

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>61</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>72.10</b> 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			
										<b>PRIVACY</b>	<b>MAY</b>	<b>2025</b>

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
 nauseous [Nausea]  
 Feeling very tired [Fatigue]  
 muscle loss [Muscle atrophy]  
 Ozempic use for fat liver [Product use in unapproved indication]

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)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) Semaglutide B 1.34 mg/ml PDS290 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1.34 mg/mL		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 ) 0.25 mg, qw	16. ROUTE(S) OF ADMINISTRATION #1 ) Subcutaneous	
17. INDICATION(S) FOR USE #1 ) Fat liver (Hepatic steatosis)		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 ) MAY-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)		
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      Fatty liver (Hepatic steatosis)		

## 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. <b>1468268</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>20-JUN-2025</b>	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 <b>11-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

11-Jul-2025 07:19

---

**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 weight: 72.1 kg.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "nauseous(Nauseous)" beginning on MAY-2025 , "Feeling very tired(Tiredness)" beginning on MAY-2025 , "muscle loss(Muscle atrophy)" beginning on MAY-2025 , "Ozempic use for fat liver(Product use in unapproved indication)" beginning on MAY-2025 and concerned a 61 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE 1.34 mg/mL) from MAY-2025 and ongoing for "Fat liver",

Dosage Regimens:

Ozempic: ??-MAY-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: Fat liver.

Treatment medications included - DILEX(VALPROATE SEMISODIUM).

Batch Numbers:

Ozempic: UNK;

Action taken to Ozempic was reported as No Change.

The outcome for the event "nauseous(Nauseous)" was Not recovered.

The outcome for the event "Feeling very tired(Tiredness)" was Not recovered.

The outcome for the event "muscle loss(Muscle atrophy)" was Not recovered.

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

Reporter's causality (Ozempic) -

nauseous(Nauseous) : Unlikely

Feeling very tired(Tiredness) : Unlikely

muscle loss(Muscle atrophy) : Unlikely

Ozempic use for fat liver(Product use in unapproved indication) : Unknown

Company's causality (Ozempic) -

nauseous(Nauseous) : Possible

Feeling very tired(Tiredness) : Possible

muscle loss(Muscle atrophy) : Unlikely

Ozempic use for fat liver(Product use in unapproved indication) : Possible

Reporter Comment: The patient is being managed with nutritional support.