

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 40 Years	3. SEX Female	3a. WEIGHT 92.00 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					MAY	2025		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
reflux [Gastroesophageal reflux disease]
A lot of headaches [Headache]

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 checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 0.6 mg, qd	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous	
17. INDICATION(S) FOR USE #1) Weight loss (Weight control)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) MAY-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 Menopause (Menopause)		

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. 1457469	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 11-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 09-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

09-Jul-2025 07:32

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

Patient's height: 172 cm.

Patient's weight: 92 kg.

Patient's BMI: 31.09789080.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "reflux(Gastroesophageal reflux)" beginning on MAY-2025 , "A lot of headaches(Headache)" beginning on MAY-2025 and concerned a 40 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2025 and ongoing for "Weight loss",

Dosage Regimens:

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

Current Condition: Menopause period.

Batch Numbers:

Saxenda: UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "reflux(Gastroesophageal reflux)" was Recovering/resolving.

The outcome for the event "A lot of headaches(Headache)" was Recovering/resolving.

Reporter's causality (Saxenda) -

reflux(Gastroesophageal reflux) : Possible

A lot of headaches(Headache) : Possible

Company's causality (Saxenda) -

reflux(Gastroesophageal reflux) : Possible

A lot of headaches(Headache) : Possible