

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 Male	3a. WEIGHT 103.00 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	MAR	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 patient has gained 2 kg [Weight increased]
 Lack of efficacy [Drug ineffective]

 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		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 3 mg, qd	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous	
17. INDICATION(S) FOR USE #1) for weight loss (Weight control)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) MAR-2025 / Ongoing	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)		
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 Blood pressure high (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. 1441881	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 22-MAY-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 26-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

26-Jun-2025 08:01

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

Patient's height: 186 cm.

Patient's weight: 103 kg.

Patient's BMI: 29.772228.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "patient has gained 2 kg(Weight gain)" beginning on MAR-2025 , "Lack of efficacy(Lack of drug effect)" beginning on MAR-2025 and concerned a 45 Years old Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAR-2025 and ongoing for "for weight loss",

Dosage Regimens:

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

Current Condition: High blood pressure..

Lab Data included:

Test Date: MAR-2025

Lab Data Test as Reported: weight

Test Name: Weight

Comments: On an unknown date in MAR-2025, patient has gained 2 kg of weight

Batch Numbers:

Saxenda: UNK;

Action taken to Saxenda was Not reported.

The outcome for the event "patient has gained 2 kg(Weight gain)" was Not recovered.

The outcome for the event "Lack of efficacy(Lack of drug effect)" was Not recovered.

Reporter's causality (Saxenda) -

patient has gained 2 kg(Weight gain) : Possible

Lack of efficacy(Lack of drug effect) : Possible

Company's causality (Saxenda) -

patient has gained 2 kg(Weight gain) : Possible

Lack of efficacy(Lack of drug effect) : Possible

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAR-2025	Weight		
On an unknown date in MAR-2025, patient has gained 2 kg of weight				

13. Relevant Tests

On an unknown date in MAR-2025, patient has gained 2 kg of weight