

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 48 Years	3. SEX Female	3a. WEIGHT Unk	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					24	MAY	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
 itching on the body, more in the back and buttocks during the second application [Pruritus]
 Diarrhea [Diarrhoea]
 headache [Headache]
 stomach pain [Abdominal pain upper]
 Constipation [Constipation]
 Nausea [Nausea]
 Doctor instructed the patient to administer ozempic using clicks (20 clicks, 35 clicks, 55 clicks, 50 clicks) and endocrinologist prescribed ozempic use for overweight [Off label use]

(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 (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # (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) qw(20 clicks)	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous	
17. INDICATION(S) FOR USE #1) overweight (Overweight)		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) 24-MAY-2025 / 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)														
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>Unknown to Ongoing</td> <td>Current Condition</td> <td>Overweight (Overweight)</td> </tr> <tr> <td></td> <td>Duration not reported.</td> <td></td> </tr> <tr> <td>Unknown to Ongoing</td> <td>Current Condition</td> <td>Premenopause (Menopause)</td> </tr> </table>			From/To Dates	Type of History / Notes	Description	Unknown to Ongoing	Current Condition	Overweight (Overweight)		Duration not reported.		Unknown to Ongoing	Current Condition	Premenopause (Menopause)
From/To Dates	Type of History / Notes	Description												
Unknown to Ongoing	Current Condition	Overweight (Overweight)												
	Duration not reported.													
Unknown to Ongoing	Current Condition	Premenopause (Menopause)												

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. 1446188	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 25-JUN-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 type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

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

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

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.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "itching on the body, more in the back and buttocks during the second application(Generalized itching)" beginning on 2025 , "Diarrhea(Diarrhea)" beginning on 24-MAY-2025 , "headache(Headache)" beginning on 24-MAY-2025 , "stomach pain(Stomach pain)" beginning on 24-MAY-2025 , "Constipation(Constipation)" beginning on 29-JUN-2025 , "Nausea(Nausea)" beginning on 29-JUN-2025 , "Doctor instructed the patient to administer ozempic using clicks (20 clicks, 35 clicks, 55 clicks, 50 clicks) and endocrinologist prescribed ozempic use for overweight(Off label use)" beginning on 24-MAY-2025 and concerned a 48 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 24-MAY-2025 and ongoing for "overweight",

Dosage Regimens:

Ozempic 1.0 mg: 24-MAY-2025 to Not Reported, Not Reported to Not Reported, 21-JUN-2025 to Not Reported, 29-JUN-2025 to Not Reported (Dosage Regimen Ongoing);

Current Condition: overweight, Premenopause.

Batch Numbers:

Ozempic 1.0 mg: PP5L760, PP5L760, PP5L760, PP5L760;

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

The outcome for the event "itching on the body, more in the back and buttocks during the second application(Generalized itching)" was Not Reported.

On 25-MAY-2025 the outcome for the event "Diarrhea(Diarrhea)" was Recovered.

On 25-MAY-2025 the outcome for the event "headache(Headache)" was Recovered.

On 25-MAY-2025 the outcome for the event "stomach pain(Stomach pain)" was Recovered.

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

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

The outcome for the event "Doctor instructed the patient to administer ozempic using clicks (20 clicks, 35 clicks, 55 clicks, 50 clicks) and endocrinologist prescribed ozempic use for overweight(Off label use)" was Not recovered.

Reporter's causality (Ozempic 1.0 mg) -

itching on the body, more in the back and buttocks during the second application(Generalized itching) : Possible

Diarrhea(Diarrhea) : Possible

headache(Headache) : Possible

stomach pain(Stomach pain) : Possible

Constipation(Constipation) : Unknown

Nausea(Nausea) : Unknown

Doctor instructed the patient to administer ozempic using clicks (20 clicks, 35 clicks, 55 clicks, 50 clicks) and endocrinologist prescribed ozempic use for overweight(Off label use) : Unknown

Company's causality (Ozempic 1.0 mg) -

itching on the body, more in the back and buttocks during the second application(Generalized itching) : Possible

Diarrhea(Diarrhea) : Possible

headache(Headache) : Possible

stomach pain(Stomach pain) : Possible

Constipation(Constipation) : Possible

Nausea(Nausea) : Possible

Doctor instructed the patient to administer ozempic using clicks (20 clicks, 35 clicks, 55 clicks, 50 clicks) and endocrinologist prescribed ozempic use for overweight(Off label use) : Possible

Reporter Comment: Patient does not use any concomitant drugs.

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
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #1	qw(20 clicks); Subcutaneous	overweight (Overweight)	24-MAY-2025 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #2	qw(35 clicks); Subcutaneous	overweight (Overweight)	Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #3	qw(55 clicks); Subcutaneous	overweight (Overweight)	21-JUN-2025 / Unknown; Unknown
#1) Semaglutide B 1.34 mg/ml PDS290 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg {Lot # PP5L760; Exp.Dt. JAN-2027}; Regimen #4	qw(50 clicks) ((on Saturday); Subcutaneous	overweight (Overweight)	29-JUN-2025 / Ongoing; Unknown