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		72 Years	Male	80.70 kg	13	JUN	2024

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

Other Serious Criteria: Medically Significant
exacerbation of the liver condition (cirrhosis) [Hepatic cirrhosis] ([Condition aggravated])
tumor in the liver [Hepatic neoplasm]
hemoglobin levels decreased [Haemoglobin decreased]
bleeding [Haemorrhage]
PAIN DUE TO HAEMORRHOIDS [Haemorrhoids]
constipated [Constipation]
little bit of heartburn [Dyspepsia]
constipation [Constipation]

(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 1.0 mg (SEMAGLUTIDE) Solution for injection, 1.34 mg/mL

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

15. DAILY DOSE(S)
#1) 18 clicks, qw

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

17. INDICATION(S) FOR USE
#1) Prediabetes (Glucose tolerance impaired)

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

18. THERAPY DATES(from/to)
#1) 13-JUN-2024 / APR-2025

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) EXFORGE (AMLODIPINE BESILATE, VALSARTAN) ; 2014 / Ongoing
#2) MULTIVITAMIN [VITAMINS NOS] (MULTIVITAMIN [VITAMINS
#3) PROPANOLOL [PROPRANOLOL] (PROPRANOLOL) ; 2020 / Ongoing

(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.	Prediabetes (Glucose tolerance impaired)
Unknown to Ongoing	Current Condition	Overweight (Overweight)

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.
1280042

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

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

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

DATE OF THIS REPORT
30-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

nausea [Nausea]
Ozempic use for Prediabetes [Product use in unapproved indication]
ozempic dosage: 18 clicks [Wrong technique in product usage process]

Case Description: Study ID: 199-NovoDia

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: 178 cm.

Patient's weight: 80.7 kg.

Patient's BMI: 25.47026890.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "exacerbation of the liver condition (cirrhosis)(Liver cirrhosis)" beginning on MAY-2025 , "exacerbation of the liver condition (cirrhosis)(Condition aggravated)" beginning on MAY-2025 , "tumor in the liver(Liver tumour)" beginning on MAY-2025 , "hemoglobin levels decreased(Haemoglobin decreased)" beginning on MAY-2025 , "bleeding(Bleeding)" beginning on MAY-2025 , "PAIN DUE TO HAEMORRHOIDS(Haemorrhoids aggravated)" beginning on MAR-2025 , "constipated(Constipation)" beginning on JUL-2024 , "little bit of heartburn(Heartburn)" beginning on AUG-2024 , "constipation(Constipation)" beginning on MAR-2025, “Nausea (Nausea)” beginning on an unspecified date in AUG-2024, “Ozempic use for Prediabetes (Product use in unapproved indication)” beginning on 13-JUN-2024, “Ozempic dosage: 18 clicks (Wrong technique in product usage process)” beginning on 13-JUN-2024 and concerned a 72 Years old Male patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from 13-JUN-2024 to APR-2025 for "Prediabetes".

Dosage Regimens:
Ozempic 1.0 mg: 13-JUN-2024 to ??-APR-2025;

Current Condition: Prediabetes, Overweight, liver condition (cirrhosis) , Hypertension, Hemorrhoids.

Concomitant medications included - EXFORGE(AMLODIPINE BESILATE, VALSARTAN), MULTIVITAMIN [VITAMINS NOS], PROPANOLOL PROPRANOLOL.

Since 13-JUN-2024, patient started using Ozempic for prediabetes in clicks.

On an unknown date, patient's weight (Weight) was 76.7kg.

On an unknown date in JUL-2024, patient was constantly constipated. He went 1 to 2 times a day but with a lot of effort, very hard stools. This did not happen before the treatment.

On an unknown date in AUG-2024, patient had nausea one day, was having a little bit of heartburn, after lunch.

Since an unknown date in MAR-2025, constipation increased significantly in the last few weeks (he mentioned that he changed his diet a bit and was out of the country for almost a month), with discomfort and a sensation of being intoxicated (unable to go to the bathroom) and as a consequence had discomfort from haemorrhoids. Discomfort was confirmed to be pain due to haemorrhoids.

On an unknown date in APR-2025, due to the events patient discontinued using Ozempic.

On an unknown date in MAY-2025, a month or more after discontinuing the suspect, patient received a diagnosis of a tumor in the liver. During examinations (Investigation), the patient presented with bleeding, hemoglobin (Haemoglobin) levels decreased and was currently in palliative care. Although all of this happened when the patient was no longer using the treatment, the reporter mentioned that for the reporter, Ozempic was related not to the cause of the current condition (tumour, bleeding, hemoglobin decreased) but to the exacerbation of the liver condition (cirrhosis) that the patient has had for the past 20 years.

Batch Number for Ozempic 1.0 mg was not reported.

Action taken to Ozempic 1.0 mg was reported as Not Applicable.

The outcome for the event "exacerbation of the liver condition (cirrhosis)(Liver cirrhosis)" was Not recovered.
The outcome for the event "exacerbation of the liver condition (cirrhosis)(Condition aggravated)" was Not recovered.
The outcome for the event "tumor in the liver(Liver tumour)" was Not recovered.
The outcome for the event "hemoglobin levels decreased(Haemoglobin decreased)" was Not recovered.
The outcome for the event "bleeding(Bleeding)" was Not recovered.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The outcome for the event "PAIN DUE TO HAEMORRHOIDS(Haemorrhoids aggravated)" was Recovering/resolving.
The outcome for the event "constipated(Constipation)" was Recovered.
The outcome for the event "little bit of heartburn(Heartburn)" was Not recovered.
On APR-2025 the outcome for the event "constipation(Constipation)" was Recovered.
On AUG-2024 the outcome for the event Nausea (Nausea) was Recovered.
On APR-2025 the outcome for the event Ozempic use for Prediabetes (Product use in unapproved indication) was Not Recovered.
On APR-2025 the outcome for the event Ozempic dosage: 18 clicks (Wrong technique in product usage process) was Not Recovered.

Reporter's causality (Ozempic 1.0 mg) -
exacerbation of the liver condition (cirrhosis)(Liver cirrhosis) : Possible
exacerbation of the liver condition (cirrhosis)(Condition aggravated) : Possible
tumor in the liver(Liver tumour) : Unknown
hemoglobin levels decreased(Haemoglobin decreased) : Unknown
bleeding(Bleeding) : Unknown
PAIN DUE TO HAEMORRHOIDS(Haemorrhoids aggravated) : Possible
constipated(Constipation) : Possible
little bit of heartburn(Heartburn) : Possible
constipation(Constipation) : Possible
Nausea (Nausea): Possible
Ozempic use for Prediabetes (Product use in unapproved indication): Unknown
Ozempic dosage: 18 clicks (Wrong technique in product usage process): Unknown

Company's causality (Ozempic 1.0 mg) -
exacerbation of the liver condition (cirrhosis)(Liver cirrhosis) : Unlikely
exacerbation of the liver condition (cirrhosis)(Condition aggravated) : Unlikely
tumor in the liver(Liver tumour) : Unlikely
hemoglobin levels decreased(Haemoglobin decreased) : Unlikely
bleeding(Bleeding) : Unlikely
PAIN DUE TO HAEMORRHOIDS(Haemorrhoids aggravated) : Unlikely
constipated(Constipation) : Possible
little bit of heartburn(Heartburn) : Possible
constipation(Constipation) : Possible
Nausea (Nausea): Possible
Ozempic use for Prediabetes (Product use in unapproved indication): Possible
Ozempic dosage: 18 clicks (Wrong technique in product usage process): Possible

This case was re-classified from non-serious to serious on 21-JUL-2025 due to addition of events exacerbation of the liver condition (cirrhosis), tumor in the liver, bleeding and hemoglobin levels decreased with medically significant marked as seriousness criterion.

No consent for safety follow-up questions, hence no further follow-up is possible.

Company comment:
'Hepatic cirrhosis' (condition aggravated), 'Hepatic neoplasm', 'Hemoglobin decreased', 'Hemorrhage', 'Hemorrhoids', are assessed as unlisted; 'Dyspepsia', 'Constipation', and 'Nausea' are assessed as listed according to Novo Nordisk current CCDS on Ozempic. The available information regarding the onset latency of events, the chronology of occurrences, and the detailed clinical course is insufficient. There is a lack of comprehensive medical history, including any past liver disorders, co-morbidities, blood disorders, and episodes of hemorrhoids. Furthermore, laboratory investigations, such as liver function tests, imaging studies (ultrasound, CT scan, MRI) to evaluate liver tumor characteristics and the extent of cirrhosis, and histopathological reports to distinguish between benign and malignant tumors, are also lacking. Additionally, the patient's history of alcohol and drug use is not documented. Despite these gaps, the reported events appear interconnected, suggesting a clinical scenario where chronic liver disease (cirrhosis) may predispose the patient to liver tumors. This, in turn, could lead to decreased hemoglobin levels due to hemorrhagic events, which may be exacerbated by gastrointestinal disturbances such as constipation and hemorrhoid complications. Considering the available information and known safety profile of suspect product, the causality is assessed as unlikely related to the suspect product.
This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAY-2025	Haemoglobin On an unknown date in MAY-2025, patient's haemoglobin levels decreased (units and values not reported).		
2	MAY-2025	Investigation		

Mfr. Control Number: 1280042

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		On an unknown date in MAY-2025, patient underwent examination (test name, results not reported).		
3		Weight	76.7 kg	

13. Relevant Tests

Patient's current weight was 76.7 kg.
On an unknown date in MAY-2025, patient underwent examination (test name, results not reported).
On an unknown date in MAY-2025, patient's haemoglobin levels decreased (units and values not reported).

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

#2) MULTIVITAMIN [VITAMINS NOS] (MULTIVITAMIN [VITAMINS NOS]) ; 2024 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition for the past 20 years	Liver cirrhosis (Hepatic cirrhosis);
Unknown to Ongoing	Current Condition	Hypertension (Hypertension);
Unknown to Ongoing	Current Condition	Hemorrhoids (Haemorrhoids);