CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		41 Years	Female	Unk	11	MAY	2025

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

she could not sleep [Insomnia]
nausea [Nausea]
vomiting [Vomiting]
had tremors in her hands [Tremor]

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)
#1) 1.8 mg, qd

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

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

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

18. THERAPY DATES(from/to)
#1) 02-MAY-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.	Overweight (Overweight)
Unknown to Ongoing	Current Condition	Cyst (Cyst)

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.
1438117

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

24c. DATE RECEIVED BY MANUFACTURER
16-MAY-2025

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

DATE OF THIS REPORT
01-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1438117

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).

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "she could not sleep(Sleep difficult)" beginning on 11-MAY-2025 , "nausea(Nausea)" beginning on 11-MAY-2025 , "vomiting(Vomiting)" beginning on 11-MAY-2025 , "had tremors in her hands(Tremor of hands)" beginning on 11-MAY-2025 and concerned a 41 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 02-MAY-2025 and ongoing for "for weight loss",

Dosage Regimens:
Saxenda: 02-MAY-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Overweight, Cysts, Fibroids in the ovaries, Thyroid cysts.

Treatment medications included - ANTIMETIL(ZINGIBER OFFICINALE).

Batch Numbers:
Saxenda: PP5L468, PP5L468;

Action taken to Saxenda was reported as Dose Decreased.

On 13-MAY-2025 the outcome for the event "she could not sleep(Sleep difficult)" was Recovered.
On 13-MAY-2025 the outcome for the event "nausea(Nausea)" was Recovered.
On 13-MAY-2025 the outcome for the event "vomiting(Vomiting)" was Recovered.
On 13-MAY-2025 the outcome for the event "had tremors in her hands(Tremor of hands)" was Recovered.

Reporter's causality (Saxenda) -
she could not sleep(Sleep difficult) : Unknown
nausea(Nausea) : Unknown
vomiting(Vomiting) : Unknown
had tremors in her hands(Tremor of hands) : Unknown

Company's causality (Saxenda) -
she could not sleep(Sleep difficult) : Possible
nausea(Nausea) : Possible
vomiting(Vomiting) : Possible
had tremors in her hands(Tremor of hands) : Unlikely

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	1.2 mg, qd (Dose decreased); Subcutaneous	for weight loss (Weight control)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Fibroids (Uterine leiomyoma);
Unknown to Ongoing	Current Condition	Thyroid cyst (Thyroid cyst);