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		32 Years	Female	82.00 kg		JUN	2025

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

more hair loss [Alopecia]
aversions to eating [Food aversion]
less energy [Asthenia]
nausea [Nausea]

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
(Continued on Additional Information Page)

15. DAILY DOSE(S)
#1) 0.6 mg, qd

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

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

18. THERAPY DATES(from/to)
#1) JUN-2025 / Unknown

19. THERAPY DURATION
#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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

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.
1470633

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1470633

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: 160 cm.

Patient's weight: 82 kg.

Patient's BMI: 32.031250.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "more hair loss(Hair loss)" beginning on JUN-2025 , "aversions to eating(Food aversion)" beginning on JUN-2025 , "less energy(Loss of energy)" beginning on JUN-2025 , "nausea(Nausea)" beginning on JUN-2025 and concerned a 32 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JUN-2025 and ongoing for "For weight loss",

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

Medical history was not provided.

Batch Numbers:
Saxenda: UNK, UNK, UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "more hair loss(Hair loss)" was Not recovered.
The outcome for the event "aversions to eating(Food aversion)" was Not recovered.
The outcome for the event "less energy(Loss of energy)" was Not recovered.
The outcome for the event "nausea(Nausea)" was Not recovered.

Reporter's causality (Saxenda) -
more hair loss(Hair loss) : Possible
aversions to eating(Food aversion) : Possible
less energy(Loss of energy) : Possible
nausea(Nausea) : Possible

Company's causality (Saxenda) -
more hair loss(Hair loss) : Unlikely
aversions to eating(Food aversion) : Unlikely
less energy(Loss of energy) : Possible
nausea(Nausea) : 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; Subcutaneous	For weight loss (Weight control)	Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #3	1.8 mg, qd; Subcutaneous	For weight loss (Weight control)	Ongoing; Unknown