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		40 Years	Female	80.00 kg	24	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]
loss of appetite [Decreased appetite]
Application of Saxenda every other day (qod) [Inappropriate schedule of product administration]

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

(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 {Lot # PP5L468; Exp.Dt. JUN-2026}

(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) 1.2 mg, qd	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 24-MAR-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
Unknown to Ongoing	Current Condition	Diabetes (Diabetes mellitus)
	Type and duration not reported.	
Unknown to Ongoing	Current Condition	Obesity (Obesity)

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.
1411547

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

24c. DATE RECEIVED BY MANUFACTURER
09-JUN-2025

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

DATE OF THIS REPORT
17-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1411547

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

support program with focus on exercise, motivation, nutrition & maintaining strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 161 cm.

Patient's weight: 80 kg.

Patient's BMI: 30.86300680.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Nausea(Nausea)" beginning on 24-MAR-2025 , "loss of appetite(Appetite lost)" with an unspecified onset date , "Application of Saxenda every other day (qod)(Once daily dose taken less frequently)" with an unspecified onset date and concerned a 40 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 24-MAR-2025 and ongoing for "Obesity",

Dosage Regimens:
Saxenda: 24-MAR-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Diabetes, Obesity.

Treatment medications included - SODIUM BICARBONATE.

Batch Numbers:
Saxenda: PP5L468, PP5L468;

Action taken to Saxenda was reported as No Change.

The outcome for the event "Nausea(Nausea)" was Not recovered.
The outcome for the event "loss of appetite(Appetite lost)" was Not recovered.
The outcome for the event "Application of Saxenda every other day (qod)(Once daily dose taken less frequently)" was Not recovered.

Reporter's causality (Saxenda) -
Nausea(Nausea) : Unknown
loss of appetite(Appetite lost) : Unknown
Application of Saxenda every other day (qod)(Once daily dose taken less frequently) : Unknown

Company's causality (Saxenda) -
Nausea(Nausea) : Possible
loss of appetite(Appetite lost) : Unlikely
Application of Saxenda every other day (qod)(Once daily dose taken less frequently) : 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 {Lot # PP5L468; Exp.Dt. JUN-2026}; Regimen #2	3 mg, qod; Subcutaneous	Obesity (Obesity)	Ongoing; Unknown