

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 53 Years	3. SEX Female	3a. WEIGHT 123.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year				Day	Month	Year	
			PRIVACY						MAR	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 Stomachache [Abdominal pain upper]
 stomach discomfort. [Abdominal discomfort]
 'viral episode' with high fevers [Pyrexia]
 Urinary infection [Urinary tract infection]
 anxiety for sweet things [Anxiety]
 'viral episode' with diarrhea [Viral diarrhoea]
 Ozempic administered in clicks [Wrong technique in product usage process]
 Ozempic for obesity [Product use in unapproved indication]

Case Description: ***This is an auto generated narrative*** (Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 36 clicks qw	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous	
17. INDICATION(S) FOR USE #1) obesity (Obesity)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) MAR-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) ZOPICLONE (ZOPICLONE) ; JUN-2025 / Ongoing #2) FLUOXETINE (FLUOXETINE) ; Ongoing #3) MELATONIN (MELATONIN) ; 2025 / Ongoing		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown to Ongoing	Type of History / Notes Current Condition Duration was not reported	Description Obesity (Obesity) Glucose tolerance impaired (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. 1475695	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 03-JUL-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 23-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

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: 154 cm.

Patient's weight: 123 kg.

Patient's BMI: 51.86372070.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "Stomachache(Stomachache)" beginning on JUN-2025 , "stomach discomfort.(Stomach discomfort)" beginning on JUN-2025 , "'viral episode' with high fevers(Fever)" beginning on JUN-2025 , "Urinary infection(Urinary infection)" beginning on JUN-2025 , "anxiety for sweet things(Anxiety)" beginning on JUN-2025 , "'viral episode' with diarrhea(Viral diarrhoea)" beginning on JUN-2025 , "Ozempic administered in clicks(Wrong technique in product usage process)" beginning on MAR-2025 , "Ozempic for obesity(Product use in unapproved indication)" beginning on MAR-2025 and concerned a 53 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from MAR-2025 and ongoing for "obesity",

Dosage Regimens:

Ozempic 1.0 mg: ??-MAR-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Obesity, Glucose tolerance impaired, circulatory problems, Insomnia.

Concomitant medications included - ZOPICLONE, FLUOXETINE, MELATONIN.

Treatment medications included - TRIMETHOPRIM, PHENAZOPYRIDINE HYDROCHLORIDE.

Batch Numbers:

Ozempic 1.0 mg: UNK;

Action taken to Ozempic 1.0 mg was reported as No Change.

On JUN-2025 the outcome for the event "Stomachache(Stomachache)" was Recovered.

On JUN-2025 the outcome for the event "stomach discomfort.(Stomach discomfort)" was Recovered.

On JUN-2025 the outcome for the event "'viral episode' with high fevers(Fever)" was Recovered.

The outcome for the event "Urinary infection(Urinary infection)" was Recovering/resolving.

The outcome for the event "anxiety for sweet things(Anxiety)" was Not recovered.

On JUN-2025 the outcome for the event "'viral episode' with diarrhea(Viral diarrhoea)" was Recovered.

The outcome for the event "Ozempic administered in clicks(Wrong technique in product usage process)" was Not recovered.

The outcome for the event "Ozempic for obesity(Product use in unapproved indication)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -

Stomachache(Stomachache) : Unlikely

stomach discomfort.(Stomach discomfort) : Unlikely

'viral episode' with high fevers(Fever) : Unlikely

Urinary infection(Urinary infection) : Unlikely

anxiety for sweet things(Anxiety) : Unlikely

'viral episode' with diarrhea(Viral diarrhoea) : Unlikely

Ozempic administered in clicks(Wrong technique in product usage process) : Unknown

Ozempic for obesity(Product use in unapproved indication) : Unknown

Company's causality (Ozempic 1.0 mg) -

Stomachache(Stomachache) : Possible

stomach discomfort.(Stomach discomfort) : Possible

'viral episode' with high fevers(Fever) : Unlikely

Urinary infection(Urinary infection) : Unlikely

anxiety for sweet things(Anxiety) : Unlikely

'viral episode' with diarrhea(Viral diarrhoea) : Unlikely

Ozempic administered in clicks(Wrong technique in product usage process) : Possible

Ozempic for obesity(Product use in unapproved indication) : Possible

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Disorder circulatory system (Cardiovascular disorder);
Unknown to Ongoing	Current Condition	Insomnia (Insomnia);