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		53 Years	Female	81.00 kg		MAR	2025

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

A lot of nausea [Nausea]
Constipation [Constipation]
nausea [Nausea]

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)

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)
#1) 0.6 mg, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)

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

18. THERAPY DATES(from/to)
#1) 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) ATENOLOL (ATENOLOL) ; 2022 / Ongoing
#2) PAXIL [PAROXETINE HYDROCHLORIDE] (PAROXETINE HYDROCH

(Continued on Additional Information Page)

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 Duration was not reported.	Obesity (Obesity)

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.
1476106

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

24c. DATE RECEIVED BY MANUFACTURER
04-JUL-2025

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1476106

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

strategies (only for patients under Liraglutide 3.0 mg).

Patient's height: 158 cm.

Patient's weight: 81 kg.

Patient's BMI: 32.44672330.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "A lot of nausea(Nausea)" beginning on MAR-2025 , "Constipation(Constipation)" beginning on APR-2025 , "nausea(Nausea)" beginning on APR-2025 and concerned a 53 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 2025 and ongoing for "Obesity",

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

Current Condition: Obesity.

Concomitant medications included - ATENOLOL, PAXIL PAROXETINE HYDROCHLORIDE.

Treatment medications included - ANARA(SODIUM PICOSULFATE).

Batch Numbers:
Saxenda: ASKU, PP5P053;

Action taken to Saxenda was reported as No Change.

The outcome for the event "A lot of nausea(Nausea)" was Recovering/resolving.
The outcome for the event "Constipation(Constipation)" was Not recovered.
The outcome for the event "nausea(Nausea)" was Not recovered.

Reporter's causality (Saxenda) -
A lot of nausea(Nausea) : Possible
Constipation(Constipation) : Unknown
nausea(Nausea) : Unknown

Company's causality (Saxenda) -
A lot of nausea(Nausea) : Possible
Constipation(Constipation) : Possible
nausea(Nausea) : Possible

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 {Lot # PP5P053; Exp.Dt. JAN-2027}; Regimen #2	2.4 mg, qd (3 months ago); Subcutaneous	Obesity (Obesity)	APR-2025 / Ongoing; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) PAXIL [PAROXETINE HYDROCHLORIDE] (PAROXETINE HYDROCHLORIDE) ; 2022 / Ongoing