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		36 Years	Male	139.90 kg		APR	2025

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

Severe constipation (Patient feels discomfort in stomach refers that constipation has worsened) [Constipation]

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

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) MAR-2025 / Ongoing

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) MICARDIS (TELMISARTAN) ; Ongoing
#2) FANTER (DAPAGLIFLOZIN) ; 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	Hypertension (Hypertension)

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.
1457915

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

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 177 cm.

Patient's weight: 139.9 kg.

Patient's BMI: 44.65511190.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Severe constipation (Patient feels discomfort in stomach refers that constipation has worsened)(Constipation aggravated)" beginning on APR-2025 and concerned a 36 Years old Male 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 (Dosage Regimen Ongoing);

Current Condition: Obesity, Hypertension, Constipation, Insulin resistance, Hypertriglyceridaemia, High LDL (Low-Density Lipoprotein), Asthma, Prediabetes.

Concomitant medications included - MICARDIS(TELMISARTAN), FANTER(DAPAGLIFLOZIN).

Treatment medications included - MAGNESIA REY MAGNESIUM HYDROXIDE, LACTULOSE.

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "Severe constipation (Patient feels discomfort in stomach refers that constipation has worsened)(Constipation aggravated)" was Recovering/resolving.

Reporter's causality (Saxenda) -
Severe constipation (Patient feels discomfort in stomach refers that constipation has worsened)(Constipation aggravated) : Possible

Company's causality (Saxenda) -
Severe constipation (Patient feels discomfort in stomach refers that constipation has worsened)(Constipation aggravated) : Possible

Reporter Comment: Concomitant medication: Salbutamol + Simbicort (Formoterol and budesonide) [non codable]

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Constipation (Constipation);
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance);
Unknown to Ongoing	Current Condition	Hypertriglyceridemia (Hypertriglyceridaemia);
Unknown to Ongoing	Current Condition	Low density lipoprotein increased (Low density lipoprotein increased);
Unknown to Ongoing	Current Condition	Asthma (Asthma);
Unknown to Ongoing	Current Condition	Prediabetes (Glucose tolerance impaired);