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

Date - Time: 23-Aug-2023 09:57:57 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, 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:

21233427	21300768	21630760	21670942
21955407	21963305	22046649	22046664
22118076	22118118	22118119	22139818

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 21233427

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** 26-Jan-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 19-Aug-2022 **Mfr Rcvd Date:** 10-Aug-2022 **Mfr Control #:** US-NOVOPROD-948538 **Application #:** 209637

Patient Information:

Age: 63 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		/	Subcutaneous	UNK	Product used for unknown indication	03-Jan-2022	30-Jun-2022

#	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	
Depression	
Insomnia	
Paranoia	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" beginning on 26-JAN-2022, "insomnia(Insomnia)" with an unspecified onset date, "paranoia(Paranoia)" with an unspecified onset date, and concerned a 63 Years old Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from 03-JAN-2022 to 30-JUN-2022 for "drug use for unknown indication". Medical history was not provided. Treatment included - ZOLOFT(SERTRALINE HYDROCHLORIDE) A patient receiving therapy with Ozempic experienced suicidal thoughts, bad depression where the patient was unable to get out of bed, insomnia, and paranoia. The patient took Zoloft and sleeping pills as treatment and stopped taking Ozempic. Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. The outcome

Case ID: 21233427

for the event "suicidal thoughts(Suicidal ideation)" was Unknown. The outcome for the event "depression(Depression)" was Unknown. The outcome for the event "insomnia(Insomnia)" was Unknown. The outcome for the event "paranoia(Paranoia)" was Unknown. Batch number was requested in follow up. Company Comment: Suicidal ideation and depression are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as related medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. 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?

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: 21300768

Case Information:

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

FDA Rcvd Date: 07-Sep-2022 **Mfr Rcvd Date:** 29-Aug-2022 **Mfr Control #:** US-NOVOPROD-954209 **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		/	Subcutaneous	UNK	Product used for unknown indication		

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

Event Information:

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

Suicidal ideation

Depression

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a consumer, via another manufacturer, as "suicidal ideation(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, and concerned a female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for an unknown indication. Medical history was not provided. A patient, who was receiving therapy with Ozempic, experienced depression and suicidal ideation. Action taken to Ozempic was reported as Product discontinued due to AE. The outcome for the event "suicidal ideation(Suicidal ideation)" was Not Reported. The outcome for the event "depression(Depression)" was Not Reported. Batch number was requested in follow up. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. The non-serious event of depression may suggest an alternative etiology. Limited information as related to Ozempic therapy dates, event onset dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits further 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: 21300768

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: 21630760

Case Information:

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

FDA Rcvd Date: 23-Nov-2022 **Mfr Rcvd Date:** 10-Nov-2022 **Mfr Control #:** CA-NOVOPROD-980674 **Application #:** 209637

Patient Information:

Age: 62 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 1.0 mg		1 Mg Milligram(S) / / WK		1 mg, qw	Diabetes mellitus		
2	Ozempic 1.0 mg		2 Mg Milligram(S) / / WK		2 mg, qw(approx 3 weeks ago. Last dose taken last Friday)	Weight decreased		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 1.0 mg		Yes	NA				NOVO NORDISK	
2	Ozempic 1.0 mg		Yes	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Headache	
Weight increased	
Pain	
Abdominal distension	
Retching	

Vomiting

Decreased appetite

Abdominal pain upper

Dysgeusia

Off label use

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Nurse as "suicidal thought(Suicidal ideation)" with an unspecified onset date, "frontal lobe headache(Frontal headache)" with an unspecified onset date, "20 lb gain suddenly(Weight gain)" with an unspecified onset date, "Extreme pain(Pain)" with an unspecified onset date, "distended stomach (distension)(Abdominal distension)" with an unspecified onset date, "dry heaving(Dry heaves)" with an unspecified onset date, "vomiting(Vomiting)" with an unspecified onset date, "lost of appetite(Appetite lost)" with an unspecified onset date, "Stomach pain(Stomach pain)" with an unspecified onset date "Metallic taste(Taste metallic)" with an unspecified onset date,"patient Dose was increased due to 20 lb gain suddenly, Taking on Tuesday and Fridays (1 mg)(Off label use)" with an unspecified onset date, and concerned a 62 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from unknown start date for "Diabetes mellitus", "weight loss", Patient's height, weight and body mass index were not reported. Current Condition: Diabetes (Type and duration not reported). It was reported that the patient was using ozempic 1 mg fromlast 5 years. On unknown date, patient has lost 100 lb over past 5y with tightly regulated diet (General physician believes not a diabetic anymore, endo believes some underlying genetic issue present). On unknown date patient’s dose was doubled from 1mg to 2mg due to 20 lb sudden weight gain. On an unknown date, the patient experienced Suicidal thoughts, distended stomach (distension), Vomiting, lost of appetite and dry heaving, Stomach pain, frontal lobe headache, Extreme pain and Metallic taste On an unknown date, blood sugars was found to be approximately 5.8 mmol/L (usually controlled as well). General physician has asked patient "to play around with the dose" and since 2 mg was not tolerated, recommended to inquire with care team on next steps Considering re-starting at 1 mg next week (date not specified). Batch Numbers: Ozempic 1.0 mg: Requested. Action taken to Ozempic 1.0 mg was reported as Product discontinued. The outcome for the event "suicidal thought(Suicidal ideation)" was Unknown. The outcome for the event "frontal lobe headache(Frontal headache)" was Not Reported. The outcome for the event "20 lb gain suddenly(Weight gain)" was Not Reported. The outcome for the event "Extreme pain(Pain)" was Not Reported. The outcome for the event "distended stomach (distension)(Abdominal distension)" was Recovering/resolving. The outcome for the event "dry heaving(Dry heaves)" was Unknown. The outcome for the event "vomiting(Vomiting)" was Unknown. The outcome for the event "lost of appetite(Appetite lost)" was Unknown. The outcome for the event "Stomach pain(Stomach pain)" was Not Reported. The outcome for the event "Metallic taste(Taste metallic)" was Not Reported. The outcome for the event patient Dose was increased due to 20 lb gain suddenly, Taking on Tuesday and Fridays (1 mg)(Off label use)" was Not Reported. Company comment: Suicidal ideation, Headache , Weight increased, and Pain are assessed as unlisted events: Abdominal distension, Retching, Vomiting, Decreased appetite, Abdominal pain upper ,and Dysgeusia are assessed as listed events according to the Novo Nordisk current Company Core Data Sheet for Ozempic 1.0 mg Information on patients complete medical history(co-morbid conditions, any infection, any previous history of suicidal thoughts, psychological disorder, substance abuse), social circumstances, relevant investigation details(including psychological assessment), treatment details and event outcome information are unavailable for complete assessment. This single case report is not considered to change the current knowledge of the safety profile of Ozempic 1.0 mg

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Diabetes mellitus			Yes

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

Case ID: 21630760

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
BLOOD GLUCOSE	5.8	mmol/L			N
WEIGHT					Y
WEIGHT					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: 21670942

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** 2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 10-Aug-2023 **Mfr Rcvd Date:** 31-Jul-2023 **Mfr Control #:** US-NOVOPROD-984376 **Application #:** 209637

Patient Information:

Age: 52 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK (qw)	Diabetes mellitus	01-Jan-2022	08-Aug-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic	33 Day	Yes	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression suicidal	
Amnesia	
Depression	
Abnormal behaviour	
Aggression	
Near death experience	
Psychotic behaviour	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "Seriously depressed and suicidal(Depression suicidal)" beginning on 2022, "Memory lapses(loss of memory)" beginning on 03-FEB-2022, "Depression anxiety(Anxiety depression)" beginning on 03-FEB-2022, "Altered mental behaviour(Abnormal behaviour)" beginning on 03-FEB-2022, "Violent(Violent)" beginning on 2022, "Almost died(Near death experience)" with an unspecified onset

date, "Psychotic(Psychotic behavior)" with an unspecified onset date, and concerned a 52 year old male patient who was treated with Ozempic (SEMAGLUTIDE) from 01-JAN-2022 to 08-AUG-2022 for "Diabetes mellitus". Current Condition: Diabetes mellitus(type and duration not reported) A patient, who was receiving therapy with Ozempic, reported the product made him seriously depressed and suicidal with the symptom of feeling not that well. The patient further stated it changed his behavior clarified as became violent. On 03-FEB-2022 date, the patient experienced depression anxiety, memory lapses, and they were seriously depressed. The patient also reported they almost died and were psychotic. Batch Number Ozempic been requested Action taken to Ozempic was reported as Product discontinued. The outcome for the event "Seriously depressed and suicidal(Depression suicidal)" was Not recovered. On 04-SEP-2022 the outcome for the event "Memory lapses(loss of memory)" was Recovered. On 04-SEP-2022 the outcome for the event "Depression anxiety(Anxiety depression)" was Recovered. On 04-SEP-2022 the outcome for the event "Altered mental behaviour(Abnormal behaviour)" was Recovered. The outcome for the event "Violent(Violent)" was Unknown. The outcome for the event "Almost died(Near death experience)" was Not Reported. The outcome for the event "Psychotic(Psychotic behavior)" was Not Reported. Since last submission, the case has been updated with the following information -Added events of almost died and psychotic. -Narrative is updated accordingly. -Company comment updated. Company Comment: Depression suicidal, amnesia, depression, abnormal behavior, aggression, near death experience, and psychotic behavior are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as related to medical history aside from diabetes, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

unk

Disease/Surgical Procedure	Start Date	End Date	Continuing?
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

Reporter Source:

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

Case ID: 21670942

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: 21955407

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** CH **Event Date:** 15-Dec-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 06-Feb-2023 **Mfr Rcvd Date:** 25-Jan-2023 **Mfr Control #:** CH-NOVOPROD-1010266 **Application #:** 209637

Patient Information:

Age: 44 YR **Sex:** Female **Weight:** 96 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/		UNK	Product used for unknown indication	Sep-2022	
2	Ozempic		/		gradually increased doses			20-Dec-2022

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

Event Information:

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

Depression suicidal

Event/Problem Narrative:

This serious Spontaneous case from SWITZERLAND was reported by a Medical Doctor as "depressive with suicidal thoughts(Depression suicidal)" beginning on 15-DEC-2022, and concerned a 44 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE) from SEP-2022 to 20-DEC-2022 for "Product used for unknown indication", Patient's height: 178 cm Patient's weight: 96 kg Patient's BMI: 30.29920460. Dosage Regimens: Ozempic: ??-SEP-2022 to Not Reported, Not Reported to 20-DEC-2022; Current Condition: anxiety disorders, Obesity, policystic overial syndrome, endogenous depression Historical Condition: psychiatric history Procedure: History of a psychiatric hospitalization. No concomitant medication taken. Treatment included - ESCITALOPRAM, TEMESTA [LORAZEPAM] (LORAZEPAM), ZOLPIDEM On 15-DEC-2022, the patient felt depressive with suicidal thoughts. On 20-DEC-2022, suicidal risk was seen by psychiatry crisis

unit. No tests or examinations were performed. After withdrawal of the suspected product, the symptoms improved, suspect product was not re-introduced. There were no (social or environmental) circumstances which may have led/contributed to the event (e.g. death in the family, divorce, unemployment/financial problems, chronic physical illness or stress). There was no prior or current treatment with psychoactive drugs (e.g. SSRIs or Benzodiazepines) or other medication that could have contributed to the Event. It is not known to the reporter if the patient previously or currently has been assessed according to any mental health questionnaires (eg. PHQ-9 or C-SSRS). Batch Numbers: Ozempic: Not reported. Action taken to Ozempic was reported as Product discontinued due to AE. On 16-JAN-2023 the outcome for the event "depressive with suicidal thoughts(Depression suicidal)" was Recovered. Since last submission, the following information was updated: - Patient initials, age, height and weight added -medical history updated -Saxenda removed and Ozempic added as suspect -Treatment drugs added -Event onset and stop dates, outcome and treatment updated -Re-challenge updated -Narrative updated accordingly. Company Comment: Depression suicidal is assessed as unlisted event according to the Novo Nordisk current CCDS on Ozempic. Endogenous depression, anxiety disorder, and history of psychiatric hospitalisation are assessed as risk factors for depression suicidal. 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?
Hospitalisation			
Mental disorder			
Anxiety disorder	2010		
Obesity			Yes
Polycystic ovaries			
Major depression			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: 21955407

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: 21963305

Case Information:

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

FDA Rcvd Date: 07-Feb-2023 **Mfr Rcvd Date:** 24-Jan-2023 **Mfr Control #:** AU-NOVOPROD-1021419 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/		60 clicks (out of 74)	Product used for unknown indication		
2	Ozempic		/		increases in dose (unspecified)			

#	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	
Constipation	
Diarrhoea	
Nausea	
Wrong technique in product usage process	

Event/Problem Narrative:

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

Case ID: 21963305

This serious Spontaneous case from AUSTRALIA was reported by a Consumer as "Suicidal thoughts(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, "Severe constipation(Constipation)" with an unspecified onset date, "diarrhoea(Diarrhoea)" with an unspecified onset date, "Nausea(Nausea)" with an unspecified onset date, "It took me a year of one click increases to get to a dose of 60 clicks (out of 74)(Wrong technique in product usage process)" with an unspecified onset date, and concerned a patient (Age and Gender not reported) who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication". Patient's Height, Weight and Body Mass Index (BMI) was not reported Medical history was not provided. Treatment included - METAMUCIL PLANTAGO OVATA It was reported that patient was sensitive to medications(unspecified) and it took a year of one click increases to get to a dose of 60 clicks (out of 74). Any higher increases in dose (unspecified) caused severe constipation, then diarrhea, depression, suicidal thoughts and nausea. This made patient very angry that all that hard work to stay on the medication and constantly measure the meals to 70%(test unspecified) of what would normally fill the patient (or else would get diarrhoea). Patient drink's Metamucil twice a day. Patient was gradually reducing dose by 5 clicks a week, and will be at zero within 6 weeks. Patient would not stop cold turkey for fear of my body's reactions to doing that Batch Numbers: Ozempic: was requested Action taken to Ozempic was No Change. The outcome for the event "Suicidal thoughts(Suicidal ideation)" was Not Reported. The outcome for the event "depression(Depression)" was Not Reported. The outcome for the event "Severe constipation(Constipation)" was Not Reported. The outcome for the event "diarrhoea(Diarrhoea)" was Not Reported. The outcome for the event "Nausea(Nausea)" was Not Reported. The outcome for the event "It took me a year of one click increases to get to a dose of 60 clicks (out of 74)(Wrong technique in product usage process)" was Not Reported. Company comment: Suicidal ideation, depression are assessed as unlisted events and diarrhoea, constipation, nausea, wrong technique in product usage process are assessed as listed events according to NovoNordisk current reference safety information on Ozempic. Information on indication of the suspect, demographic details of the patient, event onset dates with outcome, exposure details of the suspect, treatment received if any, medical confirmation, history of risk factors like previous episodes of suicidal thoughts, substance abuse, social circumstances, anxiety, relevant medical history 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 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

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

Case ID: 21963305

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: 22046649

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** Oct-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 28-Feb-2023 **Mfr Rcvd Date:** 10-Feb-2023 **Mfr Control #:** US-NOVOPROD-1025574 **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 0.25/0.50 mg		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg		Oct-2022	
2	Ozempic 0.25/0.50 mg		0.25 Mg Milligram(S) /	Subcutaneous	0.25 mg	Type 2 diabetes mellitus	Oct-2022	Oct-2022

#	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	MP5D612			NOVO NORDISK	
2	Ozempic 0.25/0.50 mg		NA	NA	MP5D612			NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Dysgeusia	
Blood glucose increased	
Drug titration error	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "feeling suicidal(Suicidal ideation)" beginning on NOV-2022, "tasting metal when drinking water(Taste metallic)" beginning on OCT-2022, "blood sugar levels have not lowered(Blood sugar increased)" beginning on OCT-2022, "starting with 0.25mg dose for 2 weeks and moving up to 0.5mg afterward(Inappropriate drug titration)" with an unspecified onset date, and concerned a Adult Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from OCT-2022 and ongoing for "Type 2 diabetes", Current Condition: Type 2 diabetes. The patient initiated the therapy with Ozempic on 0.25 mg dose. After 2 weeks the dose was titrated to 0.5 mg. Two days after titrating the dose the

Case ID: 22046649

patient had suicidal feelings. The patient additionally reported that the blood sugars have not lowered and metallic taste in mouth while drinking water. Batch Numbers: Ozempic 0.25/0.50 mg: MP5D612, MP5D612 Action taken to Ozempic 0.25/0.50 mg was reported as No Change. On NOV-2022 the outcome for the event "feeling suicidal(Suicidal ideation)" was Recovered. The outcome for the event "tasting metal when drinking water(Taste metallic)" was Unknown. The outcome for the event "blood sugar levels have not lowered(Blood sugar increased)" was Unknown. The outcome for the event "starting with 0.25mg dose for 2 weeks and moving up to 0.5mg afterward(Inappropriate drug titration)" was Unknown. 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 age, weight, BMI, medical history aside from type 2 diabetes, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. 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

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: 22046664

Case Information:

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

FDA Rcvd Date: 28-Feb-2023 **Mfr Rcvd Date:** 10-Feb-2023 **Mfr Control #:** US-NOVOPROD-1024894 **Application #:** 213051

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Rybelsus		/	Oral	UNK	Product used for unknown indication		

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

Event Information:

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

Suicidal ideation

Violence-related symptom

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician via a company representative as "Suicidal ideation(Suicidal ideation)" with an unspecified onset date, "Violent thoughts(Violent thoughts)" with an unspecified onset date, and concerned a Adult patient who was treated with Rybelsus (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication". Medical history was not provided. A patient receiving therapy with Rybelsus experienced suicidal ideation and violent thoughts. Action taken to Rybelsus was Not reported. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Unknown. The outcome for the event "Violent thoughts(Violent thoughts)" was Unknown. Batch number requested in follow-up. Company Comment: Suicidal ideation and violence-related symptom are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Rybelsus. Limited information as related to Rybelsus therapy dates, event onset dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluation results limits 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: 22046664

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: 22118076

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** IS **Event Date:** 27-Dec-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 02-Aug-2023 **Mfr Rcvd Date:** 25-Jul-2023 **Mfr Control #:** IS-NOVOPROD-1035846 **Application #:** 209637

Patient Information:

Age: 36 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 1.0 mg		1 Mg Milligram(S) / / WK		1 mg, qw	Type 2 diabetes mellitus	22-Nov-2022	
2	Ozempic 1.0 mg		0.25 Mg Milligram(S) / /WK		0.25 mg, qw		Mar-2023	Mar-2023
3	Ozempic 1.0 mg		0.5 Mg Milligram(S) / / WK		0.5 mg, qw	Overweight	Feb-2023	
4	METFORMIN EQL PHARMA		/		500 mg (2 tablets qd)	Product used for unknown indication	22-Nov-2022	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 1.0 mg	35 Day	Yes	NA				NOVO NORDISK	
2	Ozempic 1.0 mg	35 Day	Yes	NA				NOVO NORDISK	
3	Ozempic 1.0 mg	35 Day	Yes	NA				NOVO NORDISK	
4	METFORMIN EQL PHARMA		Unknown	NA					

Event Information:

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

Personality change

Suicidal ideation

Vomiting

Nausea

Sleep disorder

Drug withdrawal syndrome

Event/Problem Narrative:

This serious Spontaneous case received via Regulatory Authority of "Icelandic Medicines Agency (IS)" from ICELAND was reported by a Pharmacist as "Changed into another person(Character change)" with an unspecified onset date, "Recurrent suicidal thoughts(Suicidal ideation)" beginning on 27-DEC-2022, "Vomit(Vomited)" with an unspecified onset date, "Nausea(Nausea)" beginning on 27-DEC-2022, "Sleeps 16 hours a day(Change in sleep pattern)" with an unspecified onset date, "withdrawal syndrome(Drug withdrawal syndrome)" with an unspecified onset date, and concerned a 36 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from 22-NOV-2022 to MAR-2023 for "Type II diabetes mellitus", "overweight", , a non-Novo Nordisk suspect product METFORMIN EQL PHARMA (METFORMIN HYDROCHLORIDE) from 22-NOV-2022 for "product used for unknown indication", The events Character change, Suicidal ideation, Vomited, nausea, Change in sleep pattern, Withdrawal syndrome were medically confirmed. Patient's height: 175 cm The patient's weight and body mass index were not reported. Dosage Regimens: Ozempic 1.0 mg: 22-NOV-2022 to Not Reported, ??-FEB-2023 to Not Reported, ??-MAR-2023 to ??-MAR-2023; METFORMIN EQL PHARMA: 22-NOV-2022 to Not Reported; Current Condition: Type II diabetes mellitus(Duration not reported), Overweight, Depression, Trauma, Eating disorder, ADHD, Autism. Concomitant products included - DUSPATALIN [MEBEVERINE EMBONATE] (MEBEVERINE EMBONATE), OMEPRAZOLE ACTAVIS(OMEPRAZOLE), YASMIN(DROSPIRENONE, ETHINYLESTRADIOL), WELLBUTRIN(BUPROPION HYDROCHLORIDE), ESOPRAM(ESCITALOPRAM OXALATE) Since 27-DEC-2022 the patient had recurrent suicidal thoughts and nausea. Since an unknown date, the patient changed into another person, vomited and slept for 16 hours a day and had withdrawal syndrome Batch Numbers: Ozempic 1.0 mg: not available Action taken to Ozempic 1.0 mg was reported as Dose Decreased. Action taken to METFORMIN EQL PHARMA was Not reported. The outcome for the event "Changed into another person(Character change)" was Recovered. The outcome for the event "Recurrent suicidal thoughts(Suicidal ideation)" was Recovered. The outcome for the event "Vomit(Vomited)" was Recovered. The outcome for the event "Nausea(Nausea)" was Recovered. The outcome for the event "Sleeps 16 hours a day(Change in sleep pattern)" was Recovered. The outcome for the event "withdrawal syndrome(Drug withdrawal syndrome)" was Recovered. No further information available. Since last submission, the case has been updated with following information: - Dosage regimens and stop date of the suspect product "Ozempic 1mg" were added. - Dechallenge of the suspect product "Ozempic 1mg" was updated. - Outcome of the reported events "Suicidal ideation, Character change, Vomit, Change in sleep pattern , Nausea" were updated to Recovered. - New event 'withdrawal syndrome" was added. - Product-event details updated. - Narrative updated accordingly. References included: Reference Type: E2B Report Duplicate Reference ID#: IS-IMA-8337 Reference Notes: IMA Reference Type: E2B Authority Number Reference ID#: IS-IMA-8337 Reference Notes: Icelandic Medicines Agency, IS Company comment: Personality change, suicidal ideation, sleep disorder and drug withdrawal syndrome are assessed as unlisted events; vomiting and nausea as listed events according to the Novo Nordisk current Company Core Data Sheet (CCDS) on Ozempic. Medical history of psychiatric disorders such as depression, autism, attention deficit hyperactivity disorder (ADHD), eating disorder and history of trauma are assessed as risk factors for personality change, suicidal thoughts and altered sleep pattern. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:

Diabetes and overweight

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

Case ID: 22118076

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes
Overweight			
Depression			
Injury			
Eating disorder			
Attention deficit hyperactivity disorder	2022		
Autism spectrum disorder	2022		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	DUSPATALIN [MEBEVERINE EMBONATE]	200 Mg Milligram(S) / QD		200 mg, qd	Product used for unknown indication	01-Jan-2022		
2	OMEPRAZOLE ACTAVIS	/		20 MG	Product used for unknown indication	2016		
3	YASMIN	/		0,03 MG	Product used for unknown indication			
4	WELLBUTRIN	300 Mg Milligram(S) / QD		300 mg, qd	Product used for unknown indication	01-Oct-2021		
5	ESOPRAM	20 Mg Milligram(S) / QD		20 mg, qd	Product used for unknown indication		18-Feb-2023	

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

Case ID: 22118076

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: 22118118

Case Information:

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

FDA Rcvd Date: 21-Mar-2023 **Mfr Rcvd Date:** 08-Mar-2023 **Mfr Control #:** US-NOVOPROD-1037278 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK	Product used for unknown indication		
2	Ozempic		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg			
3	Ozempic		1 Mg Milligram(S) /	Subcutaneous	1 mg			

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		No	NA				NOVO NORDISK	
2	Ozempic		No	NA				NOVO NORDISK	
3	Ozempic		No	NA				NOVO NORDISK	

Event Information:

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

Suicidal ideation

Depression

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Nurse as "suicide ideation(Suicidal ideation)" with an unspecified onset date, "increased depression(Depression)" with an unspecified onset date, and concerned a Adult patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication", Current Condition: mental illness. The patient on therapy with Ozempic was reported to have suicidal ideation

Case ID: 22118118

and increased depression when the dose was increased to 1 mg. When the dose was decreased to 0.5 mg the patient was stabilized. Batch number is requested in follow up. Action taken to Ozempic was reported as Dose Decreased. The outcome for the event "suicide ideation(Suicidal ideation)" was Not recovered. The outcome for the event "increased depression(Depression)" was Not recovered. Company Comment: Suicidal ideation and depression are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of mental illness may suggest an alternative etiology. Limited information as related to age, Ozempic therapy dates, event onset date, more specifics on the medical history of mental illness, concomitant medications, family/ social history, and laboratory/diagnostic evaluations limits further medical assessment. 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?
Mental disorder			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

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: 22118119

Case Information:

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

FDA Rcvd Date: 21-Mar-2023 **Mfr Rcvd Date:** 08-Mar-2023 **Mfr Control #:** US-NOVOPROD-1037281 **Application #:** 209637

Patient Information:

Age: **Sex:** **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	0.5 mg, qw	Product used for unknown indication		
2	Ozempic		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw			
3	Ozempic		1 Mg Milligram(S) / / WK	Subcutaneous	1 mg, qw			

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

Event Information:

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

Event/Problem Narrative:

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

Case ID: 22118119

This serious spontaneous case from the UNITED STATES was reported by a nurse and office staff as "suicide ideation(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, and concerned an adult patient, who was treated with Ozempic (semaglutide) from an unknown start date and ongoing for an unknown indication. Current Condition: mental health issue. A nurse practitioner reported that a patient receiving therapy with Ozempic 1 mg experienced suicide ideation or depression. Action taken to Ozempic was reported as Dose Decreased. The outcome for the event "suicide ideation(Suicidal ideation)" was Recovered. The outcome for the event "depression(Depression)" was Recovered. Batch number was requested. Company Comment: Suicidal ideation and depression are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of mental health issue may suggest an alternative etiology. Limited information as related to age, Ozempic therapy dates, event onset date, more specifics on the medical history of mental health issue, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits further medical assessment. 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?
Mental disorder			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

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: 22139818

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** IE **Event Date:** Apr-2022 **Outcomes:** **Application Type:**

FDA Rcvd Date: 21-Apr-2023 **Mfr Rcvd Date:** 13-Apr-2023 **Mfr Control #:** IE-NOVOPROD-1039961 **Application #:** 209637

Patient Information:

Age: 47 YR **Sex:** Female **Weight:** 92 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		1 Mg Milligram(S) / / WK	Subcutaneous	1 mg, qw	Weight control	Apr-2022	

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

Event Information:

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

Fatigue

Off label use

Event/Problem Narrative:

This non-serious Spontaneous case from IRELAND was reported by a Consumer as "tiredness in the evening, the day of Ozempic injection(Tiredness)" with an unspecified onset date, "Ozempic indication: weight loss/ off label use(Off label use in unapproved indication)" beginning on APR-2022, and concerned a 47 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE) from APR-2022 and ongoing for "weight loss". Patient's height: 165 cm Patient's weight: 92 kg Patient's Body mass index (BMI): 33.79247020. Dosage Regimens: Ozempic: ??-APR-2022 to Not Reported (Dosage Regimen Ongoing); Current Condition: Elevated cholesterol, uncontrollable weight Family History: stroke. Concomitant medication included: Statin low dosage (in conjunction with Ozempic for the elevated cholesterol, non-codable) From APR-2022 patient started taking Ozempic for weight loss (off label use) On an unknown date, after taking Ozempic patient experienced tiredness in the evening on the day of Ozempic injection. On an unknown date patient's endless blood tests were done(results not reported) On an unknown date patient's CT scan was done(results not reported)and weekly counselling. Batch Number for Ozempic has been requested. Action taken to Ozempic was reported as No Change. The outcome for the event "tiredness in the evening, the day of Ozempic injection(Tiredness)" was Not recovered. The outcome

Case ID: 22139818

for the event "Ozempic indication: weight loss/ off label use(Off label use in unapproved indication)" was Unknown. On 13-APR-2023, the case was downgraded to non-serious from serious due to removal of event "suicidal thoughts" with medically significant seriousness criteria Since last submission, the case has been updated with the following: -Patient height, weight and gender added -Medical history of patient added -Indication, dosage regimen, action taken of suspect added -Event "suicidal thought" and "uncontrollable weight" removed -Uncontrollable weight added in medical history -Non serious events " tiredness in the evening, the day of Ozempic injection" and "Ozempic indication: weight loss/ off label use" were added -Narrative updated accordingly References included: Reference Type: E2B Company Number Reference ID#: IE-NOVOPROD-1039961 Reference Notes: Company comment: 'Fatigue' is assessed as listed event according to current NovoNordisk CCDS information on Ozempic. 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?
Blood cholesterol increased			
Weight increased			
Cerebrovascular accident			

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
BLOOD TEST					Y
COMPUTERISED TOMOGRAM					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?:**

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

Case ID: 22139818

Literature Text: