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		47 Years	Female	Unk		Unk	

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

waking up with a lot headache [Headache]
occasionally diarrhea [Diarrhoea]
stomach discomfort, [Abdominal discomfort]

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) 1.2 mg, qd

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

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

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) Ongoing

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	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Prediabetes (Glucose tolerance impaired)

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.
1463383

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

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1463383

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 "waking up with a lot headache(Headache)" with an unspecified onset date , "occasionally diarrhea(Diarrhea)" with an unspecified onset date , "stomach discomfort,(Stomach discomfort)" with an unspecified onset date and concerned a 47 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date and ongoing for "obesity", "Pre-diabetes mellitus", "metabolic syndrome",

Dosage Regimens:
Saxenda:

Current Condition: Obesity, Pre-diabetes mellitus, Metabolic syndrome.

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as No Change.

The outcome for the event "waking up with a lot headache(Headache)" was Not recovered.
The outcome for the event "occasionally diarrhea(Diarrhea)" was Not Reported.
The outcome for the event "stomach discomfort,(Stomach discomfort)" was Not recovered.

Reporter's causality (Saxenda) -
waking up with a lot headache(Headache) : Unknown
occasionally diarrhea(Diarrhea) : Unknown
stomach discomfort,(Stomach discomfort) : Unknown

Company's causality (Saxenda) -
waking up with a lot headache(Headache) : Possible
occasionally diarrhea(Diarrhea) : Possible
stomach discomfort,(Stomach discomfort) : Possible

Reporter Comment: The patient indicated that "stomach pain" referred to stomach discomfort

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 #1	1.2 mg, qd; Subcutaneous	obesity (Obesity) Pre-diabetes mellitus (Glucose tolerance impaired) metabolic syndrome (Metabolic syndrome)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Metabolic syndrome (Metabolic syndrome);