

FDA Adverse Event Reporting System (FAERS) FOIA Batch Printing Report for Cases

Date - Time: 18-Jul-2023 16:16:52 EDT

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Disclaimer:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The cover page will display all Case ID(s) included in the Batch Printing Report and FOIA case report information may include both Electronic Submissions (Esubs) and MedWatch Reports (Non-Esubs).

Cover page Case ID(s) with an asterisk (**) indicate an invalid status and are not captured in the body of the report.

Cover page Case ID(s) with an asterisk ('**') indicate an failed status and are not captured in the body of the report.

Case ID(s) Printed:

18143068	18340030	20149863	20762799

21159058 22128240

Total Cases: 6

Total number of Inactive cases: *0



Case ID: 18143068

Case Information:

Case Type : Expedited (15- eSub: Y HP: Country: BE Event Date: 04-Aug-2020 Outcomes: HO Application Type:

Day)

Patient Information:

Age: Sex: Male Weight:

QD

Suspect Products:

Product Name: Compounded Dose/Frequency Route Dosage Text Indication(s) Start Date End Date

0,5mg)

Drug?

1 Ozempic 0.5 mg 6 Mg Milligram(S) / Unknown 6 mg, qd (3 or 4 pen of 04-Aug-2020

2 Ozempic 0.5 mg / Unknown UNK Product used for unknown

indication

Product Name: Interval 1st DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Ozempic 0.5 mg Unknown Unknown NOVO NORDISK

2 Ozempic 0.5 mg Unknown Unknown NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Intentional overdose

Vomiting

Nausea

Event/Problem Narrative:

This serious Spontaneous case from BELGIUM was reported by a Diabetes Nurse Specialist as "suicide attempt by taking 6 mg Ozempic at once(Suicide attempt)" beginning on (b)(6)*****, "Patient has injected 6 mg Ozempic at once(Intentional overdose)" beginning on(b)(6)*****, "vomit(Vomiting)" beginning on (b)(6)*****,



Case ID: 18143068

"nauseous(Nauseous)" beginning on(b)(6)*****, and concerned a Male patient who was treated with Ozempic 0.5 mg (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication", Medical history was not provided. Treatment included - LITICAN ALIZAPRIDE HYDROCHLORIDE, GLUCOSE The patient's height, weight and body mass index were not reported. Dosage Regimens: Ozempic 0.5 mg: Not Reported to Not Reported, (b)(6)***** to Not Reported; On (b)(6)*****, Patient made a suicide attempt by Injecting overdose of 6 mg Ozempic at once and is on intensive care (3 or 4 pen of 0.5 mg), and was hospitalised on the same day. The patient had vomited and was nauseous at the emergency. However afterwards, the patient did not present any special gastrointestinal problems. It was reported that patient was given Litican i.v./ under glucose infusion, the glycaemia remained stable. Patient appears to be unfair in his story to the doctors, also with regard to the injected dose. One day it's 6mg and the next patient claims to have only injected 4mg. On an unknown date, patient's glycaemia of the patient is normal, between 100-130 mg/dl. It was reported that the patient would not have had a psychiatric history. The patient was not on psychotropic drugs. The overdose took place in the context of a relational problem, in which the patient said that the patient acted impulsively. Batch Numbers: Ozempic 0.5 mg; ASKU, ASKU Action taken to Ozempic 0.5 mg was Not reported. The outcome for the event "suicide attempt by taking 6 mg. Ozempic at once(Suicide attempt)" was Recovered. The outcome for the event "Patient has injected 6 mg Ozempic at once(Intentional overdose)" was Recovered. The outcome for the event "vomit(Vomiting)" was Recovered. The outcome for the event "nauseous(Nauseous)" was Recovered. Since last submission, the fllowing have been updated: -New event, nauseous added -Treatment medications added -Narrative updated accordingly Company comment: 'Suicide attempt' was assessed as unlisted event and 'Nausea', 'Vomiting', were assessed as listed events according to the Novo Nordisk current CCDS on Ozempic. Information on suspect product start date, prior suicidal ideations/attempts, action taken to the drug and relevant investigations were not available for thorough medical evaluation. However overdose of Ozempic could have caused 'nausea' and 'Vomiting'. This single case report is not considered to change the current knowledge of safety profile of Ozempic.

# Product Name:	Dose/Frequency	Route		Dosage	e Text	Indicat	ion(s)	Start Date	End Date	Interval 1st Dose to Event
Concomitant Products:										
Blood glucose		100-130		ligram per cilitre						N
Test Name		Result	Un	it		Normal Low	Range	Normal High	Range	Info Avail
Relevant Laboratory Data:										
Medical History Product(s)			Start Date	•	End D	ate	Indications		Events	
									_	
Disease/Surgical Procedure			Start Date)	End Da	ate	Continuing?			
Relevant Medical History:										



Case ID: 18143068

Reporter Source:

Study report?: No Sender organization: NOVO NORDISK 503B Compounding Outsourcing Facility?:

Literature Text:



Case ID: 18340030

Case Information:

Case Type : Expedited (15- eSub: Y HP: Country: JP Event Date: 15-Sep-2020 Outcomes: DE , OT Application Type:

Day)

FDA Rcvd Date: 10-Dec-2020 **Mfr Rcvd Date**: 14-Oct-2020 **Mfr Control #**: JP-NOVOPROD-754978 **Application #**: 209637

Patient Information:

Age: 54 YR Sex: Male Weight: 97.4 KG

Suspect Products:

Product Name: Compounded Dose/Frequency Route Dosage Text Indication(s) Start Date End Date

Drug?

1 Ozempic Subcutaneous .25 Mg Milligram(S) // Subcutaneous 0.25 mg, qw Type 2 diabetes mellitus 27-Aug-2020 15-Sep-2020

Injection 0.25mg SD WK

2 Tresiba Chu / Subcutaneous UNK Type 2 diabetes mellitus

Product Name: Interval 1st DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Ozempic Subcutaneous19 Day Not Applicable NA NOVO NORDISK

Injection 0.25mg SD

2 Tresiba Chu Not Applicable NA NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Hypoglycaemia

Intentional overdose

Event/Problem Narrative:

This serious Spontaneous case from JAPAN was reported by a Medical Doctor as "Suicide attempt(Suicide attempt)" beginning on (b)(6)*****, "Hypoglycaemia(Hypoglycaemia)" beginning on (b)(6)*****, "Overdose deliberate self-inflicted(Overdose deliberate self-inflicted)" beginning on -(b)(6)**, and concerned a 54 Years old Male patient who was treated with Tresiba Chu (Insulin Degludec) from unknown start date for "Type 2 diabetes mellitus", Ozempic



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FDA - Adverse Event Reporting System (FAERS) FOIA Case Report Information

Case ID: 18340030

Subcutaneous Injection 0.25mg SD(SEMAGLUTIDE) from 27-AUG-2020 to (b)(6)***** for "Type 2 diabetes mellitus". Patient's height: 176 cm Patient's weight: 97.4 kg Patient's BMI: 31.443. Dosage Regimens: Tresiba Chu: Ozempic Subcutaneous Injection 0.25mg SD: 27-AUG-2020 to (b)(6)*****; Current Condition: Type 2 diabetes mellitus (duration not reported), End stage renal failure, Obesity Procedure: Dialysis. On 27-AUG-2020 patient started on Ozempic 0.25 mg. The drug was administered by a nurse after dialysis at a hospital. On 27-AUG-2020 Blood lactate dehydrogenase was 175(units not reported), Blood alkaline phosphatase was 261(units not reported), and 92(units not reported), Estimated glomerular filtration rate was 5.3(units not reported), Blood glucose was 121(units not reported), Red cell distribution width(RDW-SD) was 49.2(units not reported), Red cell distribution width(RDW-CV) was 15.1(units not reported), Platelet distribution width was 8.7(units not reported), Mean platelet volume(MPV) was 9.2(units not reported), Platelet-large cell ratio(P-LCR) was 17.6(units not reported), C-reactive protein(Blood CPR) was 10.5(units not reported), Glycated albumin was 21.3(units not reported), Brain natriuretic peptide(BNP) was 31.0(units not reported), Corrected Ca level was 8.8(units not reported), FIB-4 index 0.54(units not reported) and Mentzer index was 23(units not reported) On (b)(6)***** (three weeks after the initiation of treatment with Ozempic), the patient had overdose deliberate self-inflicted with Tresiba for suicide attempt. The patient developed hypoglycaemia and died. Batch Number of Tresiba Chu and Ozempic Subcutaneous Injection 0.25mg SD has been requested. Action taken to Tresiba Chu was reported as Not Applicable. Action taken to Ozempic Subcutaneous Injection 0.25mg SD was reported as Not Applicable. The outcome for the event "Suicide attempt(Suicide attempt)" was Unknown. On (b)(6)**** the outcome for the event "Hypoglycaemia(Hypoglycaemia)" was Fatal. The outcome for the event "Overdose deliberate self-inflicted(Overdose deliberate self-inflicted)" was Unknown. On 14-OCT-2020, an Amendment was performed. Since last submission, the following information has been amended: suspect product corrected from Semaglutide B 1.34 mg/mL PDS290 to Semaglutide C DV3372. Company comment: Suicide attempt is assessed as unlisted and Hypoglycemia is assessed as listed according to the Novo Nordisk current CCDS information on Ozempic and Tresiba Chu Information on autopsy report, medical history of any psychiatric disorder previous attempts of suicide are not available. However death due to overdose of suspect product and hypoglycemia cannot be denied. As only limited information is available, it is difficult to perform a thorough medical evaluation This single case report is not considered to change the current knowledge of the safety profile of Ozempic and Tresiba Chu

Relevant Medical History: Continuing? Disease/Surgical Procedure Start Date **End Date** Type 2 diabetes mellitus End stage renal disease Obesity Dialysis Medical History Product(s) **Start Date End Date** Indications **Events Relevant Laboratory Data: Test Name** Result Unit **Normal Low Range Normal High Range** Info Avail Υ Adjusted calcium Υ Blood alkaline phosphatase



Case ID: 18340030

Study report?: No Literature Text:	Sender organiz	ation: NOVC) NORDISK	503B Coi Outsourd	mpounding cing Facility?:		
Reporter Source:							
# Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
Concomitant Products:							
Red cell distribution width							Υ
Red cell distribution width							Υ
Platelet-large cell ratio							Υ
Platelet distribution width							Υ
Mean platelet volume							Υ
Glycated albumin							Υ
Glomerular filtration rate							Υ
C-reactive protein							Υ
Brain natriuretic peptide							Y
Blood lactate dehydrogenase	<u> </u>						Y
Blood glucose							Y
Blood alkaline phosphatase							Υ



Case ID: 20149863

Case Information:

Case Type : Expedited (15- eSub: Y HP: Y Country: FR Event Date: Outcomes: HO Application Type:

Day)

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

Product Name: Compounded Dose/Frequency Route Dosage Text Indication(s) Start Date End Date

Drug?

1 Ozempic / Unknown UNK Product used for unknown

indication

Product Name: Interval 1st DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Ozempic Unknown Unknown NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Intentional overdose

Event/Problem Narrative:

This serious Spontaneous case from FRANCE was reported by a Physician as "attempted suicide(Attempted suicide)" with an unspecified onset date, "overdosing with Ozempic(Drug overdose deliberate self-inflicted)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "product used for unknown indication", Patient height, weight and body mass index was not reported. Medical history was not provided. On an unknown date patient attempted suicide by overdosing with Ozempic due to which she was hospitalised. Batch Numbers: Ozempic: Requested. Action taken to Ozempic was reported as Unknown. The outcome for the event "attempted suicide(Attempted suicide)" was Unknown. Company comment: Suicidal attempt is assessed as unlisted event according to the NovoNordisk current company core data sheet (CCDS) on Ozempic The information regarding complete medical history (psychiatric disorders), previous history of suicide attempt, concomitant medications, relevant investigation reports are unavailable which limits the medical assessment of the case This single case report is not considered to change the current knowledge of the safety profile Ozempic The outcome for the event "overdosing with Ozempic(Drug overdose deliberate self-inflicted)" was Not Reported.



Case ID: 20149863

Relevant Medical History:								
Disease/Surgical Procedure			Start Date	End [Date Continuin	g?		
Medical History Product(s)			Start Date	End [Date Indication	s	Events	
Relevant Laboratory Data:								
Test Name		Result	Unit		Normal Low Range	Normal Hig	gh Range	Info Avail
Concomitant Products:								
# Product Name:	Dose/Frequency	Route		Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Even
Reporter Source:								
Study report?: No	Sender orga	anization:	NOVO NORI	DISK		npounding ing Facility?:		
Literature Text:								



Case ID: 20762799

Case Information:

Case Type : Expedited (15- eSub: Y HP: N Country: AU Event Date: Outcomes: LT , OT Application Type:

Day)

FDA Rcvd Date: 28-Apr-2022 **Mfr Rcvd Date**: 18-Apr-2022 **Mfr Control #**: AU-NOVOPROD-911528 **Application #**: 209637

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

Product Name: Compounded Dose/Frequency Route Dosage Text Indication(s) Start Date End Date

Drug?

1 Ozempic / Unknown UNK Product used for unknown

indication

Product Name: Interval 1st DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Ozempic Unknown Unknown NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Depression

Product availability issue

Event/Problem Narrative:

This serious Spontaneous case from AUSTRALIA was reported by a Consumer as "she tried to commit suicide(Suicide attempt)" with an unspecified onset date, "So depressed(Depression)" with an unspecified onset date, "Now we can't get it, she can't keep up with her prescription(product availability issue)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication", Patient's Height, Weight and Body Mass Index was not reported Current Condition: overweight. It was reported that Ozempic gave us a good start on new lives. Patient has been overweight most of her life; finally found something that works and was helping and nowcan't get it. On an unknown date patient was so depressed she can't keep up with her prescription that she tried to commit suicide. Patient was given antidepressants(unspecified) as treatment drug for Depression Batch Number was requested Action taken to Ozempic was Not reported. The outcome for the event "she tried to commit suicide(Suicide attempt)" was Not Reported. The outcome for the event "Now we can't get it, she can't keep up



Case ID: 20762799

with her prescription(product availability issue)" was Not Reported. Company Comment: "Suicide attempt" and "Depression" are assessed as unlisted according to the Novo Nordisk current CCDS information on Ozempic. Information on medical history including any psychiatric illness, social and family behaviour, previous episodes of suicide attempt would have helped in thorough medical assessment. Patient being overweight is assessed as risk factor for depression and suicide attempt. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:									
Disease/Surgical Procedure Overweight			Start Date	End D	ate	Continuing?			
Medical History Product(s)			Start Date	End D	Date	Indications		Events	
Relevant Laboratory Data:									
Test Name		Result	Unit		Normal Low	Range	Normal High	Range	Info Avail
Concomitant Products:									
# Product Name:	Dose/Frequency	Route		Dosage Text	Indicati	ion(s)	Start Date	End Date	Interval 1st Dose to Event
Reporter Source:									
Study report?: No	Sender orga	nization:	NOVO NORI	DISK		503B Compo	ounding Facility?:		
Literature Text:									



Case ID: 21159058

Case Information:

Case Type : Expedited (15- eSub: Y HP: Y Country: CA Event Date: 11-Jul-2022 Outcomes: OT Application Type:

Day)

FDA Rcvd Date: 02-Aug-2022 Mfr Rcvd Date: 22-Jul-2022 Mfr Control #: CA-NOVOPROD-943524 Application #: 209637

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

Product Name: Compounded Dose/Frequency Route Dosage Text Indication(s) Start Date End Date

Drug?

1 Ozempic / UNK Type 2 diabetes mellitus 24-May-2022

Product Name: Interval 1st DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Ozempic 48 Day NA NA NA NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Depression

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Endocrinologist as "Suicidal attempt(Attempted suicide)" beginning on 11-JUL-2022, "Started to feel depressed (Depressed state)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from 24-MAY-2022 for "Type 2 diabetes mellitus", Patient's height, weight and body mass index were not reported. Dosage Regimens: Ozempic: 24-MAY-2022 to Not Reported; Current Condition: Type 2 diabetes mellitus (duration not reported), Fibromyalgia. Concomitant products included - METFORMIN, GLICLAZIDE, FLICK AZURE (non-codable) On an unknown date, patient started to feel depressed after taking Ozempic. On (b)(6)*****, the patient did Suicidal attempt, but survived unscathed (took all her meds at once). The patient was seen in ER at Hospital. The patient had been off all antihyperglycemics. Batch Number for Ozempic not reported. Action taken to Ozempic was reported as Product discontinued. The outcome for the event "Suicidal attempt(Attempted suicide)" was Not Reported. The outcome for the event "Started to feel depressed(Depressed state)" was Not Reported. No further information available. Company comment: 'Suicide attempt' and 'Depression' are assessed as unlisted events according to the Novo Nordisk current CCDS on Ozempic. Information regarding concomitant medications (any



Case ID: 21159058

illicit drug use) complete medical history (psychological disorder, social disturbances, stress, etc.) and relevant investigation report is unavailable which limits the medical assessment of the case. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant	Medical	History:
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Disease/Surgical Procedure Start Date End Date Continuing?

Type 2 diabetes mellitus

Yes Yes

Fibromyalgia

Start Date End Date Indications

Events

Relevant Laboratory Data:

Medical History Product(s)

Test Name Result Unit Normal Low Range Normal High Range Info Avail

Concomitant Products:

Product Name: Dose/Frequency Route **Dosage Text** Indication(s) **Start Date End Date** Interval 1st Dose to Event METFORMIN UNK Product used for unknown indication 2 GLICLAZIDE UNK Product used for unknown indication

Reporter Source:

Study report?: No Sender organization: NOVO NORDISK 503B Compounding Outsourcing Facility?:

Literature Text:



Case ID: 22128240

Case Information:

Case Type : Expedited (15- eSub: Y HP: Y Country: LB Event Date: Outcomes: HO Application Type:

Day)

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

Product Name: Compounded Dose/Frequency Route Dosage Text Indication(s) Start Date End Date

Drug?

1 Ozempic 1.0 mg / UNK Product used for unknown

indication

Product Name: Interval 1st DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Ozempic 1.0 mg Unknown NA NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Intentional overdose

Event/Problem Narrative:

This serious Spontaneous case from LEBANON was reported by a Physician as "attempted to commit suicide(Suicide attempt)" with an unspecified onset date, "taking 1 full pen of Ozempic 1mg in one day(Intentional overdose)" with an unspecified onset date, and concerned a Female patient (age not reported) who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication". Patient's height weight and body mass index were not reported Medical history was not provided. Concomitant products included - Xanax(Alprazolam), Stilnox(Zolpidem Tartrate) On an unspecified date, the patient tried to commit suicide by taking 1 full pen of Ozempic 1mg in one day, in addition to Xanax and Stilnox. The patient was hospitalized to the ER. The blood tests were normal. (Test name, values and units were not reported). After that left the hospital. Batch Numbers: Ozempic 1.0 mg: not reported. Action taken to Ozempic 1.0 mg was Not reported. The outcome for the event "taking 1 full pen of Ozempic 1mg in one day(Intentional overdose)" was Not Reported. No further information available. Since last submission case updated with the following information: New lab data has been added NFI updated Narrative updated accordingly. Company comment: Suicide attempt is assessed as unlisted event and



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intentional overdose is assessed as listed event according to NovoNordisk current reference safety information on Ozempic. Information on demographic details of the patient, history of any risk factors like psychiatric disorders, psychological disorders, anxiety, depression, social and family behavior, relevant medical history, relevant clinical and investigation results, action taken with the suspect, event onset dates with outcome, exposure details of the suspect are unavailable for thorough medical assessment. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:								
Disease/Surgical Procedure			Start Date	End D	ate Continuing?	•		
Medical History Product(s)			Start Date	End D	ate Indications		Events	
Relevant Laboratory Data:								
Test Name BLOOD TEST		Result	Unit		Normal Low Range	Normal High	Range	Info Avail Y
Concomitant Products:								
# Product Name:	Dose/Frequency	Route		Dosage Text	Indication(s)	Start Date	End Date	Interval 1st
	,				5			Dose to Event
1 XANAX	/			UNK	Product used for unknown indication			
2 STILNOX	/			UNK	Product used for			
					unknown indication			
Reporter Source:								
Study report?: No	Sender orga	inization:	NOVO NORE	DISK	503B Comp Outsourcing	ounding g Facility?:		
Literature Text:								