saxenda prescribed for type 2 diabetes(Off label use in unapproved indication)" beginning on MAR-2025 and concerned a Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAR-2025 and ongoing for "type 2 diabetes",

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

Current Condition: type 2 diabetes.

Batch Numbers:
Saxenda: ASKU, ASKU, ASKU, ASKU;

Action taken to Saxenda was reported as Dose Decreased.

The outcome for the event "Nausea(Nausea)" was Unknown.
The outcome for the event "the patient cannot eat (loss of appetite)(Appetite lost)" was Unknown.
The outcome for the event "Saxenda prescribed for type 2 diabetes(Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Saxenda) -
Nausea(Nausea) : Unknown
the patient cannot eat (loss of appetite)(Appetite lost) : Unknown
Saxenda prescribed for type 2 diabetes(Off label use in unapproved indication) : Unknown

Company's causality (Saxenda) -
Nausea(Nausea) : Possible
the patient cannot eat (loss of appetite)(Appetite lost) : Unlikely
Saxenda prescribed for type 2 diabetes(Off label use in unapproved indication) : Possible

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(performed titration); Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	3 mg, qd; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #4	UNK (dose decreased); Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus)	Ongoing; Unknown