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		42 Years	Female	72.50 kg	07	APR	2025

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

Other Serious Criteria: Medically Significant
miscarriage at 4 gestational weeks [Abortion spontaneous]
two weeks along when realizing they were pregnant and was using the medication [Maternal exposure during pregnancy]

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).

(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) 1.8 mg, qd

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

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

18. THERAPY DATES(from/to)
#1) SEP-2024 / MAY-2025

19. THERAPY DURATION
#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) CINNAMON EX (CINNAMOMUM VERUM) Capsule ; 2022 / Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
07-APR-2025		Date of LMP for pregnancy
Unknown to Ongoing	Current Condition Duration not reported.	Obesity (Obesity)

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.
1479563

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

24c. DATE RECEIVED BY MANUFACTURER
10-JUL-2025

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

DATE OF THIS REPORT
18-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 162 cm.

Patient's weight: 72.5 kg.

Patient's BMI: 27.625362.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "miscarriage at 4 gestational weeks(Early miscarriage)" beginning on ??-MAY-2025 , "two weeks along when realizing they were pregnant and was using the medication(Maternal exposure during pregnancy)" beginning on 07-APR-2025 and concerned a 42 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from SEP-2024 to MAY-2025 for "obesity",

Dosage Regimens:
Saxenda: ??-SEP-2024 to ??-MAY-2025;

Current Condition: Obesity(duration not reported)

Concomitant medications included - CINNAMON EX(CINNAMOMUM VERUM), TURMERIC (NON CODABLE)
Prospective/Retrospective: Retrospective

On an unspecified date, the patient was confirmed pregnant. The first day of last menstrual period was 07-APR-2025. The gestational age at exposure was unknown. The number of foetus was reported as 1. The expected date of delivery was not reported (auto populated as 12-JAN-2026 by Argus). No adverse events were experienced during the pregnancy period.

Patient's contraception details were unknown.

The patient was two weeks along when realizing they were pregnant and was using the medication. The patient reports that they stopped the medication immediately.

At the gestational age of 4 weeks, three weeks after stopping the medication, the patient had a miscarriage.

Batch Numbers:
Saxenda: not available

Action taken to Saxenda was reported as Not Applicable.

The outcome for the event "miscarriage at 4 gestational weeks(Early Miscarriage)" was Recovered.
On MAY-2025 the outcome for the event "two weeks along when realizing they were pregnant and was using the medication(Maternal exposure during pregnancy)" was Recovered.

Reporter's causality (Saxenda) -
miscarriage at 4 gestational weeks(Early miscarriage) : Unlikely
two weeks along when realizing they were pregnant and was using the medication(Maternal exposure during pregnancy) : Not applicable

Company's causality (Saxenda) -
miscarriage at 4 gestational weeks(Early miscarriage) : Unlikely
two weeks along when realizing they were pregnant and was using the medication(Maternal exposure during pregnancy) : Unlikely

No consent for safety follow-up questions, hence no further follow-up is possible.