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		20 Years	Female	81.70 kg		JAN	2024

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

vomit [Vomiting]
vomit [Vomiting]
nausea [Nausea]
Diarrhoea [Diarrhoea]
Too many side effects [Adverse drug reaction]
Ozempic for fatty liver [Product use in unapproved indication]

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

Study ID: 199-NovoDia

(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) 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) Fatty liver (Hepatic steatosis)

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

18. THERAPY DATES(from/to)
#1) JAN-2024 / 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) TAFIL [TADALAFIL] (TADALAFIL) ; 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 Duration not reported	Fatty liver (Hepatic steatosis)
Unknown to Ongoing	Current Condition Duration not reported	Anxiety (Anxiety)

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.
1173545

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

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

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

DATE OF THIS REPORT
10-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Study description: Trial Title: Patient support programme to support 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: 169 cm.

Patient's weight: 81.7 kg.

Patient's BMI: 28.605441.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "vomit(Vomiting)" beginning on JAN-2024 , "vomit(Vomiting)" beginning on 05-FEB-2024 , "nausea(Nausea)" beginning on JAN-2024 , "Diarrhoea(Diarrhoea)" beginning on 05-FEB-2024 , "Too many side effects(Drug side effect)" beginning on 2024 , "Ozempic for fatty liver(Product use in unapproved indication)" beginning on JAN-2024 and concerned a 20 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from JAN-2024 to JUN-2024 for "Fatty liver",

Dosage Regimens:
Ozempic 0.25/0.50 mg: ??-JAN-2024 to Not Reported, Not Reported to ??-JUN-2024;

Current Condition: Fatty liver, Anxiety, Diabetes mellitus.

Concomitant medications included - TAFIL TADALAFIL.

Batch Numbers:
Ozempic 0.25/0.50 mg: UNK, UNK;

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

On JAN-2024 the outcome for the event "vomit(Vomiting)" was Recovered.
On FEB-2024 the outcome for the event "vomit(Vomiting)" was Recovered.
On JUN-2024 the outcome for the event "nausea(Nausea)" was Recovered.
On FEB-2024 the outcome for the event "Diarrhoea(Diarrhoea)" was Recovered.
On JUN-2024 the outcome for the event "Too many side effects(Drug side effect)" was Recovered.
On JUN-2024 the outcome for the event "Ozempic for fatty liver(Product use in unapproved indication)" was Recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
vomit(Vomiting) : Possible
vomit(Vomiting) : Possible
nausea(Nausea) : Possible
Diarrhoea(Diarrhoea) : Possible
Too many side effects(Drug side effect) : Unknown
Ozempic for fatty liver(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -
vomit(Vomiting) : Possible
vomit(Vomiting) : Possible
nausea(Nausea) : Possible
Diarrhoea(Diarrhoea) : Possible
Too many side effects(Drug side effect) : Unlikely
Ozempic for fatty liver(Product use in unapproved indication) : 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) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE) Solution for injection; Regimen #2	0.5 mg, qw; Subcutaneous	Fatty liver (Hepatic steatosis)	Unknown / JUN-2024; Unknown

Mfr. Control Number: 1173545

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

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition Type and duration not reported.	Diabetes mellitus (Diabetes mellitus);