

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

Date - T me: 20-Ju -2023 09: 6:56 EDT

Run by: KIA BAZEMORE@FDA HHS GOV

Disclaimer:

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

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

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

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

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

Case ID(s) Printed:

12419571	15746941	16867156	17971467
19014613	20334416	20502066	21360692
21854592	21974341	21979556	22040650

Total Cases: 12

Total number of Inactive cases: *0



Case ID: 12419571

Case Information:

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

Day)

FDA Rcvd Date: 31-May-2016 Mfr Rcvd Date: 18-May-2016 Mfr Control #: CA-NOVOPROD-493067 Application #: 206321

Patient Information:

Age: 19 YR Sex: Female Weight:

Suspect Products:

#	Product Name:	Compounded	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
		Drug ?						
1	Saxenda		.6 Mg Milligram(S) /	Unknown	0.6 mg, qd	Product used for unknown	n	
			QD			indication		
2	Saxenda		1.2 Mg Milligram(S) /	Unknown	1.2 mg, qd			
			QD					
3	Saxenda		.6 Mg Milligram(S) /	Unknown	0.6 mg, qd			
			QD					
#	Product Name: In	nterval 1st DeC	ReC	Lot#	Exp Date	NDC #	/IFR/Labeler	отс

#	Product Name:	Interval 1st	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	отс
		Dose to Event							
1	Saxenda		Unknown	Unknown	UNKNOWN			NOVO NORDISK	
2	Saxenda		Unknown	Unknown	UNKNOWN			NOVO NORDISK	
3	Saxenda		Unknown	Unknown	UNKNOWN			NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicidal ideation

Nausea

Event/Problem Narrative:



Case ID: 12419571

This serious spontaneous case from Canada was reported by a Endocrinologist as "suicidal ideation" with an unspecified onset date, "nausea" with an unspecified onset date, and concerned a 19-year-old female patient who was treated with Saxenda (liraglutide) from unknown start date for unknown indication. Patient's height, weight and BMI(body mass index):not reported. Medical history included depression, anxiety, obese. No previous history of suicidal thoughts It was reported that the patient presented to the emergency department with suicidal ideation and was admitted to hospital. As of last night, the patient remains in hospital. The patient started Saxenda 2 weeks prior to this event with a dose of 0.6 mg qd and tried to go upto 1.2 mg qd with increased nausea returned to 0.6 mg dose. Action taken to Saxenda was Not reported. The outcome for the event "Suicidal ideation" was Not Reported. The outcome for the event "Nausea" was Not Reported. Company Comment: Suicidal Ideation is an unlisted event according to the NN current reference safety information on Saxenda. Depression and anxiety are risk factors for suicidal ideation. Studies also suggest that the suicidal ideation increases with increased BMI (body mass index) in females; thus, obesity is a possible risk factor even though the body mass index is not provided. Family history, suspect drug therapy details, action taken to suspect drug, clinical course in hospital and details of concomitant medication is not provided. This single case report is not considered to change the current knowledge of the safety profile of suspected product.

Relevant Medical History:									
Disease/Surgical Procedure			Start Date	End D	ate	Continuing?	•		
Depression						Yes			
Anxiety						Yes			
Obesity									
Medical History Product(s)			Start Date	End D	ate	Indications		Events	
Relevant Laboratory Data:									
Test Name		Result	Unit		Normal Lo	ow Range	Normal High	Range	Info Avail
Concomitant Products:									
# Product Name:	Dose/Frequency	Route		Dosage Text	Indi	cation(s)	Start Date	End Date	Interval 1st
									Dose to Event
Reporter Source:									



Case ID: 12419571

Study report?:

No

Sender organization:

NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text:



Case ID: 15746941

Case Information:

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

Day)

FDA Rcvd Date: 20-Dec-2018 Mfr Rcvd Date: 31-Oct-2018 Mfr Control #: ES-NOVOPROD-631437 Application #: 206321

Patient Information:

Age: 35 YR Sex: Male Weight:

Suspect Products:

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

Drug?

1 Saxenda .6 Mg Milligram(S) / Unknown 0.6 mg, qd Obesity 29-Oct-2018

QD

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

Dose to Event

1 Saxenda Unknown Unknown UNKNOWN NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicide attempt

Faeces discoloured

Diarrhoea

Event/Problem Narrative:

This serious Spontaneous case from SPAIN was reported by a General physician as "commit a suicide" with an unspecified onset date, "Diarrhoea" with an unspecified onset date, and concerned a 35 Years old Male patient who was treated with Saxenda (liraglutide) from 29-OCT-2018 due to "Obesity", Patients height, weight were not reported Patient's BMI: 35. Medical history included obesity, psychiatric illness. Concomitant products included - abilify(aripiprazole), olanzapine(olanzapine), lorazepam(lorazepam), cardyl(atorvastatin calcium), enalapril(enalapril) On an unknown date, the patient experienced diarrhoea, green stools and went to emergency services On an unknown date, the patient tried to commit a suicide by taking tablets (unknown) and admitted to intensive care Batch number was not available. It was reported that Saxenda was discontinued on an unknown date. Action taken to Saxenda for primary event 'commit a suicide' was reported as Not reported. Action taken to Saxenda for 'Green stools, Diarrhoea' were reported as Product discontinued The outcome for the event "Commit a suicide" was Not Reported. The outcome for the event "Diarrhoea"



Case ID: 15746941

was Not Reported. No further information available This case was reclassified from non-serious to serious on 12-DEC-2018 upon follow up due to the addition of the event "commit a suicide" with a seriousness criterion of "hospitalization". Company comment: Suicide attempt and green stool is assessed as unlisted, diarrhoea is assessed as listed according to the Novo Nordisk current CCDS information on Saxenda. The following important information is lacking: details of the psychiatric illness the patient is suffering from, previous suicide attempts, substance abuse, family history of mental illness or suicide, circumstances that led to the suicide attempt. The history of psychiatric illness is a significant risk factor for the suicide attempt. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

NI	owiedge of the safety profile	oi Saxeriua.								
R	elevant Medical History:									
Di	sease/Surgical Procedure		Sta	rt Date	End D	ate	Continuing?	,		
0	pesity						Yes			
М	ental disorder						Yes			
M	edical History Product(s)		Sta	rt Date	End D	ate	Indications		Events	
R	elevant Laboratory Data:									
Te	est Name		Result	Unit		Normal	Low Range	Normal High	Range	Info Avail
C	oncomitant Products:									
#	Product Name:	Dose/Frequency	Route		Dosage Text	In	dication(s)	Start Date	End Date	Interval 1st
										Dose to Event
1	ABILIFY	/	Unknown		5 mg					
2	OLANZAPINE	/	Unknown		5 mg					
3	LORAZEPAM	/	Unknown		1 mg					
_										

Reporter Source:

4 CARDYL

5 ENALAPRIL

10 mg

UNK

Unknown



Case ID: 15746941

Study report?: No

Sender organization:

NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text:



Case ID: 16867156

Case Information:

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

Day)

Patient Information:

Age: 46 YR Sex: Female Weight:

Suspect Products:

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

Drug?

1 Saxenda / Unknown 231 Weight control

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

Dose to Event

1 Saxenda NA Unknown NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicidal ideation

Suicide attempt

Loss of consciousness

Depression

Drug ineffective

Mental impairment

Drug diversion

Product use in unapproved indication

Weight loss poor

Event/Problem Narrative:



Case ID: 16867156

This serious Spontaneous Regulatory Authority case received via MHRA (Medicines and Healthcare Products Regulatory Agency), GBR from UNITED KINGDOM was reported by a Nurse as "using Saxenda is making her feel suicidal (Suicidal intention)" with an unspecified onset date, "tried to kill herself-Attempted suicide(Attempted suicide)" with an unspecified onset date, "slumped(Unconsciousness)" with an unspecified onset date, "Had become depressed within weeks(Depression)" with an unspecified onset date, "Drug ineffective(Drug ineffective)" with an unspecified onset date, "deterioration in her mental health(Mental deterioration)" with an unspecified onset date, "Taking controversial weight loss injection jabs (Saxenda)(Drug diversion)" with an unspecified onset date, "Having healthy Body Mass Index took saxenda(Drug use for unapproved indication)" with an unspecified onset date, "weight was the same(Weight loss poor)" with an unspecified onset date and concerned a 46 Years old Female patient who was treated with Saxenda (liraglutide) from unknown start date for "Weight loss". The patient weight, height and body mass index were not reported Medical history was not provided. On an unknown date patient started using a controversial weight loss injection Jabs (Saxenda), despite having healthy body mass index. On an unknown date the patient tried to kill herself using a controversial weight loss injection. After three weeks of treatment with saxenda the patient weight was same, it was reported that the drug was ineffective and began to feel depressed the patient was also crying all the time and did not know why. The patient was rushed to hospital after overdosing on a cocktail of pills (not specified). On an unknown date, the police found the patient slumped in the car and immediately got the patient to the hospital and discontinued the product. The hospital had said that the patient using Saxenda was making the patient feel suicidal. It was reported that the patient was referred on (b)(6)*****due to a deterioration in her mental health and will remain with the team until her condition improves, the patient had not attended any of the appointments that had been scheduled for her to attend. On an unknown date. Body mass index of the patient was reported as 27 Batch number of Saxenda was not available. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "using Saxenda is making her feel suicidal (Suicidal intention)" was Unknown. The outcome for the event "tried to kill herself-Attempted suicide(Attempted suicide)" was Unknown. The outcome for the event "slumped(Unconsciousness)" was Unknown. The outcome for the event "Had become depressed within weeks(Depression)" was Unknown. The outcome for the event "Drug ineffective(Drug ineffective)" was Not Reported. The outcome for the event "deterioration in her mental health(Mental deterioration)" was Not Reported. The outcome for the event "Taking controversial weight loss injection jabs (Saxenda)(Drug diversion)" was Not Reported. The outcome for the event "Having healthy Body Mass Index took saxenda(Drug use for unapproved indication)" was Not Reported. The outcome for the event "weight was the same(Weight loss poor)" was Unknown, References included: Reference Type: E2B Company Number Reference ID#: GB-NOVOPROD-672421 Reference Notes: No further information was available Since last submission the case was updated -Non-HCP added as reporter -Lab data updated - Dose description and action taken to suspect drug updated - Outcome of the unconsciousness updated -Narrative updated accordingly Company Comment: 'Suicidal ideation', 'suicide attempt', 'Loss of consciousness', 'depression', 'drug diversion', 'mental impairement' was assessed as unlisted and 'drug ineffective', 'weight loss poor' was assessed as listed event according to Novo Nordisk current CCDS on Saxenda. Information on relevant medical history including risk factors (psychiatric illness, substance abuse, previous history of suicide attempts, familial history of depression), details of the cocktail of drugs are all required for thorough medical assessment. Suicidal ideation and suicide attempt can be due to depression, loss of consciousness can be secondary to overdose with cocktail of pills. This single case report is not considered to change the current knowledge of the safety profile of Saxenda

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)

Start Date

End Date

Indications

Events

Relevant Laboratory Data:



Literature Text:

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

Case ID: 16867156

Test Name Body mass index	F	Result	Unit	Normal Low Range	Normal Hiç	gh Range	Info Avail 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 organi	zation: NO	VO NORDISK	503B Con Outsourc	npounding ing Facility?:		



Case ID: 17971467

Case Information:

Case Type : Expedited (15- eSub: Y HP: Country: SE Event Date: 15-May-2020 Outcomes: OT Application Type:

Day)

FDA Rcvd Date: 08-Feb-2021 Mfr Rcvd Date: 19-Jun-2020 Mfr Control #: SE-NOVOPROD-736179 Application #: 206321

Patient Information:

Age: 44 YR Sex: Male Weight:

Suspect Products:

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

Drug?

1 Saxenda / Subcutaneous UNK Obesity Jan-2019 Jan-2020

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

Dose to Event

1 Saxenda Yes Unknown NOVO NORDISK

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Major depression Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous Regulatory Authority case from SWEDEN was reported via Medical Products Agency/Läkemedelsverket, SWE (MPA) by a Physician as "Major depression(Major depression)" beginning on 15-MAY-2020, "Suicidal ideation(Suicidal ideation)" beginning on 15-MAY-2020, and concerned a 44 Years old Male patient who was treated with Saxenda (liraglutide) from JAN-2019 to JAN-2020 for "Obesity", The events Major depression and Suicidal ideation were medically confirmed. Patient's height, weight and BMI were not reported. Dosage Regimens: Saxenda: ??-JAN-2019 to ??-JAN-2020; Current Condition: Obesity, Hypertension. On 15-MAY-2020, the patient began to experience major depression and have suicidal ideation. Batch Numbers: Saxenda: UNK Action taken to Saxenda was reported as Product discontinued. The outcome for the event "Major depression(Major depression)" was Recovered. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Recovered. No further information available. References included: Reference Type: E2B Report Duplicate Reference ID#: SE-MPA-2020-003527 Reference Notes: MPA Reference Type: E2B Authority Number Reference ID#: SE-MPA-2020-003527 Reference Notes: On 08-FEB-2021, it was discovered during preparation of an aggregate report that the events are listed according to the local label. Therefore, the initial submission of this report to the FDA was not required. As the events have been updated from unlisted to listed, the case will be re-submitted to let the FDA know of the change in status. COMPANY COMMENT - Major depression and suicidal ideation are assessed as unlisted according to the Novo Nordisk current CCDS information on Saxenda.



Case ID: 17971467

The information on relevant medical history (on traumatic or stressful events, substance abuse) are not available. However, chronic medical conditions like obesity and hypertension are risk factors for developing depression. Hence the medical history of the patient is confounding factor in the case. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

Relevant Medical History:									
Disease/Surgical Procedure	•		Start Date	End D	ate	Continuing?	•		
Obesity						Yes			
Hypertension						Yes			
Medical History Product(s)			Start Date	End D	ate	Indications		Events	
Relevant Laboratory Data:									
Test Name		Result	Unit		Normal Low	Range	Normal High	n Range	Info Avail
Concomitant Products:									
# Product Name:	Dose/Frequency	Route		Dosage Text	Indicat	ion(s)	Start Date	End Date	Interval 1st Dose to Event
Reporter Source:									
Study report?: No	Sender org	anization:	NOVO NOR	DISK		503B Compo Outsourcing			
Literature Text:									



Case ID: 19014613

Case Information:

Case Type : Expedited (15- eSub: Y HP: N Country: CA Event Date: Nov-2020 Outcomes: OT Application Type:

Day)

FDA Rcvd Date: 03-Feb-2022 Mfr Rcvd Date: 14-Jan-2021 Mfr Control #: CA-NOVOPROD-781457 Application #: 206321

Patient Information:

Age: 43 YR Sex: Female Weight:

Suspect Products:

#	Product Name:	Compounded	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
		Drug ?						
1	Saxenda		/	Unknown	3 mg	Weight control	Jul-2020	Dec-2020
2	Saxenda		/	Unknown	0.6 mg		05-Jan-2021	10-Jan-2021
#	Product Name:	Interval 1st DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	отс
		Dose to Event						
1	Saxenda	Yes	Yes				NOVO NORDISK	
2	Saxenda	Yes	Yes				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicidal ideation

Night sweats

Hypersomnia

Nausea

Vomiting

Fatigue

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Consumer as "suicidal thoughts(Suicidal tendency)" beginning on NOV-2020, "night sweats(Night sweats)" beginning on NOV-2020, "sleeping a lot(Sleep excessive)" beginning on NOV-2020, "nausea(Nausea)" with an unspecified onset date,



Case ID: 19014613

"vomiting(Vomiting)" with an unspecified onset date, "intense fatique(Fatique extreme)" beginning on NOV-2020, and concerned a 43 Years old Female patient who was treated with Saxenda (liraglutide) from JUL-2020 to 10-JAN-2021 for "weight loss". Patient's height, weight and BMI not reported. Dosage Regimens: Saxenda: ??-JUL-2020 to ??-DEC-2020, 05-JAN-2021 to 10-JAN-2021; Medical history was not provided. On an unknown date, patient had nausea and vomiting. On NOV-2020, patient had night sweats so much that clothes and bed sheets were wet, really low moral (mood) and suicidal thoughts. Patient slept a lot, had intense fatigue. On 2nd week of DEC-2020, patient discontinued Saxenda and after 1 week being off, her moral (mood) returned. But on 05-JAN-2021, patient re-started Saxenda again and felt psychological distress returned. Patient moral (mood)was also back. Batch Numbers: Saxenda: ASKU, ASKU Action taken to Saxenda was reported as Product discontinued. The outcome for the event "suicidal thoughts(Suicidal tendency)" was Recovering/resolving. The outcome for the event "night sweats(Night sweats)" was Recovering/resolving. The outcome for the event "sleeping a lot(Sleep excessive)" was Not recovered. The outcome for the event "nausea(Nausea)" was Not Reported. The outcome for the event "vomiting(Vomiting)" was Not Reported. The outcome for the event "intense fatigue(Fatigue extreme)" was Not recovered. On 03-FEB-2022 an amendment was performed. Since last submission, it was discovered during preparation of an aggregate report that this case did not require expedited reporting to the FDA as the event is labelled per the USPI. The case is being re-submitted to notify FDA of the change in status Company comment: 'Suicidal ideation', 'Night sweats', Hypersomnia' were assessed as unlisted events and 'Nausea', Vomiting' and 'Fatigue' were assessed as listed events according to Novo Nordisk reference safety information (CCDS) on Saxenda. Information on patient's BMI, medical history of any chronic illness, psychiatric disorder, history of any stressful life event, feeling hopeless or socially isolated, history of substance abuse problem, family history of mental disorders or substance, concomitant medications, socioeconomic status were not available for thorough medical assessment of the event suicidal ideation. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

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 Lov	v Range	Normal High	n Range	Info Avail
Concomitant Products:									
# Product Name:	Dose/Frequency	Route		Dosage Text	Indica	ation(s)	Start Date	End Date	Interval 1st Dose to Event
Reporter Source:									



Case ID: 19014613

Study report?:

No

Sender organization:

NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text:



Case ID: 20334416

Case Information:

Case Type : Expedited (15- eSub: Y HP: N Country: ZA Event Date: 10-Dec-2021 Outcomes: OT Application Type:

Day)

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

#	Product Name:	Compounded	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
		Drug ?						
1	Saxenda		/	Unknown	3 mg			29-Dec-2021
2	Saxenda		/	Unknown	UNK (low dose)	Weight control	Nov-2021	
#	Product Name:	Interval 1st DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	отс
		Dose to Event						
1	Saxenda	No	NA				NOVO NORDISK	
2	Saxenda	No	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicidal ideation

Depression suicidal

Event/Problem Narrative:

This serious spontaneous case from South Africa was reported by a consumer as "She is not herself mentally (suicidal thoughts) (Suicidal tendency)" beginning on 10-DEC-2021, "Depression and suicidal thoughts (Depression suicidal)" beginning on 10-DEC-2021, and concerned a female patient (age not reported) who was treated with Saxenda (liraglutide) from NOV-2021 to 29-DEC-2021 for "weight loss". Patient's height weight and body mass index (BMI) not reported Dosage Regimens: Saxenda: ??-NOV-2021 to Not Reported, Not Reported to 29-DEC-2021; Medical history was not provided. On 10-DEC-2021, patient was not herself mentally. Patient suffered from depression and suicidal thoughts. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "She is not herself mentally (suicidal thoughts)(Suicidal tendency)" was Not yet recovered. The outcome for the event "Depression and suicidal thoughts(Depression suicidal)" was Not yet recovered. Since last submission following information has been added: -Product stop date updated -action taken updated -event onset date updated -event outcome updated -narrative updated Company comment: 'Suicidal ideation' and 'Depression suicidal' are assessed as unlisted according to the



Case ID: 20334416

Novo Nordisk current CCDS information on Saxenda. Information on medical history including comorbidties, psychiatric illness like anxiety or depression, social and family circumstances, substance abuse, previous episodes of suicide attempt would have helped in thorough medical assessment. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

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



Case ID: 20502066

Case Information:

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

FDA Rcvd Date: 22-Feb-2022 **Mfr Rcvd Date**: 01-Jan-2021 **Mfr Control #**: US-NOVOPROD-779681 **Application #**: 206321

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

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

Drug?

1 Saxenda / Subcutaneous UNK Product used for unknown

indication

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

Dose to Event

1 Saxenda Unknown Unknown 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 as "strong thoughts of suicide(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, and concerned an adult female patient, who was treated with Saxenda (liraglutide) from an unknown start date for an unknown indication. Medical history was not provided. A patient, who was receiving therapy with Saxenda, developed strong thoughts of suicide and depression, described as felt terrified and lost. Action taken to Saxenda was Not reported. The outcome for the event "strong thoughts of suicide(Suicidal ideation)" was Not recovered. Patient declined to provide any further information including product batch number. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. Limited information as related to indication for Saxenda use, weight, BMI, age, 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.



Case ID: 20502066

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



Case ID: 21360692

Case Information:

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

Day)

ELI_LILLY_AND_COMPANY-

US202209005617

Patient Information:

Age: Sex: Male Weight: 258 KG

Suspect Products:

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

Drug?

1 Mounjaro 2.5mg 2.5 Mg Milligram(S) / Subcutaneous 2.5 mg, unknown 10045242 18-Aug-2022 06-Sep-2022

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

Dose to Event

1 Mounjaro 2.5mg Yes NA ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicidal ideation

Anxiety

Depression

Event/Problem Narrative:

This spontaneous case, reported by a physician via a sales representative, concerns a 65-years-old Caucasian male patient. The patients medical history included Type 2 diabetes mellitus. Historical medications included Ozempic for Type 2 diabetes mellitus. The patient was switched from Ozempic to tirzepatide. Concomitant medications included insulin aspart, insulin aspart protamine, motine, hydrochlorothiazide, valsartan, insulin glargine, gabapentine, nystatin, pravastatin, econazole nitrate, dapagliflozin propanediol monohydrate, pioglitazone, metformin, tadalafil, paracetamol and amlodipine, all for an unknown indication. The patient received tirzepatide (Mounjaro), 2.5 mg, for type II diabetes, unknown frequency, subcutaneously, beginning on 18Aug2022. On an unknown date, reported as the second week of treatment, the patient started to have anxiety, depression, and suicidal thoughts. The event of suicidal thoughts was



Case ID: 21360692

considered serious by the company due to medically significant reasons. On 25Aug2022, the patient administrated last dose of tirzepatide therapy (as reported). On 06Sep2022, the patient s physician immediately discontinued the treatment upon being informed of the events. No treatment was administered. As of follow up information on 12Oct2022, the patient was recovered from the events. The physician stated that there was no motive or trigger for suicidal thoughts, there was no history of depression in past. The tirzepatide therapy was not restarted. No further information was provided. The reporting physician related all the events to tirzepatide and did not relate all the events to the device. No other relatedness opinion was provided. Update 20Oct2022: Additional information received from the physician on 12Oct2022. Added drug start date and last date of drug administration details. Added patient s demographics (initials, date of birth, height, and weight). Added medical history and concomitant medication. Added tirzepatide therapy route of administration. Updated outcome of all the events from unknown to recovered. Narrative and corresponding fields were updated accordingly.

Relevant Medical History:						
Disease/Surgical Procedure Type 2 diabetes mellitus		Start Date	End Date	Continuing?	,	
Medical History Product(s) OZEMPIC		Start Date	End Date	Indications 10067585	Events 10067482	
Relevant Laboratory Data:						
Test Name	Result	Unit	Normal	Low Range	Normal High Range	Info Avail

C	oncomitant Products.	incommant Froducts.									
#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st			
								Dose to Event			
1	NOVOLOG MIX	/	Unknown	UNK, unknown	10070592						
2	VALSARTAN	/	Unknown	UNK, unknown	10070592						
	HYDROCHLOROTHIAZIDE										
	KRKA										
3	LANTUS	/	Unknown	UNK, unknown	10070592						
4	GABAPENTINE	/	Unknown	UNK, unknown	10070592						
5	NYSTATIN	/	Unknown	UNK, unknown	10070592						
6	PRAVASTATIN	/	Unknown	UNK, unknown	10070592						



Case ID: 21360692

NITRATE] 8 FARXIGA 9 PIOGLITAZONE 10 METFORMIN 11 TADALAFIL 12 TYLENOL 13 AMLODIPINE	OLE [ECONAZOLE /	Unknown	UNK, unknown	10070592	
9 PIOGLITAZONE10 METFORMIN11 TADALAFIL12 TYLENOL					
10 METFORMIN11 TADALAFIL12 TYLENOL	/	Unknown	UNK, unknown	10070592	
11 TADALAFIL 12 TYLENOL	ZONE /	Unknown	UNK, unknown	10070592	
12 TYLENOL	MIN /	Unknown	UNK, unknown	10070592	
_	IL /	Unknown	UNK, unknown	10070592	
13 AMLODIPINE	. /	Unknown	UNK, unknown	10070592	
	INE /	Unknown	UNK, unknown	10070592	

Reporter Source:

Study report?: No **Sender organization:** ELI LILLY AND CO

503B Compounding Outsourcing Facility?:

Literature Text:



Case ID: 21854592

Case Information:

Case Type : Direct eSub: N HP: Country: US Event Date: 08-Jan-2023 Outcomes: OT **Application Type:**

FDA Rcvd Date: 11-Jan-2023 Mfr Rcvd Date: Mfr Control #: FDA-CDER-Application #:

CTU-2023-3141

Patient Information:

Age: 34 YR Sex: Male Weight: 117.9 KG

Suspect Products:

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

Drug?

1 Wegovy 1mg/0.5mL four 1 Dosage Form / 999 Subcutaneous OTHER QUANTITY: Obesity (weight management) 08-Jan-2023

pen injectors (1mg per 1 Injection(s); OTHER injector)

FREQUENCY: 1/wk;

2 mounjaro

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

Dose to Event

1 Wegovy 1mg/0.5mL Yes Not Applicable **NOVO NORDISK**

four pen injectors (1mg

per injector)

2 mounjaro NA NA

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Depressed mood NA Suicidal ideation NA Nausea NA

Motion sickness NA

Vomiting NA



Case ID: 21854592

D	ecreased appetite						NA			
E	vent/Problem Narrative:									
fo tir fo to	ook 1mg Wegovy subQ inject ir 72 hours that required treat me (which wasn't much). Was ir 4 weeks total without much that type of weight managen etween doses I changed to 0.	ment via anti-naus s essentially unabl side effects (mild nent med at the tir	sea meds to be e to eat from lat nausea for a fe ne It took about	able to walk to each to mid w hours after a month to g	around at all. V 11th due to nai injection) That get wegovy sup	omited once of usea / lack of a 's why my Dr w	n the 9th, for oppetite I had for the scrip	essentially eve taken mounjard t for 1mg wego	rything in my s o 2.5mg weekl ovy, since I wa	stomach at the y previously sn't 'naive'
R	elevant Medical History:									
Li	st known medical conditions	: Obesity, Major D	epressive Disor	der;						
D	isease/Surgical Procedure			Start Date	End D	ate	Continuing	•		
M	edical History Product(s)			Start Date	End D	ate	Indications		Events	
R	elevant Laboratory Data:									
Te	est Name		Result	Unit		Normal Low	Range	Normal High	Range	Info Avail
C	oncomitant Products:									
#	Product Name:	Dose/Frequency	Route		Dosage Text	Indicati	on(s)	Start Date	End Date	Interval 1st
1	Lexapro	/								Dose to Event
2	Lamictol	/								
3	Promethazine	/								
4	women's multivitamin	/								
5	fish oil	/								



Case ID: 21854592

Reporter Source:

Study report?:NoSender organization:FDA-CTU503B Compounding
Outsourcing Facility?:

Literature Text:

CTU #: FDA-CDER-CTU-2023-3141 | Department: CDER | RCT #: RCT-1091481 | CTU Triage Date: 11-Jan-2023 | AER #: 21854592 |

Total Pages: 5

		red in the report are in EST(G	MT-05	i:00) time zone								
	sic Deta				<u> </u>							
Co	ompany U	nit 	CDI	ER-CTU			ating Account		FAERS			
So	ource Med	ium	MW	/O (Drug)		Sourc	e Form Type		E2B XML 350	0B		
Priority			Rou	utine								
0	verride Au	to Calculation Rule	No									
F	DA Receiv	ed Date	11-	Jan-2023		CTU F	Received Date		11-Jan-2023			
C.	TU Triage	Date				CTU Data Entry Date						
Re	Report Type			ontaneous		Repor	t Classification		Drug			
As	ssign To		Use	User								
Us	ser/Group											
Fo	orward to I	Department	$\overline{\mathbf{Z}}$	1								
Ca	ase Priorit	у	Dire	ect	_							
Cc	ntact											
	ase eporter	First Name		Last Name			Email Address		Phone			
V	3	(b) (6)		(b) (6)			(b) (6)		(b) (6)			
		About the Problem		J								
	What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker											
		problem occurred		Jan-2023								
	Serious		Yes	S	_							
		of the following happen? ill that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)									
		rious/important medical Please Describe Below)					(,				
4.1 an	Tell us w	nat happened and how nal documents if nece	w it h	appened (Incli	ude as	many	details as possi	ble FDA	may reach out t	to you for		
	Took 1mg wegovy subQ injector pen on Jan 8th, side effects were strong sadness feelings, suicidal ideation (for about 48 hours) and nausea / motion sickness for 72 hours that required treatment via anti-nausea meds to be able to walk around at all. Vomited once on the 9th, for essentially everything in my stomach at the time (which wasn't much). Was essentially unable to eat from late 8th to mid 11th due to nausea / lack of appetite I had taken mounjaro 2.5mg weekly previously for 4 weeks total without much side effects (mild nausea for a few hours after injection) That's why my Dr wrote the script for 1mg wegovy, since I wasn't 'naive' to that type of weight management med at the time It took about a month to get wegovy supplied, so by then I had run out of mounjaro and had about a month between doses I changed to 0.5mg wegovy so that may help with side effects											
Re	levant T	est/Laboratory Data								1 of 1		
	Test Nar	j				Test D	Date					
	Test Result Test Unit											

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CTU #: FDA-CDER-CTU-2023-3141 | Department: CDER | RCT #: RCT-1091481 | CTU Triage Date: 11-Jan-2023 | AER #: 21854592 |

Total Pages: 5

	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
					
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?				
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Co				1 -5 1	=
Se	ction C - About the Products Suspect	Yes		1 of 1	
	Primary?	Yes			
	Type	Drug/Biologic			
	This report is about	Other			
	Name of the product as it appears on the box, bottle, or package (Include as many		n injectors (1mg per injector)		
	names as you see) Name of the company that makes (or compounds) the	Novo Nordisk			
	product Product Type/abook all that				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar	or an Outsourcing Facility		
	Strength	1mg / 0.5mL mg milligram(s)	If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				<u> </u>
	Dosage Form		1		<u> </u>
	Quantity	Other		1 Injection(s)	<u> </u>
	Frequency	Other		1/wk	_
	How was it taken or used	Subcutaneous	If Other		l

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CTU #: FDA-CDER-CTU-2023-3141 | Department: CDER | RCT #: RCT-1091481 | CTU Triage Date: 11-Jan-2023 | AER #: 21854592 |

Total Pages: 5

	Date the person first started taking or using the product	08-Jan-2023		
	Date the person stopped taking or using the product			
	Date the person reduced dose of the product	11-Jan-2023		
	Give best estimate of duration			
	Is therapy still on-going?	Yes		
W	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to treat)	1 of 1
	Obesity (weight management)			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice	·	
	Name of medical device			
	Name of the company that makes the medical device			
		e model, catalog, lot, seri	al, or UDI number, and the expira	tion date, if you can
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem occurred?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast implants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Male		
	Gender	Other Gender category		
	Please Specify Other Gender	demi-masc		
	Age (specify unit of time for age)	34 Year(s)		
	Date of Birth			
	Weight	117.9 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		

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CTU #: FDA-CDER-CTU-2023-3141 | Department: CDER | RCT #: RCT-1091481 | CTU Triage Date: 11-Jan-2023 | AER #: 21854592 |

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	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
l is	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
	Obesity, Major Depressive Disord		
Ple	ease list all allergies (such as t	o drugs, foods, pollen or others)	
	sace net an anergies (easir as t	- alago, locae, policil el calelo,	
l ic	et any other important informati	on about the person (such as smoking, pregnancy, alcohol use, etc.)	
	st arry other important imorriati	on about the person (such as smoking, pregnancy, alcohol ase, etc.)	
Lic	et all current procerintian modic	eations and medical devices being used.	
		Img 2/d) Promethazine 12.5mg (as needed)	
	Lexapro (2011g 1/d) Lamictor (130	ang 2/u) i Tomethazine 12.5mg (as needed)	
l ia	t all according to		
LIS		ons and any vitamins, minerals, supplements, and herbal remedies being us	ea.
	women's multivitamin, fish oil		
Se	ection F - About the Person Fill	ing Out This Form 1 of	1
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(h) (6)	
	Middle Name	(b) (6)	
	First name		
	Number/Street		
	City		
	State/Province		
	Country		
	ZIP or Postal code		

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Telephone number	(h) (6)
Email address	(b) (6) ——————————————————————————————————
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	11-Jan-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

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Case ID: 21974341

Case Information:

Case Type : Direct eSub: N HP: Y Country: US Event Date: 02-Feb-2023 Outcomes: LT

FDA Rcvd Date: 08-Feb-2023 Mfr Rcvd Date: Mfr Control #: FDA-CDER- Application #:

CTU-2023-10933

Patient Information:

Age: 55 YR Sex: Male Weight: 168.75 KG

Suspect Products:

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

Drug?

1 Mounjaro (tirzepatide) 5 Mg Milligram(S) / Subcutaneous OTHER FREQUENCY :Type 2 diabetes mellitus 23-Jan-2023

999

weekly;

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

Dose to Event

1 Mounjaro (tirzepatide) Not Applicable Not Applicable 0002-1495-80 ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Suicidal ideation NA

Depression NA

Decreased appetite NA

Event/Problem Narrative:

Tell us what happened and how it happened: Describe Event, Problem, or Product Use Error: Two weeks after increasing his Mounjaro (tirzepatide) dose to 5 mg, the patient became depressed with suicidal ideation. After two days it lessened but had not gone away completely. He had previously been on Ozempic (semaglutide) without issue. Since starting the Mounjaro (tirzepatide) his appetite had decreased significantly, though his weight hadn't changed.;

Relevant Medical History:

Application Type:



Case ID: 21974341

List known medical conditions: NKDA, History of hypertension, hyperlipidemia, Type 2 diabetes mellitus with neuropathy, allergic rhinitis, morbid obesity, metabolic syndrome, GERD, depression, erectile dysfunction, spinal stenosis;

Disease/Surgical Procedure				Start Date	Ena L	End Date		Continuing?		
Medical History Product(s)				Start Date	End [)ate	Indications		Events	
R	elevant Laboratory Data:									
T	est Name		Result	Unit		Normal Low	Range	Normal High	n Range	Info Avail
	GA1C									
С	REATININE									
С	oncomitant Products:									
#	Product Name:	Dose/Frequency	Route		Dosage Text	Indicat	tion(s)	Start Date	End Date	Interval 1st
										Dose to Event
1	Duloxetine	/								
2	insulin glargine	/								
3	famotidine	/								
4	pregabalin	/								
5	Humalog	/								
6	hydrochlorathiazide	/								
7	amlodipine	/								
8	metformin	/								
9	lisinopril	/								
10	atorvastatin	/								
11	l sildenafil	/								
12	2 ibuprofen	/								



Case ID: 21974341

Reporter Source:

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

Literature Text:

21 Receipt No: RCT-1101860 FDA 3500 Form

CTU #: FDA-CDER-CTU-2023-10933 | Department: CDER | RCT #: RCT-1101860 | CTU Triage Date: 08-Feb-2023 | AER #: 21974341

| Total Pages: 14

All dates displayed in the report are in EST(GMT-05:00) time zone												
	c Detai											
Com	pany U	nit	CDI	ER-CTU	Origi	nating Account		FAERS				
Sour	rce Med	ium	MW	O (Drug)	Sour	ce Form Type		E2B XML 3500				
Prior	rity		Rou	utine								
Over	rride Au	to Calculation Rule	No									
FDA	Receiv	ed Date	08-F	Feb-2023	CTU Received Date			08-Feb-2023				
CTU Triage Date					CTU Data Entry Date							
Report Type		Spc	ontaneous	Repo	ort Classification		Drug					
Assi	gn To		Use	User								
User	r/Group											
Forw	vard to [Department										
Case	e Priority	y	Dire	ect								
Cont	act											
Case		First Name		Last Name		Email Address		Phone				
		(b) (6)		(b) (6)		(b) (6)		(b) (6)				
IA PA	ATIFN'	T INFORMATION										
		dentifier (In Confidence)	(b)	(6)								
	\ge	zontinoi (iii oomidonoo)	(0)	(0)								
	Date of E	Rirth	(b)	(6)								
	Sex)	Mal									
	Sender		-	gender man/boy								
		pecify Other Gender										
	Veight	peony other defider	168	168.75 kg								
E	Ethnicity	(Check single best	Not Hispanic/Latino									
	inswer) Race (Cl	neck all that apply)										
'	100 (01	reak all triat apply)	Asian									
			American Indian or Alaska Native									
			☐ Black or African American White									
			₩ White Native Hawaiian or Other Pacific Islander									
B. Al	DVERS	SE EVENT, PRODUC			10 1314110	GI .						
		Report (check all that	$\overline{}$	Adverse Event								
a	ipply)			Product Use/Medication Error								
				Product Problem (e.g., defects	/malfunc	tions)						
	Problem with Different Manufacturer of Same Medicine											
S	Serious Yes											
		Attributed to Adverse										
E	ent (C	heck all that apply)	☐ Death ☐ Life Threatening									
				Hospitalization (initial or prolon	naed)							
				Other Serious or Important Me		ents						
	Disability or Permanent Damage											

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21 Receipt No: RCT-1101860 FDA 3500 Form

CTU #: FDA-CDER-CTU-2023-10933 | Department: CDER | RCT #: RCT-1101860 | CTU Triage Date: 08-Feb-2023 | AER #: 21974341

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15	Tot.	al I	Б,	٠~.			4.	4	
1	Γota	aı ı	Г(יטג	ಆಶ		14	+	

		Congenital Anomaly/Birth Defects						
		Required Intervention to Preve	ent Permanent Impairment/Damage					
	Date of Death							
	Date of Event	02-Feb-2023						
	Date of this Report 08-Feb-2023							
De	escribe Event, Problem or Proc							
Describe Event, Problem, or Product Use Error: Two weeks after increasing his Mounjaro (tirzepatide) dose to 5 mg, the patient became depressed with suicidal ideation. After two days it lessened but had not gone away completely. He had previously been on Ozempic (semaglutide) without issue. Since starting the Mounjaro (tirzepatide) his appetite had decreased significantly, though his weight hadn't changed.								
Re	elevant Test/Laboratory Data			1 of 2				
	Test Name	HGA1C	Test Date	03-Feb-2023				
	Test Result	6.5	Test Unit	PERCENT				
	Low Test Range		High Test Range	< 5.7				
	More Information Available?		L		_			
Re	elevant Test/Laboratory Data			2 of 2				
	Test Name	CREATININE	Test Date	03-Feb-2023				
	Test Result	0.86	Test Unit	MICROGRAMS PER DEC				
	Low Test Range	0.7	High Test Range	1.5				
	More Information Available?							
Ac	lditional Comments							
Ot	her Relevant History, Including	Preexisting Medical Cor	nditions					
	NKDA, History of hypertension, hyperlipidemia, Type 2 diabetes mellitus with neuropathy, allergic rhinitis, morbid obesity, metabolic syndrome, GERD, depression, erectile dysfunction, spinal stenosis							
C.	PRODUCT AVAILABILITY							
	Product Available for Evaluation? (Do not send product to FDA)	No						
	Returned to Manufacturer on							
	Do you have a picture of the product? (check yes if you are including a picture)	No						
D.	PRODUCT(S)			1 of 13				
	Suspect	Yes			=			
	Primary?	Yes			_			

Generated by: SYSTEM Generated on: 08-Feb-2023 10:46:55 Page 2 of 14 21 Receipt No: RCT-1101860 FDA 3500 Form

CTU #: FDA-CDER-CTU-2023-10933 | Department: CDER | RCT #: RCT-1101860 | CTU Triage Date: 08-Feb-2023 | AER #: 21974341

| Total Pages: 14

	Туре	Drug/Biologic				
	This report involves:	Other				
Na	ame,Strength,Manufacturer/Co	npounder (from product label)				
	Product Name	Mounjaro (tirzepatide)				
	Strength	5 mg milligram(s)	If Other			
	Manufacturer/Compounder	Lilly				
	NDC# or Unique ID	0002-1495-80				
	Product Type(check all that apply)	OTC Compounded Generic Biosimilar				
	Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply				
	Event Reappeared after Reintroduction ?	Doesn't Apply				
Dr	ug Therapy			1 of 1		
	Dose or Amount	5 mg milligram(s)	If Other			
	Frequency	Other	If Other	weekly		
	Route	Subcutaneous	If Other	,	_	
	Dosage Form				_	
	Start	23-Jan-2023				
	Stop					
	Dose Reduced	07-Feb-2023				
	Therapy Duration		If Other		_	
	Is therapy still on-going?	Yes				
	Lot Number					
	Expiration Date		-			
Dia	agnosis for Use (indication)			1 of 1		
	Type 2 diabetes mellitus					
D.	PRODUCT(S)			2 of 13		
	Concomitant	Yes				
	Primary?					
	Туре	Drug/Biologic				
	This report involves:					
Name,Strength,Manufacturer/Co			label)			
	Product Name	Duloxetine	T			
	Strength		If Other			
	Manufacturer/Compounder		-			
	NDC# or Unique ID					
	Product Type(check all that apply)	OTC Compounded				

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CTU #: FDA-CDER-CTU-2023-10933 | Department: CDER | RCT #: RCT-1101860 | CTU Triage Date: 08-Feb-2023 | AER #: 21974341

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		Generic		
		Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			
Dr	ug Therapy			1 of 1
	Dose or Amount		If Other	
	Frequency		If Other	
	Route		If Other	
	Dosage Form			
	Start	24-Sep-2019		
	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?		1	
	Lot Number			
	Expiration Date			
Dia	agnosis for Use (indication)			1 of 1
D.	PRODUCT(S)			3 of 13
D.	PRODUCT(S) Concomitant	Yes		3 of 13
D.		Yes		3 of 13
D.	Concomitant	Yes Drug/Biologic		3 of 13
	Concomitant Primary? Type This report involves:	Drug/Biologic		3 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co	Drug/Biologic mpounder (from product	label)	3 of 13
	Concomitant Primary? Type This report involves:	Drug/Biologic		3 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co	Drug/Biologic mpounder (from product	label)	3 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder	Drug/Biologic mpounder (from product		3 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength	Drug/Biologic mpounder (from product		3 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder	Drug/Biologic mpounder (from product		3 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced?	Drug/Biologic mpounder (from product insulin glargine OTC Compounded Generic		3 of 13
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction?	Drug/Biologic mpounder (from product insulin glargine OTC Compounded Generic		
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy	Drug/Biologic mpounder (from product insulin glargine OTC Compounded Generic	If Other	3 of 13
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy Dose or Amount	Drug/Biologic mpounder (from product insulin glargine OTC Compounded Generic	If Other	
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy	Drug/Biologic mpounder (from product insulin glargine OTC Compounded Generic	If Other	

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	Dosage Form				
	Start				
	Stop				_
	Dose Reduced				_
	Therapy Duration		If Other		
	Is therapy still on-going?				_
	Lot Number				_
	Expiration Date				_
Dia	agnosis for Use (indication)			1 of 1	
D.	PRODUCT(S)			4 of 13	
	Concomitant	Yes			
	Primary?				
	Туре	Drug/Biologic			
	This report involves:				
Na	me,Strength,Manufacturer/Co		label)		
	Product Name	famotidine			
	Strength		If Other		
	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that apply)	OTC Compounded Generic Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?				
	Event Reappeared after Reintroduction ?				
Dr	ug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				_
	Expiration Date				
Dia	agnosis for Use (indication)			1 of 1	

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D.	PRODUCT(S)			5 of 13
	Concomitant	Yes		
	Primary?		_	
	Туре	Drug/Biologic		
	This report involves:			
Na	ame,Strength,Manufacturer/Co	mpounder (from produc	t label)	
	Product Name	pregabalin		
	Strength		If Other	
	Manufacturer/Compounder			
	NDC# or Unique ID			
	Product Type(check all that	Отс		
	apply)	Compounded		
		Generic		
		Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			
Dr	ug Therapy			1 of 1
	Dose or Amount		If Other	
	Dose or Amount Frequency		If Other If Other	
	Frequency Route		If Other	
	Frequency	29-Mar-2017	If Other	
	Frequency Route Dosage Form Start	29-Mar-2017	If Other	
	Frequency Route Dosage Form	29-Mar-2017	If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced	29-Mar-2017	If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration	29-Mar-2017	If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced	29-Mar-2017	If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number	29-Mar-2017	If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date	29-Mar-2017	If Other If Other	1 of 1
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number	29-Mar-2017	If Other If Other	1 of 1
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date	29-Mar-2017	If Other If Other	1 of 1
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date	29-Mar-2017	If Other If Other	1 of 1
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date	29-Mar-2017	If Other If Other	1 of 1
Dia	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date	29-Mar-2017	If Other If Other	1 of 1
Dia	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication)	29-Mar-2017 Yes	If Other If Other	
Dia	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication)		If Other If Other	
Dia	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) PRODUCT(S) Concomitant		If Other If Other	

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Na	me,Strength,Manufacturer/Co	mpounder (from product	label)		
	Product Name	Humalog			
	Strength		If Other		
	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that apply)	OTC Compounded Generic			
		Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?				
	Event Reappeared after Reintroduction ?				
Dru	ug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form		I		
	Start		-		
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				
Dia	agnosis for Use (indication)			1 of 1	
D.	PRODUCT(S)			7 of 13	
	Concomitant	Yes			
	Primary?				
	Туре	Drug/Biologic			
	This report involves:				
Na	me,Strength,Manufacturer/Co		label)		
	Product Name	hydrochlorathiazide			
	Strength		If Other		
	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that apply)	OTC Compounded Generic Riccimilar			

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	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			
Dr	rug Therapy			1 of 1
	Dose or Amount		If Other	1 31 1
	Frequency		If Other	
	Route		If Other	
			II Otilei	
	Dosage Form		_	
	Start		_	_
	Stop			_
	Dose Reduced		[
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			
Dia	agnosis for Use (indication)			1 of 1
ח				9 of 12
υ.	PRODUCT(S) Concomitant	Yes		8 of 13
		res	_	_
	Primary?	5 (5:1 :	-	_
	Туре	Drug/Biologic		
	This report involves:			
Na	ame,Strength,Manufacturer/Co		label)	
Na	ame,Strength,Manufacturer/Co Product Name	mpounder (from product amlodipine		
Na	ame,Strength,Manufacturer/Co Product Name Strength		label)	
Na	ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder			
Na	ame,Strength,Manufacturer/Co Product Name Strength			
Næ	ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that			
Na	ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID	amlodipine		
Næ	ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that	amlodipine otc		
Næ	ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that	amlodipine OTC Compounded		
Na	ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that	amlodipine OTC Compounded Generic		
Næ	Product Name Strength, Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped	amlodipine OTC Compounded Generic		
	Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after	amlodipine OTC Compounded Generic		1 of 1
	Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction?	amlodipine OTC Compounded Generic		1 of 1
	Ame, Strength, Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? Tug Therapy	amlodipine OTC Compounded Generic	If Other	1 of 1
	Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy Dose or Amount	amlodipine OTC Compounded Generic	If Other	1 of 1
	Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? rug Therapy Dose or Amount Frequency	amlodipine OTC Compounded Generic	If Other If Other If Other	1 of 1

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	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				
Dia	agnosis for Use (indication)			1 of 1	
					1
					1
D.	PRODUCT(S)			9 of 13	
	Concomitant	Yes			
	Primary?				
	Туре	Drug/Biologic			
	This report involves:				
Na	me,Strength,Manufacturer/Co	mpounder (from product	label)		
	Product Name	metformin			
	Strength		If Other		
	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that	Отс			
	apply)	Compounded			ı
		Generic			1
		Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?				ı
	Event Reappeared after				ı
Dr	Reintroduction ? ug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?		L		
	Lot Number				
	Expiration Date				
Dia	agnosis for Use (indication)	l .		1 of 1	

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I T-4-1	D	4.4
i iota	Pages:	14

D.	PRODUCT(S)			10 of 13
	Concomitant	Yes		
	Primary?			
	Туре	Drug/Biologic		
	This report involves:			
Na	ame,Strength,Manufacturer/Co	mpounder (from produc	t label)	
	Product Name	lisinopril		
	Strength		If Other	
	Manufacturer/Compounder		-	
	NDC# or Unique ID			
	Product Type(check all that apply)	OTC Compounded Generic Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			
Dr	rug Therapy			1 of 1
			1	
	Dose or Amount		If Other	
	Dose or Amount Frequency		If Other If Other	
	Frequency Route		If Other	
	Frequency Route Dosage Form		If Other	
	Frequency Route Dosage Form Start		If Other	
	Frequency Route Dosage Form Start Stop		If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced		If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration		If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going?		If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number		If Other If Other	
Dia	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date		If Other If Other	1 of 1
Di	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number		If Other If Other	1 of 1
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date		If Other If Other	1 of 1
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication)	Yes	If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication)	Yes	If Other If Other	
	Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) PRODUCT(S) Concomitant	Yes Drug/Biologic	If Other If Other	

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Na	lame,Strength,Manufacturer/Compounder (from product label)					
	Product Name	atorvastatin				
	Strength		If Other			
	Manufacturer/Compounder					
	NDC# or Unique ID					
	Product Type(check all that apply)	OTC Compounded Generic Biosimilar				
	Event Abated After Use Stopped or Dose Reduced?	Li Biosimilar				
	Event Reappeared after Reintroduction ?					
Dr	ug Therapy			1 of 1		
	Dose or Amount		If Other			
	Frequency		If Other			
	Route		If Other			
	Dosage Form					
	Start					
	Stop					
	Dose Reduced					
	Therapy Duration		If Other			
	Is therapy still on-going?				_	
	Lot Number					
	Expiration Date					
Dia	agnosis for Use (indication)			1 of 1		
D.	PRODUCT(S)			12 of 13		
	Concomitant	Yes				
	Primary?					
	Туре	Drug/Biologic				
	This report involves:					
Na	me,Strength,Manufacturer/Co		label)			
	Product Name	sildenafil				
	Strength		If Other			
	Manufacturer/Compounder		_			
	NDC# or Unique ID					
	Product Type(check all that apply)	OTC Compounded Generic Biosimilar				

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	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			
Dr	ug Therapy			1 of 1
	Dose or Amount		If Other	
	Frequency		If Other	
	Route		If Other	
	Dosage Form		• • • • • • • • • • • • • • • • • •	
	Start			
	Stop			_
	Dose Reduced			_
	Therapy Duration		If Other	
	Is therapy still on-going?		ii Guici	
	Lot Number		_	
	Expiration Date			
Di	agnosis for Use (indication)			1 of 1
וטופ	agriosis for Ose (indication)			1 01 1
				<u> </u>
D.	PRODUCT(S)			13 of 13
D.	PRODUCT(S) Concomitant	Yes		13 of 13
D.		Yes		13 of 13
D.	Concomitant	Yes Drug/Biologic		13 of 13
D.	Concomitant Primary?			13 of 13
	Concomitant Primary? Type	Drug/Biologic	t label)	13 of 13
	Concomitant Primary? Type This report involves:	Drug/Biologic	t label)	13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co	Drug/Biologic mpounder (from product	t label)	13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name	Drug/Biologic mpounder (from product		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength	Drug/Biologic mpounder (from product		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder	Drug/Biologic mpounder (from product ibuprofen		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID	Drug/Biologic mpounder (from product ibuprofen		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that	Drug/Biologic mpounder (from product ibuprofen		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that	Drug/Biologic mpounder (from product ibuprofen		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic		13 of 13
	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic		13 of 13
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic		13 of 13
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction ?	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic		
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic	If Other	
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy Dose or Amount	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic	If Other	
Na	Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy Dose or Amount Frequency	Drug/Biologic mpounder (from product ibuprofen OTC Compounded Generic	If Other If Other If Other	

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	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				_
Dia	agnosis for Use (indication)			1 of 1	
	CHEDECT MEDICAL DEVICE	-			
С.	SUSPECT MEDICAL DEVICE Brand Name	<u> </u>			
	Common Device Name			_	
	Procode				
	Manufacturer Name				
	City				
	State		-		_
	Model #				_
	Lot#				
	Catalog #				
	Expiration Date				
	Serial #				
	Unique Identifier (UDI)#				
	Operator of Device	Health Professional			
		Patient/Consumer			
	Other	Other Other			
	If Implanted, Give Date If Explanted, Give Date				
	•				
	Is this a single-use device that was reprocessed and reused on a patient?				
	If Yes for the above field, Enter Name and Address of				
	Reprocessor Was this device serviced by a				
	third party?				_
F.	OTHER (CONCOMITANT) ME				
	CONCOMITANT MEDICAL PROD	UCT DESCRIPTION			

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G.	REPORTER			1 of 1	
	Primary?	Yes			
	Reporter is Patient?				
	Title				
	Last Name	/1_ \ //	\sim		
	Middle Name	I	~ 1		
	First Name	(b) (6	JI		
	Address	'			
	City				
	State/Province/Region				
	Country				
	ZIP/Postal Code				
	Phone				
	Email				
	Fax		_		
	Reporter Organization				
	Department				
	Reporter Speciality				
	Health Professional?	Yes			
	Occupation	Physician	If Other		
	Also Reported to	☐ Manufacturer/Compoun☐ User Facility☐ Distributor/Importer	der		
	If you do NOT want your identity disclosed to the manufacturer	No			

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

Case ID: 21979556

Case Information:

Case Type : Direct eSub: N HP: Country: US Event Date: 16-Jan-2023 Outcomes: OT

FDA Rcvd Date: 09-Feb-2023 Mfr Rcvd Date: Mfr Control #: FDA-CDER- Application #:

CTU-2023-11602

Patient Information:

Age: 42 YR Sex: Female Weight: 99 KG

Suspect Products:

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

Drug?

1 Mounjaro Other / 999 Subcutaneous OTHER QUANTITY: Type 2 diabetes 18-Dec-2022 16-Jan-2023

1 Injection(s); OTHER

NA

FREQUENCY:

Weekly;

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

Dose to Event

1 Mounjaro Yes Not Applicable D552770C 20-Oct-2024 0002149580 ELI LILLY AND CO

Event Information:

Suicidal ideation

Preferred Term (MedDRA Version: v.26.0) ReC

Depressed mood NA Apathy NA

Fatigue NA

Panic attack NA

Event/Problem Narrative:

Tell us what happened and how it happened: Upon starting mounjaro 2.5 mg weekly I noted new onset sadness, lack of motivation, and fatigue. Took 2.5 mg weekly for 4 weeks. On 1/15/2023 prior to bed took increased dose of mounjaro 5 mg. Within 12 hours the fatigue and decreased motivation were significantly

Application Type:



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

Case ID: 21979556

worse and I started having suicidal ideation and panic attacks. I saw my health care provider on 1/17/23. Mounjaro was discontinued and sertraline was started. Within 1 week all symptoms were improved.;

Re	elevant Medical History:								
Lis	st known medical conditions :	Diabetes;							
Di	sease/Surgical Procedure			Start Date	End Date	Continuing	?		
Me	edical History Product(s)			Start Date	End Date	Indications		Events	
Re	elevant Laboratory Data:								
Te	est Name		Result	Unit	No	rmal Low Range	Normal Hig	h Range	Info Avail
Co	oncomitant Products:								
#	Product Name:	Dose/Frequency	Route		Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	Progesterone only birth control	1							
2	famotidine	/							
3	sertraline	/							
Re	eporter Source:								
St	udy report?: No	Sender orga	nization:	FDA-CTU		503B Comp Outsourcing	ounding g Facility?:		
Lit	terature Text:								

CTU #: FDA-CDER-CTU-2023-11602 | Department: CDER | RCT #: RCT-1102786 | CTU Triage Date: 10-Feb-2023 | AER #: 21979556

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All d	ates display	ed in the report are in EST(G	MT-05	:00) time zone						
Ва	sic Detai	ls								
Co	ompany U	nit	CDE	R-CTU	Orig	inating /	Account		FAERS	
Sc	ource Med	ium	MW	O (Drug)	Sou	rce Forr	n Type		E2B XML 3500B	
Pr	iority		Rou	tine					1	
O۱	erride Au	to Calculation Rule	No						_	
FD	DA Receiv	ed Date	09-F	eb-2023	CTL	Receiv	ved Date		09-Feb-2023	
C1	ΓU Triage	Date			CTL	Data E	Intry Date			
Re	eport Type)	Spo	ntaneous	Rep	ort Clas	sification		Drug	
As	sign To		Use	r					1	
Us	ser/Group									
Fo	rward to [Department	$\overline{\mathcal{L}}$							
Ca	ase Priorit	у	Dire	•					_	
	ntact									
	ase	First Name		Last Name		Emai	l Address		Phone	
	eporter	i ii st ivairie		Last Name		Liliai	Address		THORE	
$\overline{\mathbf{Z}}$	1	(b) (6)		(b) (6)		(b)	(6)		(b) (6)	
						(~)	(0)			
Se	ction A -	About the Problem								
		d of problem was it?	\square	Vere hurt or had a bad side	e effect (inc	cluding ne	w or worsening sympt	toms)		
	(Check a	all that apply)		Jsed a product incorrectly v				·		
				Noticed a problem with the	quality of t	he produc	et			
				· lad problems after switchir				er		
	Date the	problem occurred		lan-2023						
	Serious		Yes							
	Did any	of the following happen?	Hospitalization - admitted or stayed longer							
	(Check a	all that apply)		Required help to prevent pe	,	Ü				
				Disability or health problem		aiiii				
				Birth defect						
				ife-threatening						
				Death						
			_	Dther serious/important me	المنصما المماما	t/Dl	- December Below)			
	Other se	rious/important medical	الكار	other serious/important me	dicai incide	nt(Please	e Describe Below)			
		Please Describe Below)								
		nat happened and how nal documents if nece			as mar	y detai	ils as possible l	FDA m	nay reach out to you fo	r
	for 4 wee	arting mounjaro 2.5 mg weks. On 1/15/2023 prior to on were significantly wors Mounjaro was discontinu	bed e and	took increased dose I started having suic	of moun dal idea	jaro 5 m tion and	ng. Within 12 houi I panic attacks. I s	rs the fa saw my	atigue and decreased health care provider on	
Re		est/Laboratory Data							1 of 1	
	Test Nar	ne			Test	Date				
	Test Res	sult			Test	Unit				

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					_
	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
	otion D. Droduot Availability				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the product? (check yes if you are including a picture)	No			_
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			_
	Primary?	Yes			_
	Туре	Drug/Biologic			
	This report is about	Other			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Mounjaro			
	Name of the company that makes (or compounds) the product	Lilly			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar	or an Outsourcing Facility		
	Strength	5mg mg milligram(s)	If Other		
	NDC number	0002149580			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	20-Oct-2024			
	Lot number	D552770C			
	Dosage Form				
	Quantity	Other	If Other	Injection(s)	
	Frequency	Other	If Other \	Veekly	_
	How was it taken or used	Subcutaneous	If Other		_
	Date the person first started taking or using the product	18-Dec-2022			

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	Date the person stopped taking or using the product	16-Jan-2023	
	Date the person reduced dose of the product		
	Give best estimate of duration		
	Is therapy still on-going?		
W	hy was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Type 2 diabetes		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that		_
	makes the medical device		
Ot loc	ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the		
	medical device when the problem occurred?		
Га		NLY (such as pacemakers, breast implants, etc.)	_
	ate the implant was put in	Date the implant was taken out (If	
ט	ate the implant was put in	relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		_
	Age (specify unit of time for age)	42 Year(s)	_
	Date of Birth		
	Weight	99 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
	I and the second		

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		Asian				
		White				
		Black or African Ar	merican			
Lis	st known medical conditions (S	Such as diabetes.	high blood press	sure. cancer. hear	t disease. or others)	
	Diabetes		3			$\overline{}$
Ple	ease list all allergies (such as t	to druas, foods, p	ollen or others)			
		,e a. a.g., .e e a.e, p			<u>- </u>	
ll is	st any other important informat	ion about the per	son (such as sm	oking pregnancy	alcohol use etc)	
LIC	st arry other important imormat	ion about the per-	3011 (Such as 311)	oking, pregnancy	alcorlor use, etc.)	
	t all according to a sociation mandi					
LIS	st all current prescription medic			usea.		
	Progesterone only birth control, fa	amoudine 20 mg, se	rtrailine 50 mg			
LIS	st all over-the-counter medicat	ions and any vitar	mins, minerals, s	upplements, and	herbal remedies being used	d.
Se	ection F - About the Person Fill	ling Out This Form	n		1 of 1	
	Primary?	Yes				
	Reporter is Patient?				_	
	Title				_	
	Last name	/1 \	101		_	
	Middle Name	(b)	161			
	First name	$\mathbf{I} \cup \mathbf{I}$	101			
	Number/Street	- \	()			
	City	-				
	State/Province	-				
	Country	-				
-	ZIP or Postal code	-				\perp
	Lii Oi i Ostai OOUE					
1	Telephone number	-				
	Telephone number Email address	-				

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CTU #: FDA-CDER-CTU-2023-11602 | Department: CDER | RCT #: RCT-1102786 | CTU Triage Date: 10-Feb-2023 | AER #: 21979556

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Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	09-Feb-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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

Case ID: 22040650

Case Information:

Case Type : Direct eSub: N HP: Country: US Event Date: 26-Dec-2022 Outcomes: HO , RI

FDA Rcvd Date: 25-Feb-2023 Mfr Rcvd Date: Mfr Control #: FDA-CDER- Application #:

CTU-2023-15879

Patient Information:

Age: 57 YR Sex: Male Weight: 119.25 KG

Suspect Products:

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

Drug?

1 Mounjaro / Weight loss, diabetes 01-Nov-2022 30-Dec-2022

diabetes

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

Dose to Event

1 Mounjaro Yes Not Applicable ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA Version: v.26.0) ReC

Panic attack NA

Suicidal ideation NA

Event/Problem Narrative:

Tell us what happened and how it happened: Mounjaro caused panic attacks and thoughts of suicide;

Relevant Medical History:

List known medical conditions: Diabetes obesity depression; List any other important information about the person: Non smoker

Disease/Surgical Procedure Start Date End Date Continuing?

Application Type:



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

Case ID: 22040650

Medical History Product(s)			Start Date	End [Date Indications	;	Events	
Relevant Laboratory Data:								
Test Name		Result	Unit		Normal Low Range	Normal Hig	gh Range	Info Avail
Concomitant Products:								
# Product Name:	Dose/Frequency	Route		Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
Reporter Source:								
Study report?: No	Sender orga	nization:	FDA-CTU		503B Comp Outsourcin	oounding g Facility?:		
Literature Text:								

CTU #: FDA-CDER-CTU-2023-15879 | Department: CDER | RCT #: RCT-1108446 | CTU Triage Date: 27-Feb-2023 | AER #: 22040650

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All dates display	yed in the report are in EST(G	MT-05	:00) time zone						
Basic Deta	ils								
Company U	Init	CDI	ER-CTU	Origi	nating Account		FAERS		
Source Med	dium	MW	O (Drug)	Sour	ce Form Type		E2B XML 3500B		
Priority		Rou	Routine						
Override Au	ito Calculation Rule	No							
FDA Receiv	ved Date	25-l	eb-2023	CTU	Received Date		25-Feb-2023		
CTU Triage	Date			CTU	Data Entry Date				
Report Type	Э	Spo	ontaneous	Repo	ort Classification		Drug		
Assign To		Use	er						
User/Group									
Forward to	Department	∇]						
Case Priorit	ty	Dire	ect						
Contact									
Case Reporter	First Name		Last Name		Email Address		Phone		
Reporter	(b) (6)		(b) (6)		(b) (6)		(b) (6)		
	About the Drobless								
	About the Problem								
	nd of problem was it? all that apply)	M	Were hurt or had a bad side eff	fect (inc	uding new or worsening symp	otoms)			
	77	닏	Used a product incorrectly which	ch could	have or led to a problem				
		ᄖ	Noticed a problem with the qua	lity of th	e product				
D (11			Had problems after switching fr	om one	product maker to another ma	ker			
	problem occurred	26-Dec-2022							
Serious	(11 (11) 1 0	Yes							
	of the following happen? all that apply)	Hospitalization - admitted or stayed longer							
		Required help to prevent permanent harm							
		Disability or health problem							
			Birth defect						
		片	_ife-threatening						
			Death						
			Other serious/important medica						
	hat happened and how nal documents if nece			man	y details as possible	FDA ma	y reach out to you for		
Mounjar	o caused panic attacks ar	nd the	oughts of suicide						
Relevant T	est/Laboratory Data						1 of 1		
Test Na	me			Test	Date				
Test Res	sult			Test	 Unit				
Low Tes	t Range			High	Test Range				
More Inf	formation Available?								

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Ad	ditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Other			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Mounjaro			
	Name of the company that makes (or compounds) the product	Eli lilly and co			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number		_		
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	01-Nov-2022			
	Date the person stopped taking or using the product	30-Dec-2022			
	Date the person reduced dose of the product				

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	Give best estimate of duration				
	Is therapy still on-going?				_
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	Weight loss, diabetes				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the expira	tion date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				_
	Expiration date				
	Was someone operating the medical device when the problem occurred?				_
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast implants, etc.)		
	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Male			
	Gender	Cisgender man/boy			
	Please Specify Other Gender				
	Age (specify unit of time for age)	57 Year(s)			_
	Date of Birth				_
	Weight	119.25 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White			
		Plack or African American			

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Lis		Such as diabetes, high b	lood pressure, cancer, heart disease, or others)	
	Diabetes obesity depression			
Ple	ease list all allergies (such as t	o drugs, foods, pollen c	or others)	
		<u> </u>		
Lis	st any other important informati	ion about the person (s	uch as smoking, pregnancy, alcohol use, etc.)	
	Non smoker			
Lis	st all current prescription medic	cations and medical dev	ices being used.	
	t all aver the accompany mandicati	ione and any vitamine v		a a a d
LIS	st all over-the-counter medicati	ons and any vitamins, i	ninerals, supplements, and herbal remedies being	g usea.
	<u> </u>			
Se	ection F - About the Person Fill	ing Out This Form		1 of 1
	Primary?	Yes		
	Reporter is Patient?			
	Title			
_	Last name	(b) (6)		
<u> </u>	Middle Name	(D)(D)	/	
			<u> </u>	
_	Number/Street			
_	City Ctate/Province			
<u> </u>	State/Province Country			
	ZIP or Postal code			
	Telephone number			
	Email address			
	Fax			
-	Reporter Organization			

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Department	
Reporter Speciality	
Today's date	25-Feb-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

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