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		34 Years	Female	136.00 kg	13	APR	2025

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

severe bleeding caused by the fibroids in the uterus [Abnormal uterine bleeding]

Case Description: 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).

Patient's height: 164 cm.

(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)	16. ROUTE(S) OF ADMINISTRATION
#1) 3 mg, qd	#1) Subcutaneous

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

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 15-MAR-2025 / 13-APR-2025	#1) 29 days

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	Uterine fibroids (Uterine leiomyoma)
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.
1465418

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

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

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

DATE OF THIS REPORT
27-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1465418

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's weight: 136 kg.
Patient's BMI: 50.56513980.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "severe bleeding caused by the fibroids in the uterus(Abnormal uterine bleeding)" beginning on 13-APR-2025 and concerned a 34 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 15-MAR-2025 and ongoing for "weight loss", "prediabetes",

Dosage Regimens:
Saxenda: 15-MAR-2025 to 13-APR-2025, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: 3 uterine fibroids, prediabetes.

Treatment medications included - TRAMAL(TRAMADOL HYDROCHLORIDE), SULINDAC, VOLTAREN DICLOFENAC,Dorginal (non codable)

On 13-APR-2025, the patient experienced severe bleeding caused by the fibroids in the uterus, then hospitalized on the same day. and discharged on 18-APR-2025.The doctor recommended to discontinue saxenda. The patient later realized that event was not related to the medication, so the patient resumed taking it a week ago and not had any problems.

Batch Numbers:
Saxenda: requested

Action taken to Saxenda was reported as Drug discontinued temporarily.

On 18-APR-2025 the outcome for the event "severe bleeding caused by the fibroids in the uterus(Abnormal uterine bleeding)" was Recovered.

Reporter's causality (Saxenda) -
severe bleeding caused by the fibroids in the uterus(Abnormal uterine bleeding) : Unlikely

Company's causality (Saxenda) -
severe bleeding caused by the fibroids in the uterus(Abnormal uterine bleeding) : 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; Regimen #1	3 mg, qd; Subcutaneous	weight loss (Weight control) prediabetes (Glucose tolerance impaired)	15-MAR-2025 / 13-APR-2025; 29 days
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	UNK(resumed); Unknown	weight loss (Weight control) prediabetes (Glucose tolerance impaired)	Ongoing; Unknown