

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 45 Years	3. SEX Female	3a. WEIGHT 79.50 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year			Day	Month	Year		
			PRIVACY				31	MAY	2025		

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

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)

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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 1.2 mg, qd (at night)	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous	
17. INDICATION(S) FOR USE #1) Obesity (Obesity)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) FEB-2025 / Unknown	19. THERAPY DURATION #1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) LEVOTHYROXINE (LEVOTHYROXINE) ; 2005 / Ongoing		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates 2004 to Ongoing	Type of History / Notes Current Condition duration not reported	Description Obesity (Obesity)
Unknown to Ongoing	Current Condition	Hypothyroidism (Hypothyroidism)

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. 1458604	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 30-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 28-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

28-Aug-2025 09:20

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Patient's height: 153 cm.

Patient's weight: 79.5 kg.

Patient's BMI: 33.96129690.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "urinary tract infection(Urinary tract infection)" beginning on 31-MAY-2025 and concerned a 45 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from FEB-2025 and ongoing for "Obesity",

Dosage Regimens:

Saxenda: ??-FEB-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, hypothyroidism.

Concomitant medications included - LEVOTHYROXINE.

Treatment medications included - MONUROL(FOSFOMYCIN TROMETAMOL), AXTAR CEFTRIAZONE SODIUM, DOLGENAL KETOROLAC, NEUROBION [CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE MONONITRATE](CYANOCOBALAMIN, PYRIDOXINE HYDROCHLORIDE, THIAMINE MONONITRATE), DEXAMETHASONE.

Batch Numbers:

Saxenda: ASKU, ASKU;

Action taken to Saxenda was reported as Dose Decreased.

On 08-JUN-2025 the outcome for the event "urinary tract infection(Urinary tract infection)" was Recovered.

Reporter's causality (Saxenda) -

urinary tract infection(Urinary tract infection) : Unknown

Company's causality (Saxenda) -

urinary tract infection(Urinary tract infection) : Unlikely

Reporter Comment: start date of saxenda :4 months ago

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 #2	0.6 mg, qd (Dose Decreased); Subcutaneous	Obesity (Obesity)	Ongoing; Unknown