

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 54 Years	3. SEX Female	3a. WEIGHT 68.00 kg	4-6 REACTION ONSET Day Month Year FEB 2025	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
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Severe pain on the right side (below the breast) [Pain] Nausea [Nausea] desperate headache [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 (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 {Lot # PP5L468; Exp.Dt. JUN-2026}	20. DID REACTION ABATE AFTER STOPPING DRUG? <input checked="" 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) lose weight (Weight control)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 16-DEC-2024 / 17-FEB-2025	19. THERAPY DURATION #1) 63 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Capsule ; 2023 / 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 Menopause (Menopause) Duration not reported	

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. 1461351	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 16-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 09:04

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

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 153 cm.

Patient's weight: 68 kg.

Patient's BMI: 29.04865650.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Severe pain on the right side (below the breast)(Pain)" beginning on FEB-2025 , "Nausea(Nausea)" with an unspecified onset date , "desperate headache(Headache)" with an unspecified onset date and concerned a 54 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 16-DEC-2024 to 17-FEB-2025 for "lose weight",

Dosage Regimens:

Saxenda: 16-DEC-2024 to 17-FEB-2025;

Current Condition: Menopause.

Concomitant medications included - VITAMIN C [ASCORBIC ACID].

Batch Numbers:

Saxenda: PP5L468;

Action taken to Saxenda was reported as Product discontinued due to AE.

On 17-FEB-2025 the outcome for the event "Severe pain on the right side (below the breast)(Pain)" was Recovered.

The outcome for the event "Nausea(Nausea)" was Not Reported.

The outcome for the event "desperate headache(Headache)" was Not Reported.

Reporter's causality (Saxenda) -

Severe pain on the right side (below the breast)(Pain) : Possible

Nausea(Nausea) : Unknown

desperate headache(Headache) : Unknown

Company's causality (Saxenda) -

Severe pain on the right side (below the breast)(Pain) : Unlikely

Nausea(Nausea) : Possible

desperate headache(Headache) : Possible