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

Date - Time: 24-Jul-2024 16:41:35 EDT

Run by: KIA.BAZEMORE@FDA.HHS.GOV

Case ID(s) Printed:

16168258	16168264	17649453	19568192
21901179	22272286	22333699	22528366
22655639	22734945		

Total Cases: 10

Total number of Inactive cases: *0

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

Case ID: 16168258

Case Information:

Case Type : Direct **eSub:** N **HP:** Y **Country:** US **Event Date:** 05-Apr-2019 **Outcomes:** **Application Type:**

FDA Rcvd Date: 05-Apr-2019 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2019-40024 **Combination Product Report:** **Application #:**

Patient Information:

Age: 52 YR **Sex:** Male **Weight:** 76.5 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	semaglutide		.5 Mg Milligram(S) / QW	Subcutaneous	OTHER FREQUENCY:weekly;			Type 2 Diabetes mellitus

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	semaglutide		Yes	Yes				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.27.0)	ReC
Dysaesthesia	Yes
Injection site pain	Yes
Back pain	Yes

Event/Problem Narrative:

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

Case ID: 16168258

Patient describes dysesthesias when using semaglutide. He describes sensations as similar to a sunburn, affecting LLQ abdomen (injection site), upper back and arms. He denies and does not have objective rash. He notes increased sensitivity upon touching hair, causing him to apply depilatory cream to his back to reduce pain. He previously experienced symptoms on semaglutide 0.5 mg/wk with resolution of symptoms when he switched to dulaglutide for insurance coverage. He has now switched back to semaglutide 1.0 mg with return of symptoms "twice as strong." He has experienced superior glucose control and weight loss on semaglutide and prefers to continue treatment despite dysesthesias.

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
1	Invokamet	/						
2	atorvastatin	/						
3	levothyroxine	/						

Reporter Source:

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

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Apr-2019	CTU Received Date	05-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

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

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	52 Year(s)
	Date of Birth	
	Gender	Male
	Weight	76.5 kg
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

	Type of Report (check all that apply)	☑ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
	Serious	No
	Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
	Date of Death	

Date of Event	05-Apr-2019
Date of this Report	05-Apr-2019

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient describes dysesthesias when using semaglutide. He describes sensations as similar to a sunburn, affecting LLQ abdomen (injection site), upper back and arms. He denies and does not have objective rash. He notes increased sensitivity upon touching hair, causing him to apply depilatory cream to his back to reduce pain. He previously experienced symptoms on semaglutide 0.5 mg/wk with resolution of symptoms when he switched to dulaglutide for insurance coverage. He has now switched back to semaglutide 1.0 mg with return of symptoms "twice as strong." He has experienced superior glucose control and weight loss on semaglutide and prefers to continue treatment despite dysesthesias.

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	
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 4

Suspect	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?	Yes		
Type	Drug/Biologic		
Product Name	semaglutide		
Strength	0.5 mg and 1.0 mg mg milligram(s)	If Other	
Manufacturer/Compounder	Novo Nordisk		
NDC# or Unique ID			

	Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?	Yes		
	Event Reappeared after Reintroduction ?	Yes		

Drug Therapy 1 of 1

	Dose or Amount	0.5 mg milligram(s)	If Other	
	Frequency	Other	If Other	weekly
	Route	Subcutaneous	If Other	
	Dosage Form			
	Start			
	Stop			
	Therapy Duration		If Other	
	Is therapy still on-going?	Yes		
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

	Type 2 Diabetes mellitus

D. PRODUCT(S) 2 of 4

	Concomitant	Yes		
	Does this report involve cosmetic, dietary supplement or food/medical food?			
	Primary?			
	Type	Drug/Biologic		
	Product Name	Invokamet		
	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 ?			

Drug Therapy 1 of 1

	Dose or Amount		If Other	
	Frequency		If Other	

	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 3 of 4

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	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?				
	Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 4 of 4

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	levothyroxine			
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 ?				

Drug Therapy 1 of 1

Dose or Amount		If Other		
Frequency		If Other		
Route		If Other		
Dosage Form				
Start				
Stop				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
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	
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) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

Primary?	Yes
Reporter is Patient?	
Title	
Last Name	(b) (6)
Middle Name	
First Name	
Address	
City	
State/Province/Region	
Country	her
ZIP/Postal Code	
Phone	
Email	
Fax	
Reporter Organization	

	Department			
	Reporter Speciality			
	Health Professional?	Yes		
	Occupation	Physician	If Other	
	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
	If you do NOT want your identity disclosed to the manufacturer	No		

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

Case ID: 16168264

Case Information:

Case Type : Direct **eSub:** N **HP:** Y **Country:** US **Event Date:** 19-Mar-2019 **Outcomes:** **Application Type:**

FDA Rcvd Date: 05-Apr-2019 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2019-40050 **Combination Product Report:** **Application #:**

Patient Information:

Age: 64 YR **Sex:** Female **Weight:** 62.19 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	semaglutide		1 Mg Milligram(S) /	Subcutaneous	OTHER FREQUENCY:weekly;			Type 2 diabetes mellitus

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	semaglutide		Not Applicable	Not Applicable				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.27.0) **ReC**

Dysaesthesia NA

Event/Problem Narrative:

Describe Event, Problem, or Product Use Error: Patient describes dysesthesias since increasing semaglutide dose to 1 mg. She describes 5-day painful burning sensation to upper back and posterior bilateral upper arms, similar to a sunburn. She denies and does not have objective rash. She previously used semaglutide 0.5 mg/wk without problems.

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

Case ID: 16168264

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
1	Synjardy XR	/						
2	rosuvastatin	/						
3	losartan	/						

Reporter Source:

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

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Apr-2019	CTU Received Date	05-Apr-2019
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

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

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	64 Year(s)
	Date of Birth	
	Gender	Female
	Weight	62.19 kg
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

	Type of Report (check all that apply)	☑ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
	Serious	No
	Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
	Date of Death	

Date of Event	19-Mar-2019
Date of this Report	05-Apr-2019

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient describes dysesthesias since increasing semaglutide dose to 1 mg. She describes 5-day painful burning sensation to upper back and posterior bilateral upper arms, similar to a sunburn. She denies and does not have objective rash. She previously used semaglutide 0.5 mg/wk without problems.

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	
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 4

Suspect	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?	Yes		
Type	Drug/Biologic		
Product Name	semaglutide		
Strength	1.0 mg milligram(s)	If Other	
Manufacturer/Compounder	Novo Nordisk		
NDC# or Unique ID			
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			

Drug Therapy 1 of 1

	Dose or Amount	1.0 mg milligram(s)	If Other		
	Frequency	Other	If Other	weekly	
	Route	Subcutaneous	If Other		
	Dosage Form				
	Start				
	Stop				
	Therapy Duration		If Other		
	Is therapy still on-going?	Yes			
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

	Type 2 diabetes mellitus

D. PRODUCT(S) 2 of 4

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Synjardy XR			
	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 ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				

	Start			
	Stop			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 3 of 4

	Concomitant	Yes		
	Does this report involve cosmetic, dietary supplement or food/medical food?			
	Primary?			
	Type	Drug/Biologic		
	Product Name	rosuvastatin		
	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 ?			

Drug Therapy 1 of 1

	Dose or Amount		If Other	
	Frequency		If Other	
	Route		If Other	
	Dosage Form			
	Start			
	Stop			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 4 of 4

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	losartan			
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 ?				

Drug Therapy 1 of 1

Dose or Amount		If Other		
Frequency		If Other		
Route		If Other		
Dosage Form				
Start				
Stop				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
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	
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) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

Primary?	Yes
Reporter is Patient?	
Title	
Last Name	(b) (6)
Middle Name	
First Name	
Address	
City	
State/Province/Region	
Country	ther
ZIP/Postal Code	
Phone	
Email	
Fax	
Reporter Organization	

	Department			
	Reporter Speciality			
	Health Professional?	Yes		
	Occupation	Physician	If Other	
	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
	If you do NOT want your identity disclosed to the manufacturer	No		

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

Case ID: 17649453

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** **Country:** US **Event Date:** 03-Feb-2020 **Outcomes:** **Application Type:**

FDA Rcvd Date: 08-Apr-2020 **Mfr Rcvd Date:** 03-Feb-2020 **Mfr Control #:** US-NOVOPROD-711379 **Combination Product Report:** **Application #:** 213051

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Rybelsus 14mg		14 Mg Milligram(S) /	Oral	14 mg	06-Jan-2020	03-Feb-2020	Product used for unknown indication

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Rybelsus 14mg	28 Day	No	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.27.0) **ReC**

Dysaesthesia

Pain

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Medical Doctor as "Diffuse dysesthesia(dysesthesia)" beginning on 03-FEB-2020, "shingles-like pain(pain)" beginning on 03-FEB-2020, and concerned a 47 Years old Female patient who

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

Case ID: 17649453

was treated with Rybelsus 14mg (SEMAGLUTIDE) from 06-JAN-2020 to 03-FEB-2020 for "drug use for unknown indication", Dosage Regimens: Rybelsus 14mg: 06-JAN-2020 to 03-FEB-2020; Historical Condition: Shingles Historical Drug: Ozempic. Treatment included - PREDNISONE Batch Numbers: Rybelsus 14mg: ASKU Action taken to Rybelsus 14mg was reported as Product discontinued due to AE. The outcome for the event "Diffuse dysesthesia(dysesthesia)" was Not recovered. The outcome for the event "shingles-like pain(pain)" was Not recovered.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Herpes zoster	Nov-2019	Nov-2019	No

Medical History Product(s)	Start Date	End Date	Indications	Events
OZEMPIC	Oct-2019	Oct-2019	Product used for unknown indication	No adverse event

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	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: 19568192

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** **Country:** US **Event Date:** 26-Apr-2021 **Outcomes:** **Application Type:**

FDA Rcvd Date: 14-Jul-2021 **Mfr Rcvd Date:** 30-Apr-2021 **Mfr Control #:** US-NOVOPROD-810056 **Combination Product Report:** **Application #:** 213051

Patient Information:

Age: 48 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Rybelsus		7 Mg Milligram(S) / QD	Oral	7 mg, qd	01-Mar-2021		Type 2 diabetes mellitus

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Rybelsus	56 Day	NA	NA	K082344			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.27.0) **ReC**

Dysaesthesia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Consumer as "Dysesthesia(Dysesthesia)" beginning on 26-APR-2021, and concerned a 48 Years old Male patient who was treated with Rybelsus (SEMAGLUTIDE) from 01-MAR-2021 and ongoing for "Type 2 Diabetes", Dosage Regimens: Rybelsus: 01-MAR-2021 to Not Reported (Dosage Regimen Ongoing); Current Condition: Type 2 diabetes mellitus. Batch Numbers: Rybelsus: K082344 Action taken to Rybelsus was reported as No Change. The outcome for the event

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

Case ID: 19568192

"Dysesthesia(Dysesthesia)" was Not recovered. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20210406151 Reference Notes:

Relevant Medical History:

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

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

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	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: 21901179

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** Y **Country:** US **Event Date:** **Outcomes:** **Application Type:**
FDA Rcvd Date: 23-Jan-2023 **Mfr Rcvd Date:** 10-Oct-2022 **Mfr Control #:** US-NOVOPROD-989736 **Combination Product Report:** Yes **Application #:** 209637

Patient Information:

Age: 30 YR **Sex:** Male **Weight:**

Suspect Products:

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

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

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

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

Case ID: 21901179

2	Ozempic//	No	/Other	Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S
3	Ozempic//	No	/Other	Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

Preferred Term (MedDRA Version: v.27.0) **ReC**

Dysaesthesia

Arthralgia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Physician as "Skin dysesthesia(Skin dysesthesia)" with an unspecified onset date, "arthralgia(Arthralgia)" with an unspecified onset date, and concerned a 30 Years old Male patient who was treated with Ozempic (SEMAGLUTIDE) from OCT-2021 and ongoing for "Drug use for unknown indication", Dosage Regimens: Ozempic: ??-OCT-2021 to Not Reported, Not Reported to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing); Medical history was not provided. Batch Numbers: Ozempic: ASKU, ASKU, ASKU Action taken to Ozempic was reported as Dose Decreased. The outcome for the event "Skin dysesthesia(Skin dysesthesia)" was Not recovered. The outcome for the event "arthralgia(Arthralgia)" was Not recovered. References included: Reference Type: E2B Report Duplicate Reference ID#: US-Novo-20221002453 Reference Notes: Novo Reference Type: SIMS case number Reference ID#: US-Novo-20221002453 Reference Notes:

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

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

Case ID: 21901179

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: 22272286

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** 01-Mar-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 15-May-2023 **Mfr Rcvd Date:** 04-May-2023 **Mfr Control #:** US-NOVOPROD-1043976 **Combination Product Report:** Yes **Application #:** 209637

Patient Information:

Age: 63 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Ozempic 2 mg		2 Mg Milligram(S) / / WK	Subcutaneous	2 mg, qw	01-Feb-2023		Diabetes mellitus

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 2 mg	76 Day	NA	NA	MP5D954			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 2 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

Preferred Term (MedDRA Version: v.27.0)	ReC
Cerebrovascular disorder	
Dysaesthesia	

Case ID: 22272286

Insomnia

Depressed mood

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "brain blood flow abnormal(Cerebral circulatory disorder)" beginning on 18-APR-2023, "widespread dysesthesias(Skin dysesthesia)" beginning on 01-MAR-2023, "trouble sleeping(Difficulty sleeping)" beginning on 01-MAR-2023, "felt very down(Feeling down)" beginning on 01-MAR-2023, and concerned a 63 Years old Male patient who was treated with Ozempic 2 mg (SEMAGLUTIDE) from 01-FEB-2023 and ongoing for "diabetes", Current Condition: type 2 Diabetes Historical Condition: shingles. Treatment included - ALEVE(NAPROXEN SODIUM), TRAMADOL, GABAPENTIN A patient receiving therapy with Ozempic 2 mg experienced constant skin pain, trouble sleeping, and felt very down on 01-MAR-2023. As treatment for constant skin pain the patient took Aleve, which did not help, so tramadol and gabapentin were prescribed. The patient also planned to follow-up with a neurologist. On 18-APR-2023, a brain magnetic resonance imaging showed blood flow abnormal. Batch Numbers: Ozempic 2 mg: MP5D954 Action taken to Ozempic 2 mg was reported as No Change. The outcome for the event "brain blood flow abnormal(Cerebral circulatory disorder)" was Not recovered. The outcome for the event "widespread dysesthesias(Skin dysesthesia)" was Not recovered. The outcome for the event "trouble sleeping(Difficulty sleeping)" was Not recovered. The outcome for the event "felt very down(Feeling down)" was Not recovered. Since last submission the case has been update with the following information: - Event constant skin pain updated to widespread dysesthesias. -Medical history updated -Patients date of birth updated. -Reporters causality updated. -Narrative updated accordingly Company Comment: Cerebrovascular disorder is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of diabetes has been associated with an increased risk for atherosclerosis, which may lead to cerebrovascular disease, therefore considered a possible confounder. Limited information as related to more specifics on the cerebrovascular disorder, weight, BMI, 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?
Herpes zoster	2020	2020	No
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
MAGNETIC RESONANCE IMAGING HEAD					Y

Concomitant Products:

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

Case ID: 22272286

#	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: 22333699

Case Information:

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

FDA Rcvd Date: 19-Jun-2023 **Mfr Rcvd Date:** 06-Jun-2023 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202305008305 **Combination Product Report:** Yes **Application #:** 215866

Patient Information:

Age: 49 YR **Sex:** Male **Weight:** 92.1 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Mounjaro		/ /WK	Subcutaneous	UNK UNK, weekly (1/W)			10067585
2	Mounjaro		7.5 Mg Milligram(S) / / WK	Subcutaneous	7.5 mg, weekly (1/W)			

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

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

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

Case ID: 22333699

2	/TIRZEPATIDE PEN (UNKNOWN)/ No NSC	/	Adverse Event Without Identified Device or Use Problem	Eli Lilly and Company

Event Information:

Preferred Term (MedDRA Version: v.27.0) **ReC**

Dysaesthesia

Blood glucose increased

Dizziness

Paraesthesia

Pain in extremity

Visual impairment

Event/Problem Narrative:

This spontaneous case reported by a who contacted the company to report an adverse event via a sales representative, with additional information from a neurologist, concerned a 49-year-old (at the time of initial report) male patient of unknown origin. Medical history included diabetes mellitus, high cholesterol and gallbladder surgery, in addition was a smoker and occasional alcohol use. There were no illicit drug use and no know allergies. Family history of cardiac disorder, cerebrovascular accident, diabetes mellitus, malignant neoplasm, and memory loss. Concomitant medications included rosuvastatin calcium and metformin, both for unknown indication. The patient received tirzepatide (Mounjaro), via pre-filled pen (autoinjector), weekly, subcutaneously for the treatment of type 2 diabetes mellitus. Start date and dose scalation schedule were not provided. In late Mar-2023, after tirzepatide therapy was started, he experienced dysesthesia which caused his hospitalization. He was worked up for a possible Guillain-Barre syndrome (GBS) and was treated with tapering dose of high-dose steroids. The symptoms resolved after a week and was discharged from the hospital on an unspecified date. Tirzepatide therapy 7.5 mg was reached on an unspecified date. One week after administration, he experienced another episode of dysesthesia. Due to this tirzepatide therapy was discontinued on an unspecified date. On 22-May-2023, the patient had an appointment with the neurologist, neurological examination was performed, and it was essentially normal but presenting tingling and dizziness, without evidence of GBS, chronic inflammatory demyelinating polyneuropathy (CIDP), or myelopathy. Furthermore, he had high blood sugar (values, units and reference ranges were not provided, foot pain and vision loss. He recovered from the events of dizziness and tingling; outcome of the remaining events was not specified. Information regarding hospitalization dates and further corrective treatments was not provided. Neurologist recommended tirzepatide therapy discontinuation, but as 06-Jun-2023 its status was not specified. The initial reporting family/general practice physician did not know the relatedness between the event of dysesthesia and the tirzepatide therapy, while the neurologist related it with tirzepatide therapy. Both physicians did not provide an assessment of relatedness for remaining events. Update 12-Jun-2023: Additional information was received from a neurologist in response to a medical questionnaire on 06-Jun-2023. Added a new reporter. Added patient demographics, medical history, and laboratory results. Added dosage tab of tirzepatide therapy 7.5 mg and concomitant medications. Updated serious adverse event form Guillain-Barre syndrome (GBS) to dysesthesia. Added non serious events of blood glucose increased, dizziness, tingling, foot pain, and vision decreased. Updated narrative accordingly.

Relevant Medical History:

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

Case ID: 22333699

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Diabetes mellitus			
High cholesterol			
Gallbladder removal			
Family history of cardiovascular disorder			
Family history of diabetes			
Family history of cancer			
Smoker			

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
10005809					Y
10050318					Y
10057434					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	Interval 1st Dose to Event
1	CRESTOR	20 Mg Milligram(S) / QD	Oral	20 mg, daily			10057097	
2	METFORMIN	750 Mg Milligram(S) / BID	Oral	750 mg, bid			10057097	

Reporter Source:

Study report?: No **Sender organization:** ELI LILLY AND CO **503B Compounding Outsourcing Facility?:**

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

Case ID: 22333699

Literature Text:

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

Case ID: 22528366

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** DK **Event Date:** Mar-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 07-Jun-2023 **Mfr Rcvd Date:** 29-May-2023 **Mfr Control #:** DK-NOVOPROD-1063496 **Combination Product Report:** **Application #:** 215256

Patient Information:

Age: 35 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy FlexTouch 1.0 mg		0.25 Mg Milligram(S) / /WK	Subcutaneous	0.25 mg, qw	Dec-2022		Obesity
2	Wegovy FlexTouch 1.0 mg		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw			
3	Wegovy FlexTouch 1.0 mg		1.7 Mg Milligram(S) / / WK	Subcutaneous	1.7 mg, qw		17-Apr-2023	
4	Wegovy FlexTouch 1.0 mg		1 Mg Milligram(S) / / WK	Subcutaneous	1 mg, qw			
5	Wegovy FlexTouch 2.4 mg		2.4 Mg Milligram(S) / / WK	Subcutaneous	2.4 mg, qw	17-Apr-2023	05-May-2023	Obesity

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

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

Case ID: 22528366

3	Wegovy FlexTouch 1.0 mg	NA	NA		NOVO NORDISK
4	Wegovy FlexTouch 1.0 mg	NA	NA		NOVO NORDISK
5	Wegovy FlexTouch 2.4 mg	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	//	No			/			
2	//	No			/			
3	//	No			/			
4	//	No			/			
5	//	No			/			

Event Information:

Preferred Term (MedDRA Version: v.27.0)	ReC
Paraesthesia	
Allodynia	
Dysaesthesia	
IgA nephropathy	
Proteinuria	
Scleritis	
Fatigue	
Asthenia	

Event/Problem Narrative:

This serious Spontaneous case received via Regulatory Authority of "DMA (Danish Medicines Agency)" from DENMARK was reported by a Medical Doctor as "Paraesthesia(Paraesthesia)" beginning on 03-APR-2023, "Allodynia/pain at scalp, elbows and thighs - only at touch. The pain is descrribed as stinging(Allodynia)"

Case ID: 22528366

beginning on 03-APR-2023, "Dysaesthesia arms, neck, thighs and chest(Dysaesthesia)" beginning on MAR-2023, "Obs glomerulonephritis (IgA nephropathy) due to history of proteinuria, increasing tiredness and weakness(IgA nephropathy)" beginning on MAY-2023, "proteinuria(Proteinuria)" beginning on MAY-2023, "Scleritis(Scleritis)" beginning on MAR-2023, "increasing tiredness(Tiredness)" beginning on MAY-2023, "Weakness(Weakness)" beginning on MAY-2023, and concerned a 35 Years old Male patient who was treated with Wegovy FlexTouch 1.0 mg (SEMAGLUTIDE) from DEC-2022 to 17-APR-2023 for "Adipositas", , Wegovy FlexTouch 2.4 mg (SEMAGLUTIDE) from 17-APR-2023 to 05-MAY-2023 for "Adipositas", The events Scleritis, Dysaesthesia arms, neck, thighs and chest, Allodynia and Paraesthesia, increasing tiredness, proteinuria, Weakness and Obs glomerulonephritis (IgA nephropathy) were medically confirmed. Patient's height, weight and body mass index were not reported. Dosage Regimens: Wegovy FlexTouch 1.0 mg: ??-DEC-2022 to Not Reported, Not Reported to Not Reported, Not Reported to Not Reported, Not Reported to 17-APR-2023; Wegovy FlexTouch 2.4 mg: 17-APR-2023 to 05-MAY-2023; Current Condition: Adipositas. On an unknown date of MAR-2023, patient had scleritis, dysaesthesia of arms, neck, thighs and chest. On 03-APR-2023, patient had allodynia and paraesthesia /pain at scalp, elbows and thighs only at touch. The pain was described as stinging. On an unknown date of MAY-2023, patient had increasing tiredness, proteinuria, weakness and Obs glomerulonephritis (IgA nephropathy) due to history of proteinuria, increasing tiredness and weakness. On an unknown date of MAY-2023 patient's Estimated GFR(Estimated GFR) was 59 Unit not specified and Protein urine(Protein urine) was 1400 (normaly under 20) Unit not specified, Biopsy kidney(Biopsy kidney) was performed but results were not yet available. Batch Numbers: Wegovy FlexTouch 1.0 mg: Not reported Wegovy FlexTouch 2.4 mg: Not reported Action taken to Wegovy FlexTouch 1.0 mg was reported as No Change. Action taken to Wegovy FlexTouch 2.4 mg was reported as Product discontinued. The outcome for the event "Paraesthesia(Paraesthesia)" was Not recovered. The outcome for the event "Allodynia/pain at scalp, elbows and thighs - only at touch. The pain is descrribed as stinging(Allodynia)" was Not recovered. On MAY-2023 the outcome for the event "Dysaesthesia arms, neck, thighs and chest(Dysaesthesia)" was Recovered. The outcome for the event "Obs glomerulonephritis (IgA nephropathy) due to history of proteinuria, increasing tiredness and weakness(IgA nephropathy)" was Not recovered. The outcome for the event "proteinuria(Proteinuria)" was Unknown. On 2023 the outcome for the event "Scleritis(Scleritis)" was Recovered. On MAY-2023 the outcome for the event "increasing tiredness(Tiredness)" was Recovered. The outcome for the event "Weakness(Weakness)" was Recovered. No further information available. This case was reclassified from non serious to serious on 29-MAY-2023 due to addition of seriousness criteria medically significant for the events Paraesthesia, Allodynia, IgA nephropathy, Tiredness, proteinuria, Weakness, Scleritis and Dysaesthesia. References included: Reference Type: E2B Report Duplicate Reference ID#: DK-DKMA-ADR 27833708 Reference Notes: DKMA Reference Type: E2B Authority Number Reference ID#: DK-DKMA-WBS-1004361 Reference Notes: DMA (Danish Medicines Agency), DNK Reference Type: E2B Report Duplicate Reference ID#: DK-DKMA-WBS-1004361 Reference Notes: DKMAEFORMS Company Comment: “Paraesthesia”, “Allodynia” , “Dysaesthesia”, “IgA nephropathy”, “Proteinuria” and “Scleritis” are assessed as unlisted; “Fatigue” and “Asthenia” as listed according to the Novo Nordisk current CCDS information on Wegovy FlexTouch. Information on any medical history of nervous disorder, family history of nephropathy, any history of autoimmune disease, clinical course of events, investigations report and definitive diagnosis are missing. Proteinuria is common with IGA nephropathy. Limited information precludes thorough medical assessment. This single case report is not considered to change the current knowledge of the safety profile of Wegovy FlexTouch.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Obesity			

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

Relevant Laboratory Data:

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

Case ID: 22528366

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
BIOPSY KIDNEY					Y
GLOMERULAR FILTRATION RATE					Y
PROTEIN URINE					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: 22655639

Case Information:

Case Type : Direct **eSub:** N **HP:** Y **Country:** US **Event Date:** 28-Jun-2023 **Outcomes:** **Application Type:**

FDA Rcvd Date: 29-Jun-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-48325 **Combination Product Report:** No **Application #:**

Patient Information:

Age: 62 YR **Sex:** Male **Weight:** 92.25 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy		2.4 Mg Milligram(S) / QW	Subcutaneous	Frequency : Weekly;	18-Jan-2023		Obesity

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy		Not Applicable	Not Applicable				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.27.0)	ReC
Dysaesthesia	NA
Paraesthesia	NA

Event/Problem Narrative:

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

Case ID: 22655639

Tell us what happened and how it happened : Describe Event, Problem, or Product Use Error: C143421 MedDRA Code 10062872. Dysesthesia Grade I - a "pins and needles" sensation mostly in the trunk but also in the limbs that began after use of more than 1 mg of Wegovy (semaglutide). It has persisted for the last 2 months.;

Relevant Medical History:

List known medical conditions : Also taking atorvastatin 20 mg, metformin 2000 mg, amlodipine 2.5 mg, Atacand 32/25, 81 mg ASA, latanoprost ophthalmic 0.005% ou qd;

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
1	Metformin	/			01-Jan-2008			
2	Atacand	/			01-Jan-2005			
3	Atorvastatin	/			01-Jan-2010			
4	Aspirin	/						
5	aspirin	/						
6	latanoprost 0.005%	/			01-Jan-2015			
7	Amlodipine	/						

Reporter Source:

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

Case ID: 22655639

Study report?: No

Sender organization: FDA-CTU

503B Compounding Outsourcing Facility?:

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	29-Jun-2023	CTU Received Date	29-Jun-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	62 Year(s)
	Date of Birth	
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Weight	92.25 kg
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

	Type of Report (check all that apply)	☑ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
	Serious	No
	Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	28-Jun-2023
Date of this Report	29-Jun-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: C143421 MedDRA Code 10062872. Dysesthesia Grade I - a "pins and needles" sensation mostly in the trunk but also in the limbs that began after use of more than 1 mg of Wegovy (semaglutide). It has persisted for the last 2 months.

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

Also taking atorvastatin 20 mg, metformin 2000 mg, amlodipine 2.5 mg, Atacand 32/25, 81 mg ASA, latanoprost ophthalmic 0.005% ou qd

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 7

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report involves:	Other

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Wegovy		
Strength	2.4 mg milligram(s)	If Other	
Manufacturer/Compounder	Novo Nordisk		
NDC# or Unique ID			

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			

Drug Therapy 1 of 1

Dose or Amount	2.4 mg milligram(s)	If Other	
Frequency	Other	If Other	once weekly
Route	Subcutaneous	If Other	
Dosage Form			
Start	18-Jan-2023		
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?	Yes		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

Obesity

D. PRODUCT(S) 2 of 7

Concomitant	Yes		
Primary?			
Type	Drug/Biologic		
This report involves:			

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Metformin 2000g daily		
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 ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	

Frequency		If Other		
Route		If Other		
Dosage Form				
Start	01-Jan-2008			
Stop				
Dose Reduced				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 3 of 7

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Atacand 32/25 daily		
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 ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start	01-Jan-2005		
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			

	Expiration Date	

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 4 of 7

	Concomitant	Yes
	Primary?	
	Type	Drug/Biologic
	This report involves:	

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	Atorvastatin 20 mg daily		
	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 ?			

Drug Therapy 1 of 1

	Dose or Amount		If Other	
	Frequency		If Other	
	Route		If Other	
	Dosage Form			
	Start	01-Jan-2010		
	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 5 of 7

	Concomitant	Yes
	Primary?	

	Type	Drug/Biologic		
	This report involves:			

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	Aspirin 81 mg daily		
	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 ?			

Drug 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			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 6 of 7

	Concomitant	Yes		
	Primary?			
	Type	Drug/Biologic		
	This report involves:			

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	latanoprost 0.005% daily OU		
	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 ?				

Drug 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				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 7 of 7

	Concomitant	Yes
	Primary?	
	Type	Drug/Biologic
	This report involves:	

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	Amlodipine 2.5 mg			
	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 ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		

	Dosage Form			
	Start	01-Jan-2015		
	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication)

E. SUSPECT MEDICAL DEVICE

	Brand Name	
	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	
	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) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last Name	(b) (6)
Middle Name	
First Name	
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/Compounder ☐ User Facility ☐ Distributor/Importer
If you do NOT want your identity disclosed to the manufacturer	Yes

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

Case ID: 22734945

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** DK **Event Date:** 2023 **Outcomes:** HO , DS **Application Type:**

FDA Rcvd Date: 13-Oct-2023 **Mfr Rcvd Date:** 04-Oct-2023 **Mfr Control #:** DK-NOVOPROD-1089639 **Combination Product Report:** **Application #:** 215256

Patient Information:

Age: 56 YR **Sex:** Female **Weight:** 121 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy FlexTouch 0.25 mg		0.25 Mg Milligram(S) / /WK	Subcutaneous	0.25 mg, qw	20-Mar-2023	28-Mar-2023	Overweight

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy FlexTouch 0.25 mg	7 Day	No	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.27.0)	ReC
Hypersensitivity	
Fatigue	
Ocular hyperaemia	

Joint swelling

Systemic lupus erythematosus

Anaemia

Arthralgia

Lymphopenia

Dysaesthesia

General physical health deterioration

Arthritis

Skin disorder

Connective tissue disorder

Neuropathy peripheral

Event/Problem Narrative:

This serious Spontaneous Regulatory Authority case received via Danish Medicines Agency from DENMARK was reported by a Physician as "Interpreted as possible allergic reaction(Allergic reaction)" beginning on 27-MAR-2023, "Tiredness(Tiredness)" beginning on 2023, "Red eyes(Eyes red)" beginning on 23-MAY-2023, "Felt general swellings in the body(Joint swelling)" beginning on 27-MAR-2023, "Patient diagnosed with SLE. Assessed to be medically induced (Wegovy)(Systemic lupus erythematosis)" beginning on 2023, "Anemia(Anemia)" beginning on 2023, "Joint pain (Just before the second dose: pain in both wrists. Then spread to other joints: elbows, knees, ankles)(Joint pain)" beginning on 27-MAR-2023, "Lymphopenia(Lymphopenia)" beginning on 2023, "Dysaesthesia (sensation disturbance) in right hand and both feet. Suspected caused by autoimmune vasculitis/neuropathy(Dysaesthesia)" beginning on 2023, "Generally affected. Shortly after Wegovy start.(Reduced general condition)" beginning on 2023, "Joint inflammation (arthritis)(Joint inflammation)" beginning on 2023, "Significant disease activity from several organs (skin). Shortly after Wegovy start(Skin disorder)" beginning on 2023, "Significant disease activity from several organs (Peripheral nerve system). Shortly after Wegovy start(Peripheral nerve disorder NOS)" beginning on 2023, "Significant disease activity from several organs (joint/connective tissue). Shortly after Wegovy start(Connective tissue disorder)" beginning on 2023, and concerned a 56 Years old Female patient who was treated with Wegovy FlexTouch 0.25 mg (SEMAGLUTIDE) from 20-MAR-2023 to 28-MAR-2023 for "Overweight", All events were medically confirmed. Patient's height: 166 cm Patient's weight: 121 kg Patient's BMI: 43.91058210. Dosage Regimens: Wegovy FlexTouch 0.25 mg: 20-MAR-2023 to 28-MAR-2023; Current Condition: Overweight, Hypertension, Hypothyroidism, Hypercholesteraemia. Concomitant products included - LOSARTAN, SIMVASTATIN, EUTHYROX(LEVOTHYROXINE SODIUM), AMLODIPINE On an unspecified date in 2023, patient's C-reactive protein (C-reactive protein) increased between 23-MAY-2023 and 01-JUN-2023. On an unknown date in 2023 shortly after Wegovy start patient was Generally affected and experienced Significant disease activity from skin, Peripheral nerve system and joint/connective tissue, patient also experienced Joint inflammation (arthritis), Anemia , Lymphopenia, Dysaesthesia (sensation disturbance) in right hand and both feet. Suspected caused by autoimmune vasculitis/neuropathy. Patient presented Tiredness, Red eyes, Felt general swellings in the body,Patient diagnosed with SLE. Assessed to be medically induced (Wegovy), Interpreted as possible allergic reaction. On 27-MAR-2023 just before the second dose patient experienced Joint pain, pain in both wrists then spread to other joints elbows, knees, ankles. On an unspecified date in 2023, patient haemoglobin (Haemoglobin) test showed anemia,lymphocyte count (Lymphocyte count) showed Lymphopenia, antibody test (Antibody test) showed SSA antibodies,double stranded DNA antibody (Double stranded DNA antibody) resulted DS-DNA.Being examined for complement consumption, antiphospholipid antibody syndrome and secondary sj?gren disease, unspecified investigation (Investigation) result showed SLE and Sjogren and Ophthalmological examination (Ophthalmological examination) result showed dry eyes, blood pressure(Blood pressure measurement) was monitored reasult was not specified, investigation(Investigation) was Assessed in several special hospital units, patient's protein urine(Protein urine) test showed Increas in protein in the urine, Dermatologic examination(Dermatologic examination)

was performed reasult was not specified, Neurological examination(Neurological examination) was performed reasult was not specified, Rheumatological examination(Rheumatological examination) was performed reasult was not specified, patient's Ophthalmological examination(Ophthalmological examination) was done and result was not specified. On 27-JUN-2023, patient 's unspecified investigation (Investigation) was done and result showed Systemic lupus erythematosus with ds-DNA, SSA antibodies, anemia, lymphopenia, skin- and joints involvement and tiredness. It was reported the events caused disablity in the patient. Batch Numbers: Wegovy FlexTouch 0.25 mg: Not available Action taken to Wegovy FlexTouch 0.25 mg was reported as Product discontinued. The outcome for the event "Interpreted as possible allergic reaction(Allergic reaction)" was Not recovered. The outcome for the event "Tiredness(Tiredness)" was Not recovered. The outcome for the event "Red eyes(Eyes red)" was Not recovered. The outcome for the event "Felt general swellings in the body(Joint swelling)" was Not recovered. The outcome for the event "Patient diagnosed with SLE. Assessed to be medically induced (Wegovy)(Systemic lupus erythematosis)" was Not recovered. The outcome for the event "Anemia(Anemia)" was Not recovered. The outcome for the event "Joint pain (Just before the second dose: pain in both wrists. Then spread to other joints: elbows, knees, ankles)(Joint pain)" was Not recovered. The outcome for the event "Lymphopenia(Lymphopenia)" was Not recovered. The outcome for the event "Dysaesthesia (sensation disturbance) in right hand and both feet. Suspected caused by autoimmune vasculitis/neuropathy(Dysaesthesia)" was Not recovered. The outcome for the event "Generally affected. Shortly after Wegovy start.(Reduced general condition)" was Unknown. The outcome for the event "Joint inflammation (arthritis)(Joint inflammation)" was Not recovered. The outcome for the event "Significant disease activity from several organs (skin). Shortly after Wegovy start(Skin disorder)" was Unknown. The outcome for the event "Significant disease activity from several organs (Peripheral nerve system). Shortly after Wegovy start(Peripheral nerve disorder NOS)" was Unknown. The outcome for the event "Significant disease activity from several organs (joint/connective tissue). Shortly after Wegovy start(Connective tissue disorder)" was Unknown. Since last submission the case have been updated with the following: Lab data added. Event verbatim changed from "Patient assessed to have SLE" to "Patient diagnosed with SLE. Assessed to be medically induced (Wegovy)" New event added(Dysaesthesia (sensation disturbance) in right hand and both feet. Suspected caused by autoimmune vasculitis/neuropathy, Reduced general condition, Joint inflammation (arthritis), Significant disease activity from several organs (skin). Shortly after Wegovy start, Significant disease activity from several organs (Peripheral nerve system). Shortly after Wegovy start, Significant disease activity from several organs (joint/connective tissue). Shortly after Wegovy start). Seriousness criteria updated(Tiredness, anemia, Interpreted as possible allergic reaction) Narrative updated accordingly. No further information available. References included: Reference Type: E2B Report Duplicate Reference ID#: DK-DKMA-ADR 28012536 Reference Notes: DKMA Reference Type: E2B Authority Number Reference ID#: DK-DKMA-WBS-1005140 Reference Notes: DMA (Danish Medicines Agency), DNK Reference Type: E2B Report Duplicate Reference ID#: DK-DKMA-WBS-1005140 Reference Notes: DKMAEFORMS COMPANY COMMENT - The events, “allergic reaction”, "eyes red", "joint swelling", "systemic lupus erythematosis", "anemia", "joint pain", "dysaesthesia" , "reduced general condition", "joint inflammation", "skin disorder", "peripheral nerve system", "connective tissue disorder" and "lymphopenia" are assessed as unlisted and "tiredness" is assessed as listed according to the Novo Nordisk CCDS on Wegovy FlexTouch. As only limited information has been obtained so far, it is difficult to perform a thorough medical evaluation of the case. The following important information is lacking: patient’s health status prior to suspect drug therapy, nature, site and type of disability, final diagnosis, clinical course of events, medical history on trauma or tumor, baseline laboratory and diagnostic tests results, and concomitant medications. The underlying obesity, hypertension, hypothyroidism and hypercholestrolemia may be contributory. This single case report is not considered to change the current knowledge of the safety profile of Wegovy FlexTouch.

Relevant Medical History:

No previous history of joint disease

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Overweight			Yes
Hypertension			Yes
Hypothyroidism			Yes
Hypercholesterolaemia			Yes

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

Case ID: 22734945

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
ANTIBODY TEST					Y
BLOOD PRESSURE MEASUREMENT					Y
C-REACTIVE PROTEIN					Y
DERMATOLOGIC EXAMINATION					Y
DOUBLE STRANDED DNA ANTIBODY					Y
HAEMOGLOBIN					Y
INVESTIGATION					Y
INVESTIGATION					Y
INVESTIGATION					Y
INVESTIGATION					Y
LYMPHOCYTE COUNT					Y
NEUROLOGICAL EXAMINATION					Y
OPHTHALMOLOGICAL EXAMINATION					Y
OPHTHALMOLOGICAL EXAMINATION					Y
PROTEIN URINE					Y
RHEUMATOLOGICAL EXAMINATION					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	Interval 1st Dose to Event
1	LOSARTAN	/		UNK	30-Apr-2015		Hypertension	2888 Day
2	SIMVASTATIN	/		UNK	20-Apr-2012		Hypercholesterolaemia	3993 Day
3	EUTHYROX	/		UNK	10-Mar-2011		Hypothyroidism	4400 Day

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

Case ID: 22734945

4	AMLODIPINE	/		UNK	31-May-2023	Hypertension

Reporter Source:

Study report?: No

Sender organization: NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text: