SUSPECT ADVERSE REACTION REPORT																	CIO		IS F	·OI	RM
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PRIVACY COSTA RICA 199 PRIVACY WE 41 Female 80.00 199 NAME 2023 APR 2023 PRIVACY 199 PRIVA		1a. COUNTRY	2					_	4-6	3 RE	ACTION	N ON	ISET	8-1:	2	CHE	CK ALI	L			
Nausea (Nausea) Coempic use for Weight loss (Product use in unapproved indication) 0.25 mg from Ozempic 1 mg pen (Wrong technique in product usage process)  Case Description: ""This is an auto generated narrative"  This non-serious Spontaneous case from COSTA RICA was reported by a Physician as "Nausea(Nausea)" on Richard Product usage (Continued on Additional Information Page)  III. SUSPECT DRUG(S) INFORMATION  14. SUSPECT DRUG(S) (Notice genete care)  III. SUSPECT DRUG(S) INFORMATION  14. SUSPECT DRUG(S) (Notice genete care)  III. SUSPECT DRUG(S) INFORMATION  14. SUSPECT DRUG(S) (Continued on Additional Information Page)  III. SUSPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUSPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUSPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUSPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPECT DRUG(S) (INFORMATION (Continued on Additional Information Page)  III. SUBPE		COSTA RICA	,		-  41	-s Fema	ا م	)								ADV	ERSE I	REAC			
Case Description: ""This is an auto generated narrative"	Nausea [Nausea] Ozempic use for Weight loss [Product use in unapproved indication]					-	process]						ם כ	INVOLVED OR PROLONGED INPATIENT HOSPITALISATION INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR							
with an unspecified onset date, "Ozempic use for Weight loss/Product use in unapproved indication)" beginning on 23-APR-2023, "0.25 mg from Ozempic 1 mg pen(Wrong technique) in product usage (Continued on Additional Information Page)															7	LIFE					
II. SUSPECT DRUG(S) (INFORMATION   1.5 UNITY CONTROL TO BE   1.34 mg/mL) Solution for injection, 1 mg (Continued on Additional Information Page)   20 DID REACTION (BIOLOGY FAPER STOPPING (Continued on Additional Information Page)   1.5 DID REACTION (Continued on Additional Information Page)   20 DID REACTION (BIOLOGY FAPER STOPPING (Continued on Additional Information Page)   1.5 DID REACTION (Continued on Additional Information												isea	a)"	[	CONGENITAL ANOMALY						
14. SUBSECT DRUGS) (include pereir came)   17. Pereir Storping   18. Data Posterial Page   19.	beginning on 23-	APR-2023, "0.25 m	g from	Ozempic 1 r	ng pen(W	-				_		tion	Pag	<sub>je)</sub> [	OTHER						
## 1) Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg (Continued on Additional Information Page)  15. DAILY DOSE(S) 15. THERAPY DURATION 17. INDICATIONS) FOR USE 17. INDICATIONS FOR USE 18. CONCOMITANT DRUG(S) AND HISTORY  18. THERAPY DURATION 19. 1) Unknown  19. THERAPY DURATION 19. 1) Unknown  19. THERAPY DURATION 19. 1) Unknown  19. THERAPY DURATION	II. SUSPECT DRUG(S) INFORMATION																				
#1 ) 0.25 mg from 1 mg pen #1 ) Unknown	` '	#1 ) Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg									ABATE AFTER STOPPING DRUG?										
#1 ) Weight loss (Weight control)  18. THERAPY DURATION #1 ) 23-APR-2023 / JUL-2023  19. THERAPY DURATION #1 ) Unknown  11. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)  #1 ) SERTRALINE (SERTRALINE); Unknown  19. THERAPY DURATION #1 ) SERTRALINE (SERTRALINE); Unknown  10. THERAPY DURATION  24. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) #1 ) Description  10. THERAPY DURATION  24. NAME AND ADDRESS OF MANUFACTURER Nove Nordisk A/S Lise Grimmeshave Vandtaarnsvej 114 Soeborg, DK-2660 DENMARK Phone: +45 44448888  24. DATE RECEIVED BY MANUFACTURER 24. DATE RECEIVED BY MANUFACTURER 25. NAME AND ADDRESS WITHHELD.		1 mg pen											YES NO NA								
#1 ) 23-APR-2023 / JUL-2023 #1 ) Unknown						REAPPEAR AFTER						?									
22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1 ) SERTRALINE (SERTRALINE) ; Unknown    Unknown												YES NO NA									
#1 ) SERTRALINE (SERTRALINE) ; Unknown  23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates Unknown  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER NOVO Nordisk A/S Lise Grimmeshave Vandtaarnsvej 114 Soeborg, DK-2860 DENMARK Phone: +45 44448888  24b. MFR CONTROL NO. 1415641  24c. DATE RECEIVED BY MANUFACTURER 24d. REPORT SOURCE STUDY HERCESSIONAL OTHER: Spontaneous OTHER: Spontaneous DATE OF THIS REPORT  25a. REPORT TYPE			II	I. CONCO	MITANT	DRUG(	S) AND	HIS	STC	DR'	Y			•							
IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Novo Nordisk A/S Lise Grimmeshave Vandtaarnsvej 114 Soeborg, DK-2860 DENMARK Phone: +45 44448888  24b. MFR CONTROL NO. 1415641  24c. DATE RECEIVED BY MANUFACTURER 24d. REPORT SOURCE DATE OF THIS REPORT 25a. REPORT TYPE  25b. NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.					se used to trea	at reaction)	·														
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24c. DATE RECEIVED BY MANUFACTURER 20-MAY-2025  DATE OF THIS REPORT  25a. REPORT TYPE  24d. REPORT SOURCE STUDY LITERATURE OTHER: Spontaneous  25a. REPORT TYPE			NTROL	NO.									).								
20-MAY-2025  DATE OF THIS REPORT  25a. REPORT TYPE  25a. REPORT TYPE	24c. DATE RECEIVED	24d. REPOR	SOUR	E		NAI	/IE AND AI	DDR	ESS	WI	ТННЕ	ELD	).								
DATE OF THIS REPORT  25a. REPORT TYPE  25a. REPORT TYPE		OO MANY OOOF																			
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## **ADDITIONAL INFORMATION**

## 7+13. DESCRIBE REACTION(S) continued

process)" beginning on 23-APR-2023, and concerned a 41 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) from 23-APR-2023 to 12-JAN-2025 for "Weight loss",

Patient's weight: 80 kg

Dosage Regimens:

Ozempic 1.0 mg: 23-APR-2023 to ??-JUL-2023, Not Reported to Not Reported, Not Reported to 12-JAN-2025;

Medical history was not provided.

Concomitant products included - SERTRALINE

Treatment included - FAMOTIDINE

Batch Numbers:

Ozempic 1.0 mg: ASKU, ASKU, ASKU

Action taken to Ozempic 1.0 mg was reported as Product discontinued due to AE.

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

On 12-JAN-2025 the outcome for the event "Ozempic use for Weight loss(Product use in unapproved indication)" was Recovered. On JUL-2023 the outcome for the event "0.25 mg from Ozempic 1 mg pen(Wrong technique in product usage process)" was Recovered.

Reporter Comment: The doctor changes the treatment from Ozempic to Saxenda.

## 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 ) Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #2	0.5 mg; Unknown	Weight loss (Weight control)	Unknown; Unknown
#1 ) Ozempic 1.0 mg (SEMAGLUTIDE 1.34 mg/mL) Solution for injection, 1 mg; Regimen #3	1 mg; Unknown	Weight loss (Weight control)	Unknown / 12-JAN-2025; Unknown