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		23 Years	Female	85.40 kg		JAN	2025

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

episodes of diarrhea [Diarrhoea]
a lot of stress [Stress]
Saxenda used in 5 clicks [Wrong technique in product usage process]
Dosage of Saxenda 1.2 +5 clicks : Incorrect dose administered [Incorrect dose administered]

Case Description: ***This is an auto generated narrative***

Study ID: 828652-My Healthy Journey

(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)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.8 mg, qd	#1) Subcutaneous

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JAN-2025 / Unknown	#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) BELARA (CHLORMADINONE ACETATE, ETHINYLESTRADIOL) ; Unknown

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 not reported	Obesity (Obesity)
Unknown	Procedure	Contraception (Contraception)

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.
1423070

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

24c. DATE RECEIVED BY MANUFACTURER
28-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: 1423070

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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).

Patient's height: 158 cm.

Patient's weight: 85.4 kg.

Patient's BMI: 34.20926130.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "episodes of diarrhea(Diarrhea)" beginning on APR-2025 , "a lot of stress(Stress)" beginning on APR-2025 , "Saxenda used in 5 clicks(Wrong technique in product usage process)" beginning on JAN-2025 , "Dosage of Saxenda 1.2 +5 clicks : Incorrect dose administered(Incorrect dose administered)" beginning on JAN-2025 and concerned a 23 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from JAN-2025 and ongoing for "Obesity",

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

Current Condition: Obesity
Procedure: Contraceptives.

Concomitant medications included - BELARA(CHLORMADINONE ACETATE, ETHINYLESTRADIOL).

Treatment medications included - ENTEROGERMINA BACILLUS CLAUSII.

Batch Numbers:
Saxenda: UNK, UNK;

Action taken to Saxenda was reported as Dose Decreased.

On APR-2025 the outcome for the event "episodes of diarrhea(Diarrhea)" was Recovered.
On APR-2025 the outcome for the event "a lot of stress(Stress)" was Recovered.
The outcome for the event "Saxenda used in 5 clicks(Wrong technique in product usage process)" was Not recovered.
The outcome for the event "Dosage of Saxenda 1.2 +5 clicks : Incorrect dose administered(Incorrect dose administered)" was Not recovered.

Reporter's causality (Saxenda) -
episodes of diarrhea(Diarrhea) : Unknown
a lot of stress(Stress) : Unknown
Saxenda used in 5 clicks(Wrong technique in product usage process) : Unknown
Dosage of Saxenda 1.2 +5 clicks : Incorrect dose administered(Incorrect dose administered) : Unknown

Company's causality (Saxenda) -
episodes of diarrhea(Diarrhea) : Possible
a lot of stress(Stress) : Unlikely
Saxenda used in 5 clicks(Wrong technique in product usage process) : Possible
Dosage of Saxenda 1.2 +5 clicks : Incorrect dose administered(Incorrect dose administered) : 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; Regimen #2	New dosage: 1.2 + 5 clicks; Subcutaneous	Obesity (Obesity)	Ongoing; Unknown