

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 63 Years	3. SEX Female	3a. WEIGHT 79.00 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 checked="" type="checkbox"/> OTHER	
		Day	Month	Year			Day	Month	Year			
										PRIVACY	JAN	2025

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
asthmatic bronchitis." [Asthma]
neuropathy [Neuropathy peripheral]
HbA1c increased significantly; it was at 7.5 and then went up to 8.5. [Glycosylated haemoglobin increased]
insulin levels shot up very high [Blood insulin increased]
Doctor taught her to use the medication Ozempic in clicks/ 18 clicks [Off label use]

Case Description: Study ID: 199-NovoDia

(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 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection (Lot # #2) Actrapid HM(GE) 100 IU/mL (INSULIN HUMAN 100 IU/mL) Solution for (Continued on Additional Information Page)		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) 18 clicks, qw #2) 5 IU before each meal	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous #2) Subcutaneous	
17. INDICATION(S) FOR USE #1) type 2 diabetes (Type 2 diabetes mellitus) #2) type 2 diabetes mellitus (Type 2 diabetes mellitus)		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) JAN-2025 / Unknown #2) 2015 / Unknown	19. THERAPY DURATION #1) Unknown #2) 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) ; Unknown #2) ROSUVASTATIN (ROSUVASTATIN) ; Unknown #3) EUTIROX (LEVOTHYROXINE SODIUM) ; Unknown														
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) <table border="0"> <tr> <td>From/To Dates</td> <td>Type of History / Notes</td> <td>Description</td> </tr> <tr> <td>2015 to Ongoing</td> <td>Current Condition</td> <td>Type 2 diabetes mellitus (Type 2 diabetes mellitus)</td> </tr> <tr> <td>Unknown</td> <td>Historical Condition</td> <td>Bronchitis (Bronchitis)</td> </tr> <tr> <td></td> <td>but very sporadic</td> <td></td> </tr> </table>			From/To Dates	Type of History / Notes	Description	2015 to Ongoing	Current Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)	Unknown	Historical Condition	Bronchitis (Bronchitis)		but very sporadic	
From/To Dates	Type of History / Notes	Description												
2015 to Ongoing	Current Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)												
Unknown	Historical Condition	Bronchitis (Bronchitis)												
	but very sporadic													

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. 1459628	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 16-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 25-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> 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: 162 cm.

Patient's weight: 79 kg.

Patient's BMI: 30.10211860.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "asthmatic bronchitis(Bronchitis asthmatic)" beginning on 26-MAR-2025 , "neuropathy(Neuropathy)" with an unspecified onset date , "HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased)" beginning on JAN-2025 , "insulin levels shot up very high(Insulin high)" beginning on JAN-2025 , "Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use)" beginning on JAN-2025 and concerned a 63 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE 1.34 mg/mL) from JAN-2025 and ongoing for "type 2 diabetes" , , Actrapid HM(GE) 100 IU/mL (INSULIN HUMAN 100 IU/mL) from 2015 and ongoing for "type 2 diabetes mellitus" , , Novolin N Vial (INSULIN HUMAN ISOPHANE 100 IU/mL) from 2015 and ongoing for "type 2 diabetes mellitus",

Dosage Regimens:

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

Actrapid HM(GE) 100 IU/mL: ??-???-2015 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Novolin N Vial: ??-???-2015 to Not Reported (Dosage Regimen Ongoing);

Current Condition: type 2 diabetes (since 2015), hypertension

Historical Condition: Bronchitis.

Concomitant medications included - EXFORGE(AMLODIPINE BESILATE, VALSARTAN), ROSUVASTATIN, EUTIROX(LEVOTHYROXINE SODIUM).

On an unknown date, The patient had been experiencing neuropathies, something very strange and doctor detected as neuropathy. These symptoms included a burning sensation and a feeling of pins and needles, particularly in the ear and other parts of the body.

The patient also mentioned that they did not have retinopathy and that they were wearing glasses..

The patient visited the emergency room twice, but the care provided was not sufficient, and the prognosis was not properly addressed. As a result, the patient consulted a pulmonologist, who monitored her within two days.

On 26-MAR-2025, She suffered from asthmatic bronchitis for three months. Initially, she was told it was sinusitis, then a cold, and the diagnosis continued to be misdirected until she saw the pulmonologist, who diagnosed her with asthmatic bronchitis. She had been undergoing treatment with the pulmonologist for two months.

The patient mentioned that she had been to the emergency room twice but did not specify the duration of each visit.

On an unspecified date in JAN-2025, Doctor taught the patient to use the Ozempic in clicks/ 18 clicks, and the patient insulin levels (Blood Insulin) rose significantly, and her HbA1c (Glycosylated haemoglobin) increased from 7.5 (units were not reported) to 8.5 (units were not reported).

Batch Numbers:

Ozempic 0.25/0.50 mg: PP5N025, PP5L760;

Actrapid HM(GE) 100 IU/mL: requested

Novolin N Vial: requested;

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

Action taken to Actrapid HM(GE) 100 IU/mL was reported as Dose Increased.

Action taken to Novolin N Vial was reported as Dose Increased.

On MAY-2025 the outcome for the event asthmatic bronchitis(Bronchitis asthmatic)" was Recovered.

The outcome for the event "neuropathy(Neuropathy)" was Not Reported.

The outcome for the event "HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased)" was Not recovered.

The outcome for the event "insulin levels shot up very high(Insulin high)" was Not Reported.

The outcome for the event "Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use)" was Not recovered.

Reporter's causality (Ozempic 0.25/0.50 mg) -
asthmatic bronchitis(Bronchitis asthmatic) : Unknown

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

neuropathy(Neuropathy) : Unknown

HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased) : Unknown

insulin levels shot up very high(Insulin high) : Unknown

Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use) : Unknown

Company's causality (Ozempic 0.25/0.50 mg) -

she was sick for 3 months, her condition worsened, asthmatic bronchitis(Bronchitis asthmatic) : Unlikely

neuropathy(Neuropathy) : Unlikely

HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased) : Unlikely

insulin levels shot up very high(Insulin high) : Unlikely

Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use) : Possible

Reporter's causality (Actrapid HM(GE) 100 IU/mL) -

asthmatic bronchitis(Bronchitis asthmatic) : Unknown

neuropathy(Neuropathy) : Unknown

HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased) : Unknown

insulin levels shot up very high(Insulin high) : Unknown

Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use) : Unknown

Company's causality (Actrapid HM(GE) 100 IU/mL) -

asthmatic bronchitis(Bronchitis asthmatic) : Unlikely

neuropathy(Neuropathy) : Possible

HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased) : Possible

insulin levels shot up very high(Insulin high) : Unlikely

Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use) : Possible

Reporter's causality (Novolin N Vial) -

asthmatic bronchitis(Bronchitis asthmatic) : Unknown

neuropathy(Neuropathy) : Unknown

HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased) : Unknown

insulin levels shot up very high(Insulin high) : Unknown

Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use) : Unknown

Company's causality (Novolin N Vial) -

asthmatic bronchitis(Bronchitis asthmatic) : Unlikely

neuropathy(Neuropathy) : Possible

HbA1c increased significantly; it was at 7.5 and then went up to 8.5.(HbA1C increased) : Unlikely

insulin levels shot up very high(Insulin high) : Unlikely

Doctor taught her to use the medication Ozempic in clicks/ 18 clicks(Off label use) : Possible

On 16-JUL-2025, the case has been Re-classified from non-serious to serious due to the addition of the event asthmatic bronchitis and neuropathy with seriousness criteria of medical significant.

Since last submission the case has been updated with the following:

- Medical history updated
- lab data updated
- New suspect products of actrapid and Insulatard added
- New events of "asthma, neuropathy, HBA1C increased and insulin high" were added
- narrative updated accordingly.

Company Comment;

Asthma and peripheral neuropathy are assessed as unlisted event; Glycosylated haemoglobin increased, and Blood insulin increased and off label use is assessed as listed events according to NovoNordisk current reference safety information on Ozempic.

Asthma is assessed as unlisted event; peripheral neuropathy, glycosylated haemoglobin increased, and blood insulin increased is assessed as listed events according to NovoNordisk current reference safety information on Actrapid and Novolin N.

Due to rapid correction of glycemia could result in neuronal damage that may precipitate peripheral neuropathy with insulins therefore the casual relationship with the insulins is assessed as conceivable.

Wheezy bronchitis (asthma bronchitis) refers to bronchitis, an inflammation of the bronchial tubes, that is characterized by the presence of wheezing, a whistling sound during breathing, in addition to other common bronchitis symptoms like coughing and mucus production that can stem from viral or bacterial infections or exposure to irritants. Therefore, the casual role is assessed as unlikely and related to other aetiologies.

This single case report is not considered to change the current knowledge of the safety profile of suspect product.

ADDITIONAL INFORMATION**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	JAN-2025	Blood insulin insulin levels shot up very high		
2	JAN-2025	Glycosylated haemoglobin 7.5 (units were not reported)		
3	JAN-2025	Glycosylated haemoglobin 8.5 (units were not reported)		

13. Relevant Tests

On an unknown date in Jan-2025, patient's HbA1c increased significantly; it was at 7.5 (units were not reported) and then went up to 8.5 (units were not reported).

On an unknown date in Jan-2025, patient's insulin levels shot up very high

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 {Lot # PP5N025}; Regimen #1	18 clicks, qw; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus)	JAN-2025 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 0.25/0.5 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection {Lot # PP5L760}; Regimen #2	18 clicks, qw; Subcutaneous	type 2 diabetes (Type 2 diabetes mellitus)	Ongoing; Unknown
#2) Actrapid HM(GE) 100 IU/mL (INSULIN HUMAN 100 IU/mL) Solution for injection, 100 IU/mL; Regimen #1	5 IU before each meal; Subcutaneous	type 2 diabetes mellitus (Type 2 diabetes mellitus)	2015 / Unknown; Unknown
#2) Actrapid HM(GE) 100 IU/mL (INSULIN HUMAN 100 IU/mL) Solution for injection, 100 IU/mL; Regimen #2	20 IU, bid; Subcutaneous	type 2 diabetes mellitus (Type 2 diabetes mellitus)	Ongoing; Unknown
#3) Insulatard HM (GE) (INSULIN HUMAN ISOPHANE 100 IU/mL) Suspension for injection, 100 IU/mL; Regimen #1	10 IU, bid; Subcutaneous	type 2 diabetes mellitus (Type 2 diabetes mellitus)	2015 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2015 to Ongoing	Current Condition	Hypertension (Hypertension);