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	76.50 kg	04	MAY	2025

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

she feels depressed (Depressed mood) [Depressed mood]
no appetite [Decreased appetite]
vomited all the food [Vomiting]
terrible headaches [Headache]
diarrhea [Diarrhoea]

Case Description: ***This is an auto generated narrative***

Study ID: 828652-My Healthy Journey

(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

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) 04-MAY-2025 / 05-MAY-2025

19. THERAPY DURATION
#1) 1 day

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) EUTIROX (LEVOTHYROXINE SODIUM) Tablet ; Ongoing
#2) ANGELIQ (DROSPIRENONE, ESTRADIOL) Tablet ; 2023 / 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	Thyroid disorder (Thyroid disorder)
Unknown to Ongoing	Current Condition	Hormone therapy (Hormone therapy)

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.
1429921

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

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

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

Patient's height: 154 cm.

Patient's weight: 76.5 kg.

Patient's BMI: 32.25670430.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "she feels depressed (Depressed mood)(Depressed mood)" beginning on 04-MAY-2025 , "no appetite(Appetite absent)" beginning on 05-MAY-2025 , "vomited all the food(Vomited)" beginning on 05-MAY-2025 , "terrible headaches(Headache)" beginning on 04-MAY-2025 , "diarrhea(Diarrhea)" beginning on 04-MAY-2025 and concerned a 47 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 04-MAY-2025 to 05-MAY-2025 for "for weight loss",

Dosage Regimens:
Saxenda: 04-MAY-2025 to 05-MAY-2025;

Current Condition: Thyroid, hormone therapy, Menopause, Presbyopia, mild astigmatism.

Concomitant medications included - EUTIROX(LEVOTHYROXINE SODIUM), ANGELIQ(DROSPIRENONE, ESTRADIOL).

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as Product discontinued due to AE.

On 07-MAY-2025 the outcome for the event "she feels depressed (Depressed mood)(Depressed mood)" was Recovered.
On 07-MAY-2025 the outcome for the event "no appetite(Appetite absent)" was Recovered.
On 07-MAY-2025 the outcome for the event "vomited all the food(Vomited)" was Recovered.
On 04-MAY-2025 the outcome for the event "terrible headaches(Headache)" was Recovered.
On 07-MAY-2025 the outcome for the event "diarrhea(Diarrhea)" was Recovered.

Reporter's causality (Saxenda) -
she feels depressed (Depressed mood)(Depressed mood) : Possible
no appetite(Appetite absent) : Possible
vomited all the food(Vomited) : Possible
terrible headaches(Headache) : Possible
diarrhea(Diarrhea) : Possible

Company's causality (Saxenda) -
she feels depressed (Depressed mood)(Depressed mood) : Unlikely
no appetite(Appetite absent) : Unlikely
vomited all the food(Vomited) : Possible
terrible headaches(Headache) : Possible
diarrhea(Diarrhea) : Possible

Reporter Comment: Treatment for symptoms experienced: medications for headaches, but she does not provide the details of the treatments. Product start date for eutirox: for the last 5 or 7 years
Treatment : Patient took IV fluid for the event diarrhoea and vomiting (Non codable)
Patient states nausea and vomiting lasted all day

The patient presented to the hospital on Tuesday, May 6, 2025, where she was hydrated, and on Wednesday, May 7, 2025, she was placed on sick leave for her recovery. However, she does not mention being hospitalized for more than 24 hours.

23. OTHER RELEVANT HISTORY continued

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

Mfr. Control Number: 1429921

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

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