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

Date - T me: 3-Sep-2023 0:2 : 2 EDT

Run by: KIA BAZEMORE@FDA HHS GOV

Disclaimer:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distr butor, 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:

15880466	17118126	18340030	18393458
18467281	18608700	18689632	18936691
19791375	21043905	21095194	21233260

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 15880466

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** Nov-2018 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 30-May-2019 **Mfr Rcvd Date:** 21-May-2019 **Mfr Control #:** US-NOVOPROD-643097 **Application #:** 209637

Patient Information:

Age: 36 YR **Sex:** Male **Weight:** 130 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		.25 Mg Milligram(S) / / WK	Subcutaneous	0.25 mg, qw	Type 2 diabetes mellitus	07-Nov-2018	04-Dec-2018

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Yes	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Depression	
Intentional self-injury	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Pharmacist via a company representative as "suicidal thoughts" beginning in NOV-2018, "depressed" beginning in NOV-2018, "Tried to harm himself" beginning in NOV-2018, and concerned a 36 Year old Male patient who was treated with Ozempic (SEMAGLUTIDE) from 07-NOV-2018 to 04-DEC-2018 due to "type 2 diabetes mellitus". Patient's height: 185.4 cm Patient's weight: 130 kg Patient's BMI: 37.8. Medical history included type 2 diabetes mellitus. No medical history of depression or thoughts of self-harm and no relevant family history. Concomitant products included - metformin, lisinopril, lantus (insulin glargine), bydureon (exenatide, exenatide) In NOV-2018, within a few days of starting Ozempic, the patient experienced suicidal thoughts and was depressed. The patient expressed feelings of profound sadness and thoughts of self-harm on his blog. A behaviorist was called in and spoke with the patient for 20 minutes and determined that the patient was not in imminent danger of harming himself. In NOV-2018, the patient took one dose of Bydureon in order to try to harm himself. Action taken to Ozempic was reported as Product discontinued. On 27-DEC-2018 the outcome for the event

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"suicidal thoughts" was Recovered. On 27-DEC-2018 the outcome for the event "depressed" was Recovered. The outcome for the event "Tried to harm himself" was Not Reported. The pharmacist felt the events of "suicidal thoughts" and "depressed" were related to the use of Ozempic as the timing of the events matched perfectly with the start of the Ozempic and the events resolved completely within a few weeks of stopping Ozempic. Batch number was requested in follow-up. Since last submission, the following has been updated: -New event of "Tried to harm himself" added -Onset date, stop date and reporter's causality assessment for the events "suicidal thoughts" and "depressed" updated -Ozempic start date, stop date, indication and dosing details added -Type 2 diabetes mellitus added to medical history -Concomitant medications added -Alternative aetiology added -Patient's DOB, age, height, weight and BMI added -Narrative updated accordingly Comment: Company Comment: Suicidal ideation, depression, and intentional self injury are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic.Aside from a medical history of type 2 diabetes mellitus, limited information on socioeconomic circumstance, social history (e.g. alcohol, drug use), and laboratory/diagnostic evaluations limits medical assessment. Noted was a behaviorist assessment of no imminent self harm prior to reported intentional self injury. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	METFORMIN	1000 Mg Milligram(S) / BID		1000 mg, bid	Product used for unknown indication	11-Oct-2018		
2	LISINOPRIL	10 Mg Milligram(S) / QD		10 mg, qd	Product used for unknown indication	06-Nov-2018		
3	LANTUS	15 Iu International Unit(S) / QD	Subcutaneous	15 IU, qd	Product used for unknown indication	15-Oct-2018		

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4	BYDUREON	/	Subcutaneous	1 dose	Product used for unknown indication	06-Nov-2018	06-Nov-2018
5	BYDUREON	/	Subcutaneous	1 dose		Nov-2018	Nov-2018

Reporter Source:

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

Literature Text:

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

Case ID: 17118126

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** CA **Event Date:** **Outcomes:** LT **Application Type:**

FDA Rcvd Date: 05-Dec-2019 **Mfr Rcvd Date:** 27-Nov-2019 **Mfr Control #:** CA-NOVOPROD-699753 **Application #:** 209637

Patient Information:

Age: 44 YR **Sex:** Male **Weight:** 133 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK, qw	Type 2 diabetes mellitus		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Unknown	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Anger	
Dehydration	
Mental status changes	
Mood altered	
Nausea	
Product administration interrupted	

Event/Problem Narrative:

This serious Spontaneous case from regulatory authority via health Canada from CANADA was reported by a Physician as "suicidal ideation(Suicidal ideation)" with an unspecified onset date, "anger,(Anger)" with an unspecified onset date, "dehydration(Dehydration)" with an unspecified onset date, "mental status changes(Mental status changes)" with an unspecified onset date, "mood altered(Mood altered)" with an unspecified onset date, "nausea(Nausea)" with an

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unspecified onset date, "product administration interrupted(Product administration interrupted)" with an unspecified onset date, and concerned a 44 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Type 2 diabetes mellitus". Patient's height: 163 cm Patient's weight: 133 kg Patient's BMI: 50.05833870. Dosage Regimens: Ozempic: Curent Condition : Type 2 diabetes mellitus (duration not reported). Concomitant products included - ASA, ATIVAN(LORAZEPAM), AVENTYL(NORTRIPTYLINE HYDROCHLORIDE), COVERSYL PERINDOPRIL ARGININE, CRESTOR(ROSUVASTATIN CALCIUM), LYRICA(PREGABALIN), PROFERRIN(IRON), PROMETRIUM PROGESTERONE, REACTINE [CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE](CETIRIZINE HYDROCHLORIDE, PSEUDOEPHEDRINE HYDROCHLORIDE), SYMBICORT TURBUHALER(BUDESONIDE, FORMOTEROL FUMARATE), Tresiba FlexTouch(Insulin Degludec), VENTOLIN HFA(SALBUTAMOL SULFATE), WELLBUTRIN(BUPROPION HYDROCHLORIDE), ZOLOFT(SERTRALINE HYDROCHLORIDE) On an unknown date, patient was diagnosed with suicidal ideation, anger, dehydration, mental status changes, mood altered, nausea. It was reported that patient interrupted the administration of product. The batch number was not available. Action taken to Ozempic was Not reported. The outcome for the event "suicidal ideation(Suicidal ideation)" was Recovered. The outcome for the event "anger,(Anger)" was Recovered. The outcome for the event "dehydration(Dehydration)" was Recovered. The outcome for the event "mental status changes(Mental status changes)" was Recovered. The outcome for the event "mood altered(Mood altered)" was Recovered. The outcome for the event "nausea(Nausea)" was Recovered. The outcome for the event "product administration interrupted(Product administration interrupted)" was Not Reported. No further information available. Company comment: Suicidal ideation, Anger, Dehydration, Mental status changes, Mood altered are assessed as unlisted and Nausea is assessed as listed according to the Novo Nordisk current CCDS on Ozempic. Information on event onset date, outcome of the event, treatment of the event, start and stop date of suspect product, relevant medical history are not available for complete 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:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	ASA	/						
2	ATIVAN	/	Sublingual					

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3	AVENTYL	/	
4	COVERSYL [PERINDOPRIL ARGININE]	/	
5	CRESTOR	/	
6	LYRICA	/	
7	PROFERRIN	/	
8	PROMETRIUM [PROGESTERONE]	/	
9	REACTINE [CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE]	/	
10	SYMBICORT TURBUHALER	/	
11	Tresiba FlexTouch	/	Subcutaneous
12	VENTOLIN HFA	/	
13	WELLBUTRIN	/	
14	ZOLOFT	/	

Reporter Source:

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

Literature Text:

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

Case ID: 18340030

Case Information:

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

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 Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic Subcutaneous Injection 0.25mg SD		.25 Mg Milligram(S) / WK	/ Subcutaneous	0.25 mg, qw	Type 2 diabetes mellitus	27-Aug-2020	15-Sep-2020
2	Tresiba Chu		/	Subcutaneous	UNK	Type 2 diabetes mellitus		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic Subcutaneous Injection 0.25mg SD	19 Day	Not Applicable	NA				NOVO NORDISK	
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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FOIA Case Report Information

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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:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
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
Adjusted calcium					Y
Blood alkaline phosphatase					Y

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Blood alkaline phosphatase	Y
Blood glucose	Y
Blood lactate dehydrogenase	Y
Brain natriuretic peptide	Y
C-reactive protein	Y
Glomerular filtration rate	Y
Glycated albumin	Y
Mean platelet volume	Y
Platelet distribution width	Y
Platelet-large cell ratio	Y
Red cell distribution width	Y
Red cell distribution width	Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

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

Literature Text:

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

Case ID: 18393458

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** DE **Event Date:** **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 16-Oct-2020 **Mfr Rcvd Date:** 05-Oct-2020 **Mfr Control #:** DE-NOVOPROD-758886 **Application #:** 209637

Patient Information:

Age: **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.5 mg		/	Unknown	0.5 mg	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.5 mg		Unknown	Unknown				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Suicidal ideation

Gastrointestinal disorder

Event/Problem Narrative:

This serious spontaneous case from Germany was reported by a consumer as "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, "gastrointestinal problems(Gastrointestinal disorder)" with an unspecified onset date, and concerned a female patient (age not reported) who was treated with Ozempic 0.5 mg (semaglutide) from unknown start date for an unknown indication. The patient's height, weight and body mass index were not reported. Dosage Regimens: Ozempic 0.5 mg: 0.5 mg Historical Drug: Ozempic 0.25 mg. It was reported that the patient gastrointestinal problems and suicidal thoughts during use of Ozempic 0.5 mg. The patient suffered from gastrointestinal problems between the first and third day after the injection and from fourth to sixth day from suicidal thoughts. These disappear but re-occur after the new injection. These problems only occurred after dosage was increased from 0.25 mg to 0.5 mg. Batch Numbers: Ozempic 0.5 mg: ASKU Action taken to Ozempic 0.5 mg was not reported. The outcome for the event "suicidal thoughts(Suicidal ideation)" was not reported. The outcome for the event "gastrointestinal problems(Gastrointestinal disorder)" was not reported. No further information available. Company comment "Suicidal thoughts" and "gastrointestinal problems" are assessed as unlisted according to the NovoNordisk current CCDS information on Ozempic. The information

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regarding patient's age, therapy and event onset date, relevant medical history of depression, stress, mental disorders, previous history of suicide, concomitant medications, clinical and laboratory investigation results and treatment details. As only limited information is available, it is difficult to perform a thorough medical assessment of suicidal thoughts. 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 Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events
OZEMPIC			Product used for unknown indication	No adverse event

Relevant Laboratory Data:

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

Reporter Source:

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

Literature Text:

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

Case ID: 18467281

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** GB **Event Date:** 01-Oct-2020 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 05-Nov-2020 **Mfr Rcvd Date:** 28-Oct-2020 **Mfr Control #:** GB-NOVOPROD-763449 **Application #:** 209637

Patient Information:

Age: 55 YR **Sex:** Male **Weight:** 97 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25 mg		/	Subcutaneous	0.25 mg	Type 2 diabetes mellitus	24-Sep-2020	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25 mg	7 Day	NA	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Intrusive thoughts	
Suicidal ideation	
Abnormal dreams	

Event/Problem Narrative:

This serious Spontaneous regulatory authority case from United Kingdom received via. Medicines and Healthcare Products Regulatory Agency, (MHRA) GBR was reported by a Physician as "Intrusive thoughts(Intrusive thoughts)" with an unspecified onset date, "Suicidal thoughts - no intent(Suicidal ideation)" beginning on 01-OCT-2020, "Abnormal dreams(Abnormal dreams)" with an unspecified onset date, and concerned a 55 Years old Male patient who was treated with Ozempic 0.25 mg (SEMAGLUTIDE) from 24-SEP-2020 for "Type 2 diabetes mellitus", The events Intrusive thoughts and Suicidal thoughts - no intent were medically confirmed Patient's height: 177 cm Patient's weight: 97 kg Patient's BMI: 30.96172870. Dosage Regimens: Ozempic 0.25 mg: 24-SEP-2020 to Not Reported; Current Condition: Hypertension, Ischaemic heart disease, Type 2 diabetes mellitus(duration not reported), Pre infarction syndrome. Concomitant products included - GLICLAZIDE, RAMIPRIL, ATORVASTATIN, ISOSORBIDE MONONITRATE, LANSOPRAZOLE, BISOPROLOL, ADIZEM-XL(DILTIAZEM HYDROCHLORIDE), TICAGRELOR, ACETYLSALICYLIC ACID On an unknown date, patient experienced Intrusive thoughts and Abnormal dreams On 01-OCT-2020, patient had Suicidal thoughts - no intent Batch number not available Action taken to Ozempic 0.25 mg was reported as No Change. The outcome for

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the event "Intrusive thoughts(Intrusive thoughts)" was Unknown. The outcome for the event "Suicidal thoughts - no intent(Suicidal ideation)" was Not recovered. The outcome for the event "Abnormal dreams(Abnormal dreams)" was Unknown. References included: Reference Type: E2B Report Duplicate Reference ID#: GB-MHRA-ADR 24528974 Reference Notes: MHRA Reference Type: E2B Authority Number Reference ID#: GB-MHRA-EYC 00231362 Reference Notes: Reference Type: E2B Report Duplicate Reference ID#: GB-MHRA-EYC 00231362 Reference Notes: ELECTRONICYCPROD No further information available. Company comment Intrusive thoughts, suicidal ideation and abnormal dreams are assessed as unlisted according to the NovoNordisk current CCDS information on Ozempic. The following important information is lacking: relevant medical history of mental illness including depression, anxiety, schizophrenia or prior suicidal ideations/attempts,circumstances leading to suicidal ideation, clinical and laboratory investigation results and treatment details. As only limited information has been obtained so far, 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.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Hypertension			
Myocardial ischaemia			
Type 2 diabetes mellitus			Yes
Angina unstable			

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	GLICLAZIDE	/	Unknown	UNK				
2	RAMIPRIL	/	Unknown	UNK				
3	ATORVASTATIN	/	Unknown	UNK				
4	ISOSORBIDE MONONITRATE	/	Unknown	UNK				
5	LANSOPRAZOLE	/	Unknown	UNK				

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6	BISOPROLOL	/	Unknown	UNK
7	ADIZEM-XL	/	Unknown	UNK
8	TICAGRELOR	/	Unknown	UNK
9	ACETYLSALICYLIC ACID	/	Unknown	UNK

Reporter Source:

Study report?: No

Sender organization: NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text:

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

Case ID: 18608700

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** Jun-2020 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 13-Dec-2020 **Mfr Rcvd Date:** 04-Dec-2020 **Mfr Control #:** US-NOVOPROD-772669 **Application #:** 209637

Patient Information:

Age: 47 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		.25 Mg Milligram(S) /	Subcutaneous	0.25 mg	Product used for unknown indication	Jun-2020	Jun-2020

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		Yes	Unknown				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Suicidal ideation

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a Nurse Practitioner as "suicidal thoughts(Suicidal ideation)" beginning in JUN-2020, and concerned a 47 year-old male patient who was treated with Ozempic 0.25/0.50 mg (semaglutide) from JUN-2020 to JUN-2020 for an unknown indication. Medical history was not provided. A nurse practitioner reported that a patient taking Ozempic for one week in JUN-2020, experienced suicidal thoughts. Ozempic was discontinued and the suicidal thoughts resolved. Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE.. In 2020, the outcome for the event "suicidal thoughts(Suicidal ideation)" was Recovered. Batch number was requested upon follow-up. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as related to medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

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FOIA Case Report Information

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Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

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

Literature Text:

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

Case ID: 18689632

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** Dec-2020 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 31-Dec-2020 **Mfr Rcvd Date:** 24-Dec-2020 **Mfr Control #:** US-NOVOPROD-777109 **Application #:** 209637

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		Unknown	Unknown	kp52799			NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Suicidal ideation

COVID-19

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a consumer as "Patient wishes they not live much longer as their spouse just passed(Death wishes)" with an unspecified onset date, "COVID-19(COVID-19)" beginning on DEC-2020, and concerned an elderly male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication". Medical history was not provided. On an unknown date, it was reported that the patient wished that he would not live much longer, as their spouse just passed away. On an unspecified date in DEC-2020, the patient had COVID-19. Action taken to Ozempic 0.25/0.50 mg was Not reported. The outcome for the event "Patient wishes they not live much longer as their spouse just passed(Death wishes)" was Unknown. The outcome for the event "COVID-19(COVID-19)" was Not recovered. Company Comment: Suicidal ideation and COVID-19 are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as related to suspect product therapy dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

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

Case ID: 18689632

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

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

Literature Text:

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

Case ID: 18936691

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** Nov-2020 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 24-Feb-2021 **Mfr Rcvd Date:** 10-Feb-2021 **Mfr Control #:** US-NOVOPROD-787945 **Application #:** 209637

Patient Information:

Age: 47 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		/	Unknown	0.5mg	Product used for unknown indication	Nov-2020	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		NA	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Nurse as "Suicidal thoughts(Suicidal ideation)" beginning on NOV-2020, and concerned a 47 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from NOV-2020 for "Drug use for unknown indication", Dosage Regimens: Ozempic 0.25/0.50 mg: ??-NOV-2020 to Not Reported; Historical drug: Anti depression medication (since years) (non-codable) Medical history was not provided. On an unspecified date in NOV-2020, the patient had Suicidal thoughts Batch Numbers: Ozempic 0.25/0.50 mg: ASKU Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. The outcome for the event "Suicidal thoughts(Suicidal ideation)" was Not Reported. Company comment: Suicidal ideation is assessed as a unlisted event according to Novo Nordisk current CCDS on Ozempic. Lack of information on medical history, suspect drug indication and concomitant medications precludes medical assessment. However historical 'Antidepressant medication' does indicate that patient was suffering from depression, which is a significant confounder. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

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

Case ID: 18936691

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

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

Literature Text:

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

Case ID: 19791375

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** GB **Event Date:** 14-Jul-2021 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 15-Sep-2021 **Mfr Rcvd Date:** 02-Sep-2021 **Mfr Control #:** GB-NOVOPROD-841737 **Application #:** 209637

Patient Information:

Age: 37 YR **Sex:** Female **Weight:** 104.77 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25 mg		/	Parenteral	0.25 mg	Type 2 diabetes mellitus	07-Jul-2021	26-Jul-2021
2	Ozempic 0.25 mg		/			Type 3 diabetes mellitus		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25 mg	7 Day	Yes	Unknown				NOVO NORDISK	
2	Ozempic 0.25 mg	7 Day	Yes	Unknown				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Depression suicidal

Event/Problem Narrative:

This serious Spontaneous case from Regulatory Authority received via MHRA, UNITED KINGDOM was reported by a Consumer as "Suicidal depression(Suicidal depression)" beginning on 14-JUL-2021, and concerned a 37-year-old Female patient who was treated with Ozempic 0.25 mg (SEMAGLUTIDE) from 07-JUL-2021 to 26-JUL-2021 for "type 2 diabetes mellitus", "Type III diabetes mellitus". Patient's height: 162 cm Patient's weight: 104.8 kg Patient's BMI: 39.921. Current Condition: Type 2 diabetes mellitus Historical Condition: Type 3 diabetes mellitus, Psychotic disorder, Personality disorder, Affective disorder. Concomitant products included - AMISULPRIDE, COD LIVER OIL [COD-LIVER OIL], GLICLAZIDE, IRON, LANSOPRAZOLE, METFORMIN, OMEGA-3 FISH OIL(FISH OIL), SERTRALINE, TURMERIC CURCUMA LONGA, GARLIC [ALLIUM SATIVUM] On 14-JUL-2021, The patient experienced Suicidal depression and on 20-AUG-2021 recovered. The patient told to diabetic nursing team describing the depression and told them that patient will no longer take the injection. Batch Number of Ozempic 0.25 mg was requested. Action taken to Ozempic 0.25 mg was reported as Product discontinued. The outcome for the event "Suicidal depression(Suicidal depression)" was Recovering/resolving. No further information available. Since last submission case updated with the following

Case ID: 19791375

information: -Event stop date removed -Event outcome updated -Narrative updated accordingly. Company comment: Suicidal depression is assessed as unlisted according to the Novo Nordisk current CCDS information on Ozempic. Patient historical condition of Psychotic disorder, Personality disorder and Affective disorder can be considered as confounding factors for the event Suicidal depression. Considering nature of the event and safety profile of the suspect product causality is assessed as unlikely related to ozempic. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:

I have Borderline personality disorder and paranoid psychosis. Also a history of depressive moods

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes
Type 3 diabetes mellitus			Unknown
Psychotic disorder			Unknown
Personality disorder			Unknown
Affective disorder			Unknown

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	AMISULPRIDE	/	Unknown	UNK				
2	COD LIVER OIL [COD-LIVER OIL]	/		UNK				
3	GLICLAZIDE	/		UNK				
4	IRON	/		UNK				
5	LANSOPRAZOLE	/		UNK				

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

Case ID: 19791375

6	METFORMIN	/	UNK
7	OMEGA-3 FISH OIL	/	UNK
8	SERTRALINE	/	UNK
9	TURMERIC [CURCUMA LONGA]	/	UNK
10	GARLIC [ALLIUM SATIVUM]	/	UNK

Reporter Source:

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

Literature Text:

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

Case ID: 21043905

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 01-Jul-2022 **Outcomes:** OT **Application Type:** COMP

FDA Rcvd Date: 02-Jul-2022 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2022-52318 **Application #:** 99

Patient Information:

Age: 43 YR **Sex:** Female **Weight:** 99 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic (semaglutide) injection	Y	Other / 999	Other	OTHER QUANTITY : 0.25 Injection(s); OTHER FREQUENCY : One shot weekly; OTHER ROUTE : Injection into stomach area;	Diabetes and weight loss Weight loss	07-Jun-2022	28-Jun-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic (semaglutide) injection		Yes	Yes	MP5A752	30-Nov-2024	0169-4132-97	NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Vomiting	Yes
Diarrhoea	Yes
Dehydration	Yes
Abdominal distension	Yes

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

Case ID: 21043905

Abdominal pain upper	Yes
Self-injurious ideation	Yes
Therapeutic product effect incomplete	Yes
Blood glucose increased	Yes

Event/Problem Narrative:

Tell us what happened and how it happened : I took a weekly shot of 0.25mg of Ozempic for diabetes and weight loss. 3 days later, I vomited and had diarrhea simultaneously for over 12 hours straight. This happened for 5 hours with my last dose the week before. I know it's supposed to slow digestion but I threw up everything I ate from Tuesday through Friday. Most food pieces were still identifiable. I am unbelievably dehydrated and might go to the hospital later today for IV fluids. Even the slightest sip of water has me ready to vomit again. My stomach had ballooned out so large that I was afraid it was going to burst. I had sour stomach for sure and burped like crazy. It was so bad yesterday and last night that I just wanted to die. The drug works for weight loss, but it's overpowered and has not reduced my blood glucose at all.;

Relevant Medical History:

List known medical conditions : Type 2 diabetes, high blood pressure, Crohn's disease (inactive 10+ years), PCOS.; Please list all allergies : No drugs or foods, but allergic to all metals including surgical staples.; List any other important information about the person : None.

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	Metformin	/						
2	Fenof brate	/						
3	omeprazole	/						

Case ID: 21043905

4	hydrochlorothiazide	/
5	lisinopril	/

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
Override Auto Calculation Rule	No		
FDA Received Date	02-Jul-2022	CTU Received Date	02-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	01-Jul-2022
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I took a weekly shot of 0.25mg of Ozempic for diabetes and weight loss. 3 days later, I vomited and had diarrhea simultaneously for over 12 hours straight. This happened for 5 hours with my last dose the week before. I know it's supposed to slow digestion but I threw up everything I ate from Tuesday through Friday. Most food pieces were still identifiable. I am unbelievably dehydrated and might go to the hospital later today for IV fluids. Even the slightest sip of water has me ready to vomit again. My stomach had ballooned out so large that I was afraid it was going to burst. I had sour stomach for sure and burped like crazy. It was so bad yesterday and last night that I just wanted to die. The drug works for weight loss, but it's overpowered and has not reduced my blood glucose at all.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ozempic (semaglutide) injection		
Name of the company that makes (or compounds) the product	Novo Nordisk		
Product Type(check all that apply)	☐ Over-the-Counter ☑ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	0.25 mg milligram(s)	If Other	
NDC number	0169-4132-97		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

Expiration date	30-Nov-2024		
Lot number	MP5A752		
Dosage Form			
Quantity	Other	If Other	0.25 Injection(s)
Frequency	Other	If Other	One shot weekly
How was it taken or used	Other	If Other	Injection into stomach area
Date the person first started taking or using the product	07-Jun-2022		

	Date the person stopped taking or using the product	28-Jun-2022
	Date the person reduced dose of the product	
	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Diabetes and weight loss

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	
	Date of Birth	(b) (6)
	Weight	99 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Type 2 diabetes, high blood pressure, Crohn's disease (inactive 10+ years), PCOS.

Please list all allergies (such as to drugs, foods, pollen or others)

No drugs or foods, but allergic to all metals including surgical staples.

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None.

List all current prescription medications and medical devices being used.

Metformin, Fenofibrate, omeprazole, hydrochlorothiazide, lisinopril.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	
Number/Street	
City	
State/Province	
Country	
ZIP or Postal code	
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	02-Jul-2022	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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

Case ID: 21095194

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 05-Jun-2022 **Outcomes:** OT **Application Type:** COMP

FDA Rcvd Date: 16-Jul-2022 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2022-56175 **Application #:** 99

Patient Information:

Age: 58 YR **Sex:** Female **Weight:** 99 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic (semaglutide) injection	Y	Other / 999	Subcutaneous	OTHER QUANTITY : 1 Injection(s); OTHER FREQUENCY : Weekly;	Diabetes		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic (semaglutide) injection		Yes	Not Applicable	MP5B280	31-Jan-2025	0168-4132-12	NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Weight decreased	NA
Abdominal distension	NA
Diarrhoea	NA
Flatulence	NA
Constipation	NA
Nausea	NA
Illness	NA

Hypersomnia	NA
Lethargy	NA
Asthenia	NA
Abdominal pain upper	NA
Flatulence	NA
Faeces discoloured	NA
Regurgitation	NA
Self-induced vomiting	NA
Blood glucose increased	NA
Pruritus	NA
Pruritus	NA
Mental impairment	NA

Event/Problem Narrative:

Tell us what happened and how it happened : Ozempic Diary Week 1: Sunday .25 dose: Lost 5 lbs full feeling all the time. Liquid diarrhea. Ate normal food but less. Thursday: ate small fish fry. Up 3:00 AM copious gas and diarrhea. Followed by Friday-Sunday Constipation constant nausea. But can eat. Week 2 dose .25 Sunday Lost 6 lbs more. Took potassium pill for Constipation. Worked followed w explosive diarrhea. Rest of week: sick. Sleeping all day. Lethargic. Weak when I normally do renovation/construction work. Pain constant in top of belly at diaphragm; like electric gas pain. watery projectile bowel light consistent reddish brown. Night & day Super Gassy. Strangely not painful gas in intestines. Usually I have agonizing gas. painful gut bomb if I eat anything. Do not vomit but want to all the time. Worse at night. Stomach content up into throat. Induced vomit to feel better. Saturday: Fasting but still projectile diarrhea makes me wonder if I will survive. Sleep during day. Feel weak. Start drinking 32 oz Pedialyte to offset diarrhea and fasting. Sunday: stopping drug. Lost 11 pounds in 2 weeks. Fasting Blood sugar never changed in tests. 125-136 fasting. Friday/Saturday - Belly starts very itchy on top and down left side. Itch moved to hands Monday. After missing 3rd dose. Monday: stomach ache gone by end of day. blood sugar felt low - could not think straight. Tuesday: feel pretty good. Eating normally.;

Relevant Medical History:

List known medical conditions : Diabetes, high cholesterol; Please list all allergies : Vicodin, animal dander,;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

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

Case ID: 21095194

Relevant Laboratory Data:

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
1	ezetimibe	/						
2	Estradiol 0.01% cream/ 2x Wkly	/						
3	Omeprazole	/						
4	Gummy (biotin 2,500 mcg, collagen 100 mg, vitamin C 15 mg, vitamin E	/						
5	potassium	/						
6	noproxen	/						

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
Override Auto Calculation Rule	No		
FDA Received Date	16-Jul-2022	CTU Received Date	16-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	05-Jun-2022
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Ozempic Diary Week 1: Sunday .25 dose: Lost 5 lbs full feeling all the time. Liquid diarrhea. Ate normal food but less. Thursday: ate small fish fry. Up 3:00 AM copious gas and diarrhea. Followed by Friday-Sunday Constipation constant nausea. But can eat. Week 2 dose .25 Sunday Lost 6 lbs more. Took potassium pill for Constipation. Worked followed w explosive diarrhea. Rest of week: sick. Sleeping all day. Lethargic. Weak when I normally do renovation/construction work. Pain constant in top of belly at diaphragm; like electric gas pain. watery projectile bowel light consistent reddish brown. Night & day Super Gassy. Strangely not painful gas in intestines. Usually I have agonizing gas. painful gut bomb if I eat anything. Do not vomit but want to all the time. Worse at night. Stomach content up into throat. Induced vomit to feel better. Saturday: Fasting but still projectile diarrhea makes me wonder if I will survive. Sleep during day. Feel weak. Start drinking 32 oz Pedialyte to offset diarrhea and fasting. Sunday: stopping drug. Lost 11 pounds in 2 weeks. Fasting Blood sugar never changed in tests. 125-136 fasting. Friday/Saturday - Belly starts very itchy on top and down left side. Itch moved to hands Monday. After missing 3rd dose. Monday: stomach ache gone by end of day. blood sugar felt low - could not think straight. Tuesday: feel pretty good. Eating normally.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ozempic (semaglutide) injection		
Name of the company that makes (or compounds) the product	Novo Nordisk Inc		
Product Type(check all that apply)	☐ Over-the-Counter ☑ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	.25 mg milligram(s)	If Other	
NDC number	0168-4132-12		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	31-Jan-2025			
Lot number	MP5B280			
Dosage Form				
Quantity	Other	If Other	1 Injection(s)	

	Frequency	Other	If Other	Weekly	
	How was it taken or used	Subcutaneous	If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of the product				
	Give best estimate of duration	2 Week			
	Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat)	1 of 1
Diabetes	

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	58 Year(s)
	Date of Birth	

Weight	99 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Diabetes, high cholesterol

Please list all allergies (such as to drugs, foods, pollen or others)

Vicodin, animal dander,

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

ezetimibe 10 mg/day, Estradiol 0.01% cream/ 2x Wkly

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Omeprazole 20 mg/day, Gummy (biotin 2,500 mcg, collagen 100 mg, vitamin C 15 mg, vitamin E 6.75 mg) Very occasional potassium 99mg and noproxen 220 mg

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	
Number/Street	
City	
State/Province	

	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number		
	Email address		
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	16-Jul-2022	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

(b) (6)

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

Case ID: 21233260

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** CA **Event Date:** **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 19-Aug-2022 **Mfr Rcvd Date:** 09-Aug-2022 **Mfr Control #:** CA-NOVOPROD-948332 **Application #:** 209637

Patient Information:

Age: **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.50 mg, qw(Since increasing to 0.5mg weekly (estimated 6 weeks ago)			
2	Ozempic		0.25 Mg Milligram(S) / /WK	Subcutaneous	0.25 mg, qw	Type 2 diabetes mellitus	Apr-2020	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		NA	NA				NOVO NORDISK	
2	Ozempic		NA	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Depression	
Nausea	
Diarrhoea	
Constipation	

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

Case ID: 21233260

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Medical Doctor as "Suicidal ideation(Suicidal ideation)" with an unspecified onset date, "Depression(Depression)" with an unspecified onset date, "Nausea(Nausea)" with an unspecified onset date, "Diarrhea(Diarrhea)" with an unspecified onset date, "Constipation(Constipation)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from APR-2020 and ongoing for "Type 2 diabetes mellitus". Patient height, weight and body mass index (BMI) were not reported. Dosage Regimens: Ozempic: ??-APR-2020 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing); Current Condition: Type 2 diabetes mellitus(duration not reported). Patient had no issues with 0.25mg. On an unknown date, the patient experienced nausea. On an unknown date, when the patient went up to 0.5mg (about 6 weeks ago) patient had bunch of problems. Bowel problems to start with, diarrohea once a week then doesn't go again until next week and constipation for 1 week. On an unknown date, patient started experiencing depression, depressed mood with suicidal ideation. Pt was thinking about going back to 0.25 or quitting it altogether. Batch Numbers: Ozempic: Not Reported Action taken to Ozempic was reported as No Change. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Not Reported. The outcome for the event "Depression(Depression)" was Not Reported. The outcome for the event "Nausea(Nausea)" was Not Reported. The outcome for the event "Diarrhea(Diarrhea)" was Not Reported. The outcome for the event "Constipation(Constipation)" was Not Reported. No further information available. Company comment : Suicidal ideation’ is assessed as an unlisted event according to Novo Nordisk current CCDS on Ozempic. This report lacks pertinent information regarding the complete duration and risk factors around the events such a depression, concurrent life stressors, psychological assessment,information on other chronic debilitating disorder, substance abuse/dependance is lacking, it is difficult to make thorough medical assessment with available limited information . This single case report is not considered to change the current knowledge of the safety profile of NovoLog FlexPen, Ozempic, Tresiba FlexTouch and Ozempic.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

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

Case ID: 21233260

Reporter Source:

Study report?: No

Sender organization: NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text: