SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		62 Years	Male	114.10 kg		APR	2025

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

dizzy [Dizziness]
blood glucose level was 150 mg/dl [Blood glucose increased]
significant shaking in his hands [Tremor]
Ozempic prescribed for obesity and prediabetes [Off label use]

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

Study ID: 199-NovoDia

Study description: Trial Title: Patient support programme to support **(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) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.25 mg, qw

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

17. INDICATION(S) FOR USE
#1) Obesity (Obesity)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) APR-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)
#1) FANTER (DAPAGLIFLOZIN) ; APR-2025 / Ongoing
#2) TRIVERAM [AMLODIPINE BESILATE;ATORVASTATIN CALCIUM;
(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 not reported.	Obesity (Obesity)
Unknown to Ongoing	Current Condition	Prediabetes (Glucose tolerance impaired)

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.
1447296

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

24c. DATE RECEIVED BY MANUFACTURER
28-MAY-2025

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

DATE OF THIS REPORT
01-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1447296

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

physician and their daily work to maintain an optimal diabetic control of patients through added value services such as treatment starter kit, nutrition support through NovoDia call center, individual workshops, group workshops and free A1c test.

Patient's height: 177 cm.

Patient's weight: 114.1 kg.

Patient's BMI: 36.41993040.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "dizzy(Dizzy)" beginning on MAY-2025 , "blood glucose level was 150 mg/dl(Blood glucose increased)" beginning on 28-MAY-2025 , "significant shaking in his hands(Shaking of hands)" beginning on 28-MAY-2025 , "Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication)" beginning on APR-2025 and concerned a 62 Years old Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from APR-2025 and ongoing for "Obesity", "prediabetes",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-APR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Prediabetes, Fatty liver, Dyslipidaemia, consumed a lot of alcohol, High blood pressure, High cholesterol.

Concomitant medications included - FANTER(DAPAGLIFLOZIN), TRIVERAM [AMLODIPINE BESILATE;ATORVASTATIN CALCIUM;PERINDOPRIL ARGININE](AMLODIPINE BESILATE, ATORVASTATIN CALCIUM, PERINDOPRIL ARGININE).

Lab Data included:
Test Date: 28-MAY-2025
Lab Data Test as Reported: blood glucose level
Test Name: Blood glucose
Results: 150
Unit: mg/dL
Comments:

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK;

Action taken to Ozempic 0.25/0.50 mg was reported as No Change.

On MAY-2025 the outcome for the event "dizzy(Dizzy)" was Recovered.
The outcome for the event "blood glucose level was 150 mg/dl(Blood glucose increased)" was Recovering/resolving.
The outcome for the event "significant shaking in his hands(Shaking of hands)" was Recovering/resolving.
The outcome for the event "Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
dizzy(Dizzy) : Possible
blood glucose level was 150 mg/dl(Blood glucose increased) : Unlikely
significant shaking in his hands(Shaking of hands) : Unlikely
Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
dizzy(Dizzy) : Possible
blood glucose level was 150 mg/dl(Blood glucose increased) : Unlikely
significant shaking in his hands(Shaking of hands) : Unlikely
Ozempic prescribed for obesity and prediabetes(Off label use in unapproved indication) : Possible

Reporter Comment: He felt dizzy (he notes that he had not eaten dinner the night before and had not had breakfast that day). the day before event "significant shaking in his hands" patient had consumed a lot of alcohol.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	28-MAY-2025	Blood glucose	150 mg/dL	

Mfr. Control Number: 1447296

ADDITIONAL INFORMATION

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) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection; Regimen #1	0.25 mg, qw; Subcutaneous	Obesity (Obesity) prediabetes (Glucose tolerance impaired)	APR-2025 / Ongoing; Unknown

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

#2) TRIVERAM [AMLODIPINE BESILATE;ATORVASTATIN CALCIUM;PERINDOPRIL ARGININE] (AMLODIPINE BESILATE, ATORVASTATIN CALCIUM, PERINDOPRIL ARGININE) ; APR-2025 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Fatty liver (Hepatic steatosis);
Unknown to Ongoing	Current Condition	Dyslipidemia (Dyslipidaemia);
Unknown to Ongoing	Current Condition	Alcohol use (Alcohol use);
Unknown to Ongoing	Current Condition	Blood pressure high (Hypertension);
Unknown to Ongoing	Current Condition	High cholesterol (Blood cholesterol increased);