CIOMS FORM

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		74 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)

Terrible constipation [Constipation]
lot of dryness in the mouth [Dry mouth]
Saxenda use for Type 2 diabetes [Product use in unapproved indication]

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

15. DAILY DOSE(S)
#1) 1.8 mg, qd

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

17. INDICATION(S) FOR USE
#1) Type 2 diabetes (Type 2 diabetes mellitus)

18. THERAPY DATES(from/to)
#1) Unknown / APR-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) JARDIANZ DUO (EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE) ; 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	Type 2 diabetes mellitus (Type 2 diabetes mellitus)

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.
1477607

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

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

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 168 cm.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Terrible constipation(Constipation)" with an unspecified onset date , "lot of dryness in the mouth(Dry mouth)" with an unspecified onset date , "Saxenda use for Type 2 diabetes(Product use in unapproved indication)" with an unspecified onset date and concerned a 74 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from unknown start date to APR-2025 for "Type 2 diabetes",

Dosage Regimens:
Saxenda: Not Reported to ??-APR-2025;

Current Condition: Type 2 diabetes.

Concomitant medications included - JARDIANZ DUO(EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE).

Treatment medications included - FIBER(POLYCARBOPHIL CALCIUM).

Batch Numbers:
Saxenda: UNK;

Action taken to Saxenda was reported as Product discontinued.

The outcome for the event "Terrible constipation(Constipation)" was Recovered.
The outcome for the event "lot of dryness in the mouth(Dry mouth)" was Recovered.
On APR-2025 the outcome for the event "Saxenda use for Type 2 diabetes(Product use in unapproved indication)" was Recovered.

Reporter's causality (Saxenda) -
Terrible constipation(Constipation) : Possible
lot of dryness in the mouth(Dry mouth) : Possible
Saxenda use for Type 2 diabetes(Product use in unapproved indication) : Unknown

Company's causality (Saxenda) -
Terrible constipation(Constipation) : Possible
lot of dryness in the mouth(Dry mouth) : Possible
Saxenda use for Type 2 diabetes(Product use in unapproved indication) : Possible

Reporter Comment: -Product Stop Date: approximately 3 months ago. The patient stopped experiencing the effects when the treatment was changed.