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

Date - Time: 17-Jan-2024 11:34:08 EST

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:

18361396	22139837	22199705	22210589
22733609	22801610	22888868	22996790

Total Cases: 8

Total number of Inactive cases: *0

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

Case ID: 18361396

Case Information:

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

FDA Rcvd Date: 18-Oct-2020 **Mfr Rcvd Date:** 06-Oct-2020 **Mfr Control #:** US-NOVOPROD-757825 **Application #:** 209637

Patient Information:

Age: 69 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Ozempic 0.25/0.50 mg		.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw	2020	22-Sep-2020	
2	Ozempic 0.25/0.50 mg		.25 Mg Milligram(S) / / WK	Subcutaneous	0.25 mg, qw	01-Mar-2020	2020	Type 2 diabetes mellitus

#	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	
2	Ozempic 0.25/0.50 mg		Yes	Unknown				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Ozempic 0.25/0.50 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S
2	Ozempic 0.25/0.50 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

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

Case ID: 18361396

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Aspiration	
Insomnia	
Gastrooesophageal reflux disease	
Nausea	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "gastric acid with reflux and aspiration(Aspiration)" beginning on 01-MAR-2020, "cannot sleep(Sleep difficult)" with an unspecified onset date, "gastric acid with reflux and aspiration(Acid reflux (esophageal))" beginning on 01-MAR-2020, "severe nausea(Nausea)" beginning on 01-MAR-2020, and concerned a 69 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from 01-MAR-2020 to 22-SEP-2020 for "Type 2 diabetes mellitus", Current Condition: Type 2 diabetes mellitus, blood thinners Historical Condition: Ulcer. A patient receiving therapy with Ozempic experienced gastric acid with reflux and aspiration, could not sleep and severe nausea. Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. On 22-SEP-2020 the outcome for the event "gastric acid with reflux and aspiration(Aspiration)" was Recovered. The outcome for the event "cannot sleep(Sleep difficult)" was Not Reported. On 22-SEP-2020 the outcome for the event "gastric acid with reflux and aspiration(Acid reflux (esophageal))" was Recovered. On 22-SEP-2020 the outcome for the event "severe nausea(Nausea)" was Recovered. Batch number was unavailable. Since last submission of the case, the following has been updated: - Patient's date of birth and age added - Medical history added - Product dosage and indication added - Events "gastric acid with reflux and aspiration" and "nausea" start and stop dates added. - Narrative updated accordingly - Company comment updated Company Comment: Aspiration is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Co-reported non-serious event, "gastric acid reflux", has been associated with an increased risk for aspiration, therefore considered a confounder. Limited information as related to event start date, further clarification on "ulcer" medical history (type/location), concomitant medications, 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?
Type 2 diabetes mellitus			Yes
Ulcer			No
Anticoagulant therapy			Yes

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

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

Case ID: 18361396

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	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: 22139837

Case Information:

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

FDA Rcvd Date: 27-Mar-2023 **Mfr Rcvd Date:** 17-Mar-2023 **Mfr Control #:** US-NOVOPROD-1041798 **Application #:** 209637

Patient Information:

Age: 46 YR **Sex:** **Weight:**

Suspect Products:

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

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Not Applicable	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Ozempic//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

Preferred Term (MedDRA Version: v.26.1) **ReC**

Aspiration

Impaired gastric emptying

Event/Problem Narrative:

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

Case ID: 22139837

This serious spontaneous case from the UNITED STATES was reported by a physician via a company representative as "aspiration(Aspiration)" with an unspecified onset date, "full stomach after four weeks(Delayed gastric emptying)" with an unspecified onset date, and concerned a 46 year old patient, who was treated with Ozempic (semaglutide) from an unknown start date for type 2 diabetes mellitus. Current Condition: type 2 diabetes mellitus. A physician reported that a patient was instructed to stop Ozempic four weeks prior to undergoing an unspecified procedure. On the day of the procedure, imagining showed a full stomach and the patient experienced aspiration. Action taken to Ozempic was reported as Not Applicable. The outcome for the event "aspiration(Aspiration)" was Not Reported. The outcome for the event "full stomach after four weeks(Delayed gastric emptying)" was Not Reported. Batch number was requested. Company Comment: Aspiration and impaired gastric emptying are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic.
A medical history of type 2 diabetes mellitus has been associated with an increased risk for impaired gastric emptying, therefore considered a confounder. In addition, the impaired gastric emptying event may have contributed to the aspiration event. Limited information as related to Ozempic therapy dates, event onset dates, duration of diabetes, 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?
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
IMAGING PROCEDURE					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	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: 22139837

Literature Text:

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

Case ID: 22199705

Case Information:

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

FDA Rcvd Date: 08-May-2023 **Mfr Rcvd Date:** 27-Apr-2023 **Mfr Control #:** US-NOVOPROD-1048655 **Application #:** 209637

Patient Information:

Age: 51 YR **Sex:** Male **Weight:** 138.32 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Ozempic 1.0 mg 3.0 mL		1 Mg Milligram(S) / / WK	Subcutaneous	1 mg, qw on Wednesdays	29-Apr-2022	02-Apr-2023	Diabetes mellitus

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 1.0 mg 3.0 mL	223 Day	Yes	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Ozempic 1.0 mg 3.0 mL//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Aspiration	
Aspiration	
Rotator cuff syndrome	

Case ID: 22199705

Fall

Nephrolithiasis

Thymoma

Impaired gastric emptying

Pyrexia

Cough

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a medical doctor as "aspiration(Aspiration)" beginning on(b)(6)******, "aspiration(Aspiration)" beginning on (b)(6)*****, "rotator cuff tear(Rotator cuff tear)" beginning on 19-DEC-2022, "fell on ice(Fall)" beginning on 19-DEC-2022, "bilateral kidney stones(Kidney stones)" beginning on 08-NOV-2022, "thymoma(Thymoma)" beginning in 2022, "gastroparesis(Gastroparesis)" beginning on (b)(6)*****, "fever(Fever)" beginning in DEC-2022, "cough(Cough)" beginning in DEC-2022 and concerned a 52 year old male patient, who was treated with Ozempic 1.0 mg 3.0 mL (semaglutide) from 29-APR-2022 to 02-APR-2023 for diabetes mellitus. Patient's height: 184.2 cm Patient's weight: 138.3 kg Patient's BMI: 40.789 Current Condition: diabetes mellitus, hypertension, obesity, obstructive sleep apnea, cholesterol high, iron low. Family History: kidney stones, diabetes. Concomitant products included METFORMIN, LISINOPRIL, FENOFIBRATE, MODAFINIL, FERROUS SULFATE, FOLIC ACID, GLIPIZIDE XL (GLIPIZIDE), CARVEDILOL, ROSUVASTATIN, AMLODIPINE. A physician, who was also the patient and was receiving therapy with Ozempic, experienced gastroparesis 24 hours after each dose since 16-MAR-2022. On 08-NOV-2022, the patient experienced bilateral kidney stones. On (b)(6)*****, the patient went to the emergency department for bilateral kidney stones. As treatment, the patient underwent urgent bilateral stent placement with no need for intubation. On (b)(6)*****, the patient underwent kidney stone lithotripsy under anesthesia without intubation. However, kidney stones remained on the right. On(b)(6)*******as further treatment, the patient underwent laser lithotripsy and stent placement under anesthesia. Aspiration occurred mid procedure and an emergency intubation was required, despite the fact that the patient had appropriately fasted for the procedure. The patient experienced cough and mild fever, and was treated prophylactically for potential aspiration pneumonia with unspecified antibiotics. During work up for kidney stones, an incidental finding of thoracic mass was noted on computerized tomography scan. On 19-DEC-2022, the patient fell on ice in driveway causing rotator cuff tear. On(b)(6)******, the patient was hospitalized and underwent surgical removal of a thymoma, which was performed with intubation and no complications. Thymoma was benign. On (b)(6)*****, the patient was discharged. On (b)(6)*****, the patient underwent surgical rotator cuff repair. When the anesthesiologist went to intubate, he noted that patient was in the process of aspirating, which required a much more rapid intubation in order to prevent aspirating further. The patient had fasted as ordered for all procedures, and only aspirated during procedures that occurred on Thursdays (patient had taken Ozempic on Wednesdays). The patient did not have difficulties with procedures that occurred on Fridays or Saturdays. Action taken to Ozempic 1.0 mg 3.0 mL was reported as Product discontinued. The outcome for the event "aspiration(Aspiration)" was Recovered. On (b)(6)***** the outcome for the event "aspiration(Aspiration)" was Recovered. The outcome for the event "rotator cuff tear(Rotator cuff tear)" was Recovering/resolving. On 19-DEC-2022 the outcome for the event "fell on ice(Fall)" was Recovered. On 20-DEC-2022 the outcome for the event "bilateral kidney stones(Kidney stones)" was Recovered. On (b)(6)***** the outcome for the event "thymoma(Thymoma)" was Recovered. On (b)(6)***** the outcome for the event "gastroparesis(Gastroparesis)" was Recovered. The outcome for the event "fever(Fever)" was Not Reported. The outcome for the event "cough(Cough)" was Not Reported. The physician felt that the aspiration (two times) and gastroparesis were related to therapy with Ozempic. The physician felt that the bilateral kidney stones, rotator cuff tear, and fell on ice were not related. Product batch number was requested. Since last submission, the following has been updated: - Patient date of birth, height, weight, BMI. - Relevant history. - Laboratory data. - Concomitant medications. - Event of aspiration start date, outcome. - Description as reported of rotator cuff repair updated to torn rotator cuff, start date, outcome. - Event of bilateral kidney stones start date, outcome, stop date. - Events of fell on ice and thymoma added. - Physician causality. - Narrative updated with the new information from the physician. Company Comment: Aspiration , aspiration, rotator cuff syndrome, fall, nephrolithiasis, thymoma, and impaired gastric emptying are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of obesity has been associated with an increased risk for nephrolithiasis. In addition, diabetes mellitus which has been

associated with delayed gastric emptying considered a confounder for impaired gastric emptying. In addition, the use of anesthesia may have contributed to the aspiration events in this patient with other comorbidities to include obstructive sleep apnea. Limited information on 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?
Diabetes mellitus	2004		Yes
Hypertension	2004		Yes
Obesity			Yes
Obstructive sleep apnoea syndrome	2000		Yes
Blood cholesterol increased			Yes
Blood iron decreased			Yes
Nephrolithiasis			Yes
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
COMPUTERISED TOMOGRAM					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	Interval 1st Dose to Event
1	METFORMIN	1000 Mg Milligram(S) / BID	Oral	1000 mg, bid	2004		Diabetes mellitus	
2	LISINOPRIL	40 Mg Milligram(S) / QD	Oral	40 mg, qd			Hypertension	

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

Case ID: 22199705

3	FENOFIBRATE	48 Mg Milligram(S) / QD	Oral	48 mg, qd in AM	Blood cholesterol increased
4	MODAFINIL	200 Mg Milligram(S) / QD	Oral	200 mg, qd in AM	Somnolence
5	FERROUS SULFATE	325 Mg Milligram(S) / QD	Oral	325 mg, qd in AM	Blood iron decreased
6	FOLIC ACID	1 Mg Milligram(S) / QD	Oral	1 mg, qd	Product used for unknown indication
7	GLIPIZIDE XL	2.5 Mg Milligram(S) / QD	Oral	2.5 mg, qd in AM	Diabetes mellitus
8	CARVEDILOL	25 Mg Milligram(S) / BID	Oral	25 mg, bid	Hypertension
9	ROSUVASTATIN	20 Mg Milligram(S) / QD	Oral	20 mg, qd in AM	Blood cholesterol increased
10	AMLODIPINE	10 Mg Milligram(S) / QD	Oral	10 mg, qd in AM	Hypertension

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: 22210589

Case Information:

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

FDA Rcvd Date: 14-Apr-2023 **Mfr Rcvd Date:** 03-Apr-2023 **Mfr Control #:** US-NOVOPROD-1049883 **Application #:** 215256

Patient Information:

Age: 42 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy		1.7 Mg Milligram(S) / / WK	Subcutaneous	1.7 mg, qw (Dose increased)			
2	Wegovy		/	Subcutaneous	UNK, qw			Weight control

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

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S
2	Wegovy//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

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

Case ID: 22210589

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Aspiration	
Impaired gastric emptying	

Event/Problem Narrative:

This serious Literature case entitled "Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report" which was published in the "Canadian journal of anaesthesia" from the United States was reported by an Anaesthetist as "Intraoperative pulmonary aspiration of gastric contents(Pulmonary aspiration)" with an unspecified onset date, "Delayed gastric emptying(Delayed gastric emptying)" with an unspecified onset date, and concerned a 42 Years old Male patient who was treated with Wegovy (SEMAGLUTIDE) from unknown start date for "Weight loss", Patient's Body Mass Index: 37 kg/m2 Current Condition: Gastroesophageal reflux, Barrett's esophagitis with dysplasia, obesity, Obstructive sleep apnea (treated with CPAP), Mixed anxiety and depressive disorder. Historical Condition: heavy alcohol use (sober for 4 years), Pulmonary aspiration leading to Lung abscess that was conservatively treated with antibiotics (unspecified). Procedure: Four previous upper gastrointestinal endoscopies and ablation of dysplastic mucosa with the most recent procedure was before three months with deep sedation and natural airway, Continuous positive airway pressure (CPAP at night). Concomitant products included - OMEPRAZOLE, FAMOTIDINE, PAROXETINE, BUPROPION, BUSPIRONE On an unspecified date (reported as two months earlier than the fifth procedure of upper gastrointestinal endoscopy and ablation of dysplastic mucosa), the patient had started weekly injections of Wegovy which was later escalated to 1.7 mg. On an unspecified date (reported as when the patient had presented for repeat of the upper gastrointestinal endoscopy for the ablation of dysplastic areas), the patient's gastrointestinal endoscopy had revealed substantial gastric contents (large quantities of liquid and solid materials) despite fasting for 18 hours. The anesthetics used were intravenous fentanyl bolus, Propofol bolus and Propofol infusion. Hence, the food remains (a large quantity of liquid and solid materials) were removed from the patient's trachea and bronchi by insertion of a bronchoscope through the endotracheal tube after the administration of additional propofol and succinylcholine. After four hours, the patient had been extubated and they were transferred to the intensive care unit (ICU) where they had been sedated and intubated, and they remained asymptomatic. On an unspecified date (reported as the next day), the patient had been discharged. The other details of hospitalization of the patient had been unspecified. It was reported that, four months later, the patient was doing well. Batch Numbers were requested. Action taken to Wegovy was Not reported. The outcome for the event "intraoperative pulmonary aspiration of gastric contents(Pulmonary aspiration)" was Recovering/resolving. The outcome for the event "Delayed gastric emptying(Delayed gastric emptying)" was Recovering/resolving. Company Comment: 'Delayed gastric emptying' is assessed as listed and 'Pulmonary aspiration' as unlisted according to current NovoNordisk CCDS information on Wegovy. Patient with medical history of Barrett's esophagus never presented with gastric content during endoscopy procedure. Based on temporal association a causal relationship of delayed gastric emptying with the drug cannot be ruled out completely. Pulmonary aspiration could be secondary to delayed gastric emptying. This single case report is not considered to change the current knowledge of the safety profile of Wegovy.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Gastrooesophageal reflux disease			Yes
Barrett's oesophagus			Yes
Alcoholism			No

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

Case ID: 22210589

Aspiration	No
Lung abscess	No
Obesity	Yes
Obstructive sleep apnoea syndrome	Yes
Mixed anxiety and depressive disorder	Yes
Therapeutic procedure	No
Positive airway pressure therapy	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
ENDOSCOPY GASTROINTESTINAL					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	Interval 1st Dose to Event
1	OMEPRAZOLE	/		UNK, qd			Product used for unknown indication	
2	FAMOTIDINE	/		UNK, qd			Product used for unknown indication	
3	PAROXETINE	/		UNK, qd			Product used for unknown indication	
4	BUPROPION	/		UNK, qd			Product used for unknown indication	
5	BUSPIRONE	/		UNK, qd			Product used for unknown indication	

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

Case ID: 22210589

Reporter Source:

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

Literature Text: Klein, Sandra R;Hobai, Ion A. Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report. Canadian journal of anaesthesia. 2023

Can J Anesth/J Can Anesth
https://doi.org/10.1007/s12630-023-02440-3

CASE REPORTS/CASE SERIES

Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report

Sémaglutide, vidange gastrique retardée et aspiration pulmonaire peropératoire : une présentation de cas

Sandra R. Klein, BS · Ion A. Hobai, MD, PhD

Received: 6 December 2022 / Revised: 11 January 2023 / Accepted: 12 January 2023

Abstract

Purpose *We report a case in which the use of semaglutide for weight loss was associated with delayed gastric emptying and intraoperative pulmonary aspiration of gastric contents.*

Clinical features *A 42-yr-old patient with Barrett's esophagus underwent repeat upper gastrointestinal endoscopy and ablation of dysplastic mucosa. Two months earlier, the patient had started weekly injections of semaglutide for weight loss. Despite having fasted for 18 hr, and differing from the findings of prior procedures, endoscopy revealed substantial gastric content, which was suctioned before endotracheal intubation. Food remains were removed from the trachea and bronchi using bronchoscopy. The patient was extubated four hours later and remained asymptomatic.*

Conclusion *Patients using semaglutide and other glucagon-like peptide 1 agonists for weight management may require specific precautions during induction of anesthesia to prevent pulmonary aspiration of gastric contents.*

Résumé

Objectif *Nous rapportons un cas dans lequel l'utilisation de sémaglutide à des fins de perte de poids a été associée à un retard de vidange gastrique et à une aspiration pulmonaire peropératoire du contenu gastrique.*

Caractéristiques cliniques *Un patient de 42 ans souffrant d'un œsophage de Barrett a subi une cinquième endoscopie gastro-intestinale supérieure avec ablation de la muqueuse dysplasique. Deux mois plus tôt, le patient avait commencé à recevoir des injections hebdomadaires de sémaglutide pour perdre du poids. Bien qu'à jeun depuis 18 heures et à la différence des évaluations lors des interventions antérieures, l'endoscopie a révélé un contenu gastrique important, qui a été aspiré avant l'intubation endotrachéale. Les restes de nourriture ont été retirés de la trachée et des bronches par bronchoscopie. Le patient a été extubé quatre heures plus tard et est demeuré asymptomatique.*

Conclusion *Les patients utilisant du sémaglutide et d'autres agonistes du peptide analog au glucagon-1 pour la gestion du poids pourraient nécessiter des précautions spécifiques lors de l'induction de l'anesthésie pour empêcher l'aspiration pulmonaire du contenu gastrique.*

Keywords adverse reactions · endoscopy · esophago-gastro-duodenoscopy · GLP 1 · glucagon-like peptide 1 · obesity

S. R. Klein, BS
The Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, Boston, MA, USA

I. A. Hobai, MD, PhD (✉)
The Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, Boston, MA, USA
e-mail: ihobai@mgh.harvard.edu

The Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, 55 Fruit Str., GRB 444, Boston, MA 02114, USA

Semaglutide is a glucagon-like peptide 1 (GLP 1) agonist used for glycemic control in patients with diabetes, which has recently been approved for weight control in certain patients with obesity. We report a case in which the use of semaglutide for weight loss was associated with delayed gastric emptying and intraoperative pulmonary aspiration

Published online: 28 March 2023

of gastric content. A written HIPAA release form and written informed consent were obtained from the patient for publication of this case report.

Case presentation

A 42-yr-old male with gastroesophageal reflux and Barrett's esophagus with dysplasia presented for repeat upper gastrointestinal endoscopy and ablation of dysplastic mucosal areas. This was the fifth procedure in two years, four of which (including the most recent one, three months prior) he had tolerated well under deep sedation with natural airway. One prior procedure was performed under general endotracheal anesthesia. He had a remote history of heavy alcohol use with several complications, including a lung abscess, thought to be the result of aspiration, which was treated conservatively with antibiotics. He had been sober for four years. His other medical history included obesity (body mass index, 37 $kg{\cdot}m^{-2}$), obstructive sleep apnea (managed by nightly use of a continuous positive airway pressure machine), and mixed anxiety and depressive disorder. The patient had no history of diabetes. Two months prior to the procedure, he started taking semaglutide for weight loss, at a dose that escalated to weekly 1.7-mg subcutaneous injections. Other daily medications included omeprazole, famotidine, paroxetine, bupropion, and buspirone.

The patient had no gastrointestinal symptoms on the day of the procedure. He was instructed to have nothing by mouth for 8 hr; however, by the time the procedure started, he had been fasting for over 18 hr. An intravenous catheter was inserted, and standard American Society of Anesthesiologists monitoring was used. He was placed in a slight left lateral position, and deep sedation was initiated with a fentanyl bolus, propofol bolus, and propofol infusion. His eyes closed, he became unresponsive to voice and continued to breathe easily, unassisted. Upon introduction of the endoscope, large quantities of liquid and solid material were encountered in the stomach. This was different from all prior procedures, in which the stomach was found to be empty. The gastric content was suctioned through the endoscope, and the patient was intubated rapidly after the administration of additional propofol and succinylcholine. A bronchoscope was inserted through the endotracheal tube and revealed a moderate quantity of liquid and solid material resembling the gastric content, which was suctioned. The procedure was completed, and the patient was transferred to the intensive care unit, sedated, and intubated. He was extubated four hours later, remained asymptomatic, and was discharged home the next day. Four months later, he was doing well.

Discussion

Glucagon-like peptide 1 agonists have been used for glycemic control in patients with type 2 diabetes[1] for over 12 years and have proven to have a very good safety profile. The most prevalent side effects are nausea, vomiting, and diarrhea,[1] and are relatively minor. The current recommendations are that GLP 1 agonists may be continued in the perioperative period when used for diabetes.[2]

In June 2022, the U.S. Food and Drug Administration approved the use of weekly injections of semaglutide for chronic weight management in adults with obesity or overweight and one weight-related condition, such as high blood pressure, type 2 diabetes, or high cholesterol.[3] The recommended dose is 1.7–2.4 mg once weekly, subcutaneously, which is higher than the dose of 0.25–1 mg used for diabetes management. It is therefore possible that the safety profile may be worse in these conditions. Notably, if we compare two different studies (with different patient populations, admittedly), the prevalence of nausea and vomiting was much higher in patients taking 2.4 mg semaglutide subcutaneously[3] than in those taking 0.5 and 1 mg[1] (44% *vs* 2% and 5% for nausea and 31% *vs* 2% and 3% for vomiting, respectively).

As GLP 1 is an incretin hormone responsible for the regulation of gastric emptying,[4] several studies have assessed gastric emptying in patients taking semaglutide using an assay that quantifies paracetamol absorption following a standardized breakfast. Dahl *et al*.[5] showed that in diabetic patients, oral semaglutide decreased acetaminophen absorption in the first hour, but absorption after five hours was unchanged from placebo. In patients with obesity receiving weekly subcutaneous injections, a study found the same pattern as in diabetic patients,[6] whereas another study[7] found no change in absorption for either the first hour or five hours. Thus, while some controversy exists regarding whether semaglutide may decrease gastric emptying during the first hour, the overall effect appears to be negligible. Nevertheless, the test used has known limitations, and some studies have shown a poor correlation with gastric emptying assessed by scintigraphy.[8] Therefore, uncertainty persists. Regarding other GLP 1 agonists, another study found a slowing of gastric emptying in diabetic patients taking liraglutide, using a ^{13}C-octanoic acid breath test, although the extent of the difference and its clinical implications were not addressed.[9]

In our patient, the start of semaglutide therapy was associated with a clear delay in gastric emptying after 18 hr of fasting, which was not previously observed on several occasions. Although this observation cannot, in itself, unequivocally show that semaglutide causes delayed

gastric emptying, it gives, in our view, reason for a significant safety concern, especially since it is consistent with the known mechanism of action of the drug. Other possibilities exist but are less likely. A persistent alcohol-induced gastroparesis four years after quitting is doubtful since previous endoscopies during and immediately after the period of heavy alcohol use revealed an empty stomach. An undisclosed patient non-compliance with the eight hours fasting requirement is also possible, but there is no reason to suspect it, especially for a patient who has always been truthful and consistently showed a genuine concern for his well-being and safety.

Pulmonary aspiration of gastric contents remains a significant cause of postoperative morbidity and mortality.[10] Therefore, preventive adjustments in anesthesia management could be expected to improve overall perioperative outcomes. With a half-life of approximately seven days,[11] it will take 23 days (i.e., 3.3 half-lives) for semaglutide levels to drop to less than 10% of the initial blood level, but it is unknown whether holding the drug for this period preoperatively will result in a full recovery of gastric motility. Perhaps the emerging perioperative use of point-of-care ultrasound to assess gastric content[12] may provide an answer to this question. As such, until more data become available, a cautious approach would be to consider patients taking semaglutide for weight loss as having a full stomach.

Author contributions *Ion A. Hobai* contributed to making the original observation, researching the literature, writing and revising the manuscript. *Sandra R. Klein* contributed to making the original observation and editing the manuscript.

Disclosures None.

Funding statement Departmental only.

Editorial responsibility This submission was handled by Dr. Philip M. Jones, Deputy Editor-in-Chief, *Canadian Journal of Anesthesia/ Journal canadien d'anesthésie*.

References

1. *Marso SP, Bain SC, Consoli A, et al.* Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. N Engl J Med 2016; 375: 1834–44. https://doi.org/10.1056/nejmoa1607141
2. *Hulst AH, Polderman JA, Siegelaar SE, et al.* Preoperative considerations of new long-acting glucagon-like peptide-1 receptor agonists in diabetes mellitus. Br J Anaesth 2021; 126: 567–71. https://doi.org/10.1016/j.bja.2020.10.023
3. *Wilding JP, Batterham RL, Calanna S, et al.* Once-weekly semaglutide in adults with overweight or obesity. N Engl J Med 2021; 384: 989–1002. https://doi.org/10.1056/nejmoa2032183
4. *Schirra J, Katschinski M, Weidmann C, et al.* Gastric emptying and release of incretin hormones after glucose ingestion in humans. J Clin Invest 1996; 97: 92–103. https://doi.org/10.1172/jci118411
5. *Dahl K, Brooks A, Almazedi F, Hoff ST, Boschini C, Baekdal TA.* Oral semaglutide improves postprandial glucose and lipid metabolism, and delays gastric emptying, in subjects with type 2 diabetes. Diabetes Obes Metab 2021; 23: 1594–603. https://doi.org/10.1111/dom.14373
6. *Hjerpsted JB, Flint A, Brooks A, Axelsen MB, Kvist T, Blundell J.* Semaglutide improves postprandial glucose and lipid metabolism, and delays first-hour gastric emptying in subjects with obesity. Diabetes Obes Metab 2018; 20: 610–9. https://doi.org/10.1111/dom.13120
7. *Friedrichsen M, Breitschaft A, Tadayon S, Wizert A, Skovgaard D.* The effect of semaglutide 2.4 mg once weekly on energy intake, appetite, control of eating, and gastric emptying in adults with obesity. Diabetes Obes Metab 2021; 23: 754–62. https://doi.org/10.1111/dom.14280
8. *Willems M, Quartero AO, Numans ME.* How useful is paracetamol absorption as a marker of gastric emptying? A systematic literature study. Dig Dis Sci 2001; 46: 2256–62. https://doi.org/10.1023/a:1011935603893
9. *Meier JJ, Rosenstock J, Hincelin-Méry A, et al.* Contrasting effects of lixisenatide and liraglutide on postprandial glycemic control, gastric emptying, and safety parameters in patients with type 2 diabetes on optimized insulin glargine with or without metformin: a randomized, open-label trial. Diabetes Care 2015; 38: 1263–73. https://doi.org/10.2337/dc14-1984
10. *Warner MA, Meyerhoff KL, Warner ME, Posner KL, Stephens L, Domino KB.* Pulmonary aspiration of gastric contents: a closed claims analysis. Anesthesiology 2021; 135: 284–91. https://doi.org/10.1097/aln.0000000000003831
11. *Hall S, Isaacs D, Clements JN.* Pharmacokinetics and clinical implications of semaglutide: a new glucagon-like peptide (GLP)-1 receptor agonist. Clin Pharmacokinet 2018; 57: 1529–38. https://doi.org/10.1007/s40262-018-0668-z
12. *El-Boghdadly K, Wojcikiewicz T, Perlas A.* Perioperative point-of-care gastric ultrasound. BJA Educ 2019; 19: 219–26. https://doi.org/10.1016/j.bjae.2019.03.003

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

Case ID: 22733609

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** N **Country:** US **Event Date:** Dec-2021 **Outcomes:** **Application Type:**

FDA Rcvd Date: 20-Jul-2023 **Mfr Rcvd Date:** 27-Feb-2023 **Mfr Control #:** US-NOVOPROD-1041406 **Application #:** 209637

Patient Information:

Age: 61 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Ozempic		/	Subcutaneous	1mg	Dec-2021		Product used for unknown indication
2	Ozempic		/	Subcutaneous	2mg			

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Unknown	NA				NOVO NORDISK	
2	Ozempic		Unknown	NA	MP5D781			NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Ozempic//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S
2	Ozempic//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

Case ID: 22733609

Preferred Term (MedDRA Version: v.26.1)	ReC
Lacrimation increased	
Eye discharge	
Vulvovaginal pruritus	
Vulvovaginal burning sensation	
Vulvovaginal discomfort	
Dysuria	
Aspiration	
Heart rate decreased	
Nausea	

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Consumer as "Nausea(Nausea)" beginning on 12-FEB-2023, "Eyes are very watery(Watering eyes)" beginning on FEB-2023, "Eyes very sticky(Sticky eyes)" beginning on FEB-2023, "Itching in the vaginal area(Vaginal itching)" beginning on FEB-2022, "Burning in the vaginal area(Vaginal burning sensation)" beginning on FEB-2022, "Feeling pressure in the vaginal area(Pressure in vagina)" beginning on FEB-2022, "Burns when peeing(Painful urination)" beginning on FEB-2022, "Heart rate has been low at like 64(Heart rate low)" beginning on FEB-2023, "If I lay down at night and I eat anything liquidy I aspirate the food up(Food aspiration)" beginning on DEC-2021 and concerned a 61 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE) from DEC-2021 for "Product used for unknown indication", Dosage Regimens: Ozempic: ??-DEC-2021 to Not Reported, Not Reported to Not Reported; Historical Drug: HYDROCHLOROTHIAZIDE, JARDIANCE. Lab Data included: Test Date: FEB-2023 Lab Data Test as Reported: Heart rate Test Name: Heart rate Comments: 64 (units not reported) Batch Numbers: Ozempic: ASKU, MP5D781 Action taken to Ozempic was Not reported. On 12-FEB-2023 the outcome for the event "Nausea(Nausea)" was Recovered. The outcome for the event "Eyes are very watery(Watering eyes)" was Not yet recovered. The outcome for the event "Eyes very sticky(Sticky eyes)" was Not yet recovered. The outcome for the event "Itching in the vaginal area(Vaginal itching)" was Not yet recovered. The outcome for the event "Burning in the vaginal area(Vaginal burning sensation)" was Not yet recovered. The outcome for the event "Feeling pressure in the vaginal area(Pressure in vagina)" was Not yet recovered. The outcome for the event "Burns when peeing(Painful urination)" was Not yet recovered. The outcome for the event "Heart rate has been low at like 64(Heart rate low)" was Not yet recovered. The outcome for the event "If I lay down at night and I eat anything liquidy I aspirate the food up(Food aspiration)" was Not yet recovered. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20230212783 Reference Notes:

Relevant Medical History:

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: 22733609

HYDROCHLOROTHIAZIDE	Product used for unknown indication	No adverse event
JARDIANCE	Product used for unknown indication	No adverse event

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
HEART RATE					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	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: 22801610

Case Information:

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

FDA Rcvd Date: 09-Aug-2023 **Mfr Rcvd Date:** 30-Jul-2023 **Mfr Control #:** US-NOVOPROD-1099856 **Application #:** 213051

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
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		NA	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	//	No			/			

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Aspiration	
Arthroscopy	
Impaired gastric emptying	
Vomiting	

Event/Problem Narrative:

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

Case ID: 22801610

This serious Spontaneous case from the UNITED STATES was reported by a Nurse as "vomited and aspirated while under anesthesia(Aspiration)" with an unspecified onset date, "shoulder arthroscopy(Shoulder arthroscopy)" with an unspecified onset date, "delay in gastric emptying(Delayed gastric emptying)" with an unspecified onset date, "vomited and aspirated while under anesthesia(Vomited)" with an unspecified onset date, and concerned an Adult Male patient who was treated with Rybelsus (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication". Medical history was not provided. A nurse reported a patient in their 60s receiving therapy with Rybelsus followed protocol and stopped eating a set time before anesthesia for shoulder arthroscopy. However, the nurse believes the patient experienced delay in gastric emptying caused by Rybelsus which led to patient still having food in their stomach while under anesthesia. While still under the anesthesia the patient vomited and aspirated. As a result, the patient was admitted to the hospital. The nurse felt the event of delay in gastric emptying was related to therapy with Rybelsus. Action taken to Rybelsus was reported as Drug discontinued temporarily. The outcome for the event "vomited and aspirated while under anesthesia(Aspiration)" was Not Reported. The outcome for the event "shoulder arthroscopy(Shoulder arthroscopy)" was Not Reported. The outcome for the event "delay in gastric emptying(Delayed gastric emptying)" was Not Reported. The outcome for the event "vomited and aspirated while under anesthesia(Vomited)" was Not Reported. Batch number requested. Company Comment: Aspiration and arthroscopy are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Rybelsus. Impaired gastric emptying and vomiting are assessed as listed according to the Rybelsus CCDS. Of note, the patient was under the anesthesia for the shoulder arthroscopy and vomited, leading to the aspiration. Limited information as related to Rybelsus therapy dates, event onset dates, indication for the shoulder arthroscopy, 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.

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

Reporter Source:

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

Case ID: 22801610

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: 22888868

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** Jul-2023 **Outcomes:** LT , HO , OT **Application Type:**

FDA Rcvd Date: 31-Aug-2023 **Mfr Rcvd Date:** 23-Aug-2023 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202308014707 **Application #:** 215866

Patient Information:

Age: 39 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Mounjaro		/	Unknown	UNK UNK, unknown			10057097
2	DUPIXENT		300 Mg Milligram(S) /	Subcutaneous	300 mg, other	Feb-2022		10064220

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro		Unknown	NA				ELI LILLY AND CO	
2	DUPIXENT		Unknown	NA					

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	/TIRZEPATIDE PEN (UNKNOWN)/ NSC	No			/		Adverse Event Without Identified Device or Use Problem	Eli Lilly and Company
2	//	No			/			

Event Information:

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

Case ID: 22888868

Preferred Term (MedDRA Version: v.26.1) **ReC**

Aspiration

Hiatus hernia

Event/Problem Narrative:

This spontaneous case, reported by physicians and consumers who contacted the company to report adverse events, concerned a 39-year-old male patient of an unknown origin. Medical history and concomitant medications were not provided. The patient received tirzepatide (Mounjaro) via a pre-filled pen, at an unknown dose and frequency, via an unknown route of administration, for an unknown indication, beginning on an unknown date. He also received dupilumab (Dupixent) via pre- pre-filled pen, at a dose of 300 mg with an unknown frequency, via subcutaneous route, for the treatment of eosinophilic esophagitis, beginning on an unknown date in Feb-2022. On an unknown date, while on tirzepatide and dupilumab therapies, he had hiatal hernia due to which he was hospitalized. On an unknown date in (b)(6)**, he was aspirating due to which he hospitalized and was put on ventilator. On (b)(6)*****, his esophagogastroduodenoscopy was performed (result was not provided). On (b)(6)*(b)(6), he was released from ventilator. The event of aspiration was considered as serious by the company due to life-threatening reason and considered serious by reporter due to hospitalization and medically significant reasons. Information regarding further hospitalization and discharge details, the corrective treatment, outcome of the events and the status of tirzepatide and dupilumab therapies were not provided. The reporting physician related the event of aspiration with tirzepatide therapy while did not relate the event of aspiration with dupilumab therapy and did not provide relatedness assessment of the event of hiatal hernia with tirzepatide and dupilumab therapies. The reporting consumer did not provide relatedness assessment of the events with tirzepatide and dupilumab therapies. Edit 31-Aug-2023: Upon review of the information received on 23-Aug-2023, recoded suspect drug tirzepatide. No other changes were done to the case.

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
10053057					Y

Concomitant Products:

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

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

Case ID: 22888868

Reporter Source:

Study report?: No

Sender organization: ELI LILLY AND CO

503B Compounding Outsourcing Facility?:

Literature Text:

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

Case ID: 22996790

Case Information:

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

FDA Rcvd Date: 28-Sep-2023 **Mfr Rcvd Date:** 19-Sep-2023 **Mfr Control #:** US-NOVOPROD-1118644 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
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		Unknown	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Ozempic//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

Preferred Term (MedDRA Version: v.26.1) **ReC**

Aspiration

Surgery

Event/Problem Narrative:

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

Case ID: 22996790

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "aspiration(Aspiration)" with an unspecified onset date, "Surgery(Surgery)" with an unspecified onset date, and concerned an Adult patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication". Medical history was not provided. A patient receiving therapy with Ozempic had surgery and passed away shortly after due to aspiration. Action taken to Ozempic was Not reported. The outcome for the event "aspiration(Aspiration)" was Fatal. The outcome for the event "Surgery(Surgery)" was Not Reported. Batch number requested. Company Comment: Aspiration and surgery 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, laboratory/diagnostic evaluations, and reason for surgery 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:

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

Reporter Source:

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

Literature Text: