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		18 Years	Female	109.80 kg		APR	2025

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

a lot of reflux at night [Gastrooesophageal reflux disease]

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 strategies (only for patients under Liraglutide 3.0 mg).

(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) 1.8 mg, qd	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) MAR-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) CYPROTERONE ACETATE;ETHINYLESTRADIOL (CYPROTERONE ACETATE;ETHINYLESTRADIOL) ; 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 duration not reported.	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance)

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.
1470966

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: 1470966

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 159 cm.

Patient's weight: 109.8 kg.

Patient's BMI: 43.43182630.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "a lot of reflux at night(Gastrooesophageal reflux)" beginning on APR-2025 and concerned a 18 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAR-2025 and ongoing for "obesity",

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

Current Condition: Obesity, Insulin resistance.

Concomitant medications included - CYPROTERONE ACETATE;ETHINYLESTRADIOL.

Batch Numbers:
Saxenda: UNK, UNK;

Action taken to Saxenda was reported as Dose Decreased.

On MAY-2025 the outcome for the event "a lot of reflux at night(Gastrooesophageal reflux)" was Recovered.

Reporter's causality (Saxenda) -
a lot of reflux at night(Gastrooesophageal reflux) : Possible

Company's causality (Saxenda) -
a lot of reflux at night(Gastrooesophageal reflux) : 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	1.2 mg, qd; Subcutaneous	obesity (Obesity)	Ongoing; Unknown