CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		52 Years	Male	95.80 kg	12	APR	2025

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

Tachycardia during a walk, tachycardia at rest with120 beats per minute [Tachycardia]

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)

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
(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.2 mg, qd	#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) weight loss (Weight control)
(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2025 / Ongoing	#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 type and duration not reported	Diabetes (Diabetes mellitus)
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance)

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.
1425638

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

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1425638

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's height: 169 cm.

Patient's weight: 95.8 kg.

Patient's BMI: 33.54224290.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Tachycardia during a walk, tachycardia at rest with120 beats per minute.(Resting tachycardia)" beginning on 12-APR-2025 and concerned a 52 Years old Male patient who was treated with Saxenda (liraglutide 6 mg/mL) from 2025 and ongoing for "weight loss", "insulin resistance",

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

Current Condition: Diabetes mellitus, Insulin resistance, Pancreatic dysfunction.

Lab Data included:
Lab Data Test as Reported: heart rate
Test Name: Heart rate
Results: 120
Unit: beats/min
Comments:

Batch Numbers:
Saxenda: ASKU;

Action taken to Saxenda was reported as No Change.

On 15-APR-2025 the outcome for the event "Tachycardia during a walk, tachycardia at rest with120 beats per minute.(Resting tachycardia)" was Recovered.

Reporter's causality (Saxenda) -
Tachycardia during a walk, tachycardia at rest with120 beats per minute.(Resting tachycardia) : Unknown

Company's causality (Saxenda) -
Tachycardia during a walk, tachycardia at rest with120 beats per minute.(Resting tachycardia) : Possible

Reporter Comment: Treatment Received: on the day of the event, he went to the hospital, but does not know the treatment.

The patient only went to the hospital for an examination but was discharged within a few hours with instructions to rest only.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Heart rate	120 beats/min	

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 #1	1.2 mg, qd; Subcutaneous	weight loss (Weight control) insulin resistance (Insulin resistance)	2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Pancreatic insufficiency (Pancreatic failure);