

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

Disclaimer:

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

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

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

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

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

Case ID(s) Printed:

| 16168258 | 16168264 | 17649453 | 19568192 |
|----------|----------|----------|----------|
| 21901179 | 22272286 | 22333699 | 22528366 |
| 22655639 | 22734945 | | |

Total Cases: 10

Total number of Inactive cases: *0



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- Combination Product Application #:

CTU-2019-40024 Report:

Patient Information:

Age: 52 YR Sex: Male Weight: 76.5 KG

Suspect Products:

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

Drug?

1 semaglutide .5 Mg Milligram(S) / Subcutaneous OTHER Type 2 Diabetes mellitus

QW

FREQUENCY:weekly;

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

Dose to Event

1 semaglutide Yes Yes NOVO NORDISK

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

1 // No

Event Information:

Preferred Term (MedDRA Version: v.27.0) ReC

Dysaesthesia Yes Injection site pain Yes

Back pain Yes

Event/Problem Narrative:



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 | e Continui | ng? | |
| Medical History Product(s) | | | Start Date | End Date | e Indicatio | ns Events | |
| Relevant Laboratory Data: | | | | | | | |
| Test Name | | Result | Unit | No | ormal Low Range | Normal High Range | Info Avail |
| Concomitant Products: | | | | | | | |
| # Product Name: | Dose/Frequency | Route | | Dosage Text | Start Date En | d Date Indication(s) | Interval 1st |
| 1 Invokamet | / | | | | | | Dose to Event |
| 2 atorvastatin | / | | | | | | |
| 3 levothyroxine | / | | | | | | |
| Reporter Source: | | | | | | | |
| Study report?: No | Sender orga | nization: | FDA-CTU | | 503B Co Outsour | mpounding cing Facility?: | |
| Literature Text: | | | | | | | |

CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 |

Total Pages: 7

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

| | sic Deta | ils | 1011 00 | .00) time zone | | | | | |
|--------------------------------|-------------------|---------------------------|---|---|------------------|-------------------------|---|--------------|---|
| | ompany U | | CDI | ER-CTU | Origi | nating Account | | FAERS | |
| - | ource Med | | MW | O (Drug) | Source Form Type | | | E2B XML 3500 | |
| Priority | | Rou | Routine | | | | | | |
| Override Auto Calculation Rule | | No | | | | | | | |
| FDA Received Date | | | 05- | Apr-2019 | CTU | Received Date | | 05-Apr-2019 | |
| C. | TU Triage | Date | | | CTU | Data Entry Date | | | |
| R | eport Type |) | Spo | ntaneous | Repo | ort Classification | | Drug | |
| As | ssign To | | Use | r | l | | | | |
| U | ser/Group | | | | | | | | |
| Fo | orward to I | Department | | CDER (CDER-OSE-R | SS-CT | ∐@fda hhs gov) (E2B) | | | |
| C | ase Priorit | у | Dire | | 50 01 | <u> </u> | | | |
| | | - | | | | | | | |
| Cc | ntact | | | | | | | | |
| | ase eporter | First Name | | Last Name | | Email Address | | Phone | |
| V | 3 | (b) (6) | | (b) (6) | | (b) (6) | | (b) (6) | |
| Α | PATIFN | T INFORMATION | | | | | | | |
| | | dentifier (In Confidence) | (b) | (6) | | | | | |
| | Age | <u> </u> | _ | /ear(s) | | | _ | | |
| | Date of E | Birth | | | | | _ | | |
| | Gender | | Mal | e | | | | | + |
| | Weight | | 76.5 kg | | | | | | |
| | Ethnicity answer) | (Check single best | Not Hispanic/Latino | | | | | | |
| | | heck all that apply) | Asian | | | | | | |
| | | | American Indian or Alaskan Native | | | | | | |
| | | | | Black or African American White | | | | | |
| | | | | vrnite Native Hawaiian or Other Paci | fic Island | der | | | |
| B | ADVERS | SE EVENT, PRODUC | | | no iolaric | | · | | |
| <u>ا</u> | | Report (check all that | | | | | | | |
| | apply) | | Adverse Event | | | | | | |
| | | | Product Use/Medication Error Product Problem (e.g., defects/malfunctions) | | | | | | |
| | | | | Problem with Different Manufa | | | | | |
| | Serious | | No | | | | | | |
| | | Attributed to Adverse | | Death | | | | | |
| | Event (C | heck all that apply) | | Life Threatening | | | | | |
| | | | | Hospitalization (initial or prolor | iged) | | | | |
| | | | | Other Serious or Important Me | dical Ev | ents | | | |
| | | | | Disability or Permanent Dama | ge | | | | |
| | | | | Congenital Anomaly/Birth Defe | ects | | | | |
| _ | <u> </u> | - · · · | Ш | Required Intervention to Preve | nt Perm | anent Impairment/Damage | | | _ |
| | Date of [| Death | | | | | | | |

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CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 | Total Page 27

Total Pages: 7

| 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.

| Rε | elevant Test/Laboratory Data | | | 1 of 1 | |
|-----------------|---|--------------------------------------|-----------------|--------|---|
| | Test Name | | Test Date | | |
| | Test Result | | Test Unit | | |
| | Low Test Range | | High Test Range | | |
| | More Information Available? | | | | |
| Ac | lditional Comments | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | = |
| Ot | her Relevant History, Including | g Preexisting Medical Co | onditions | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| 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 | No | | | |
| | including a picture) | | | | |
| D- | PRODUCT(S) | | | 1 of 4 | |
| _ا ل. | | | | 1 01 4 | |
| | Suspect | Yes | | | |
| | Does this report involve cosmetic, dietary supplement or | | | | |
| | food/medical food? | | | | |
| | Primary? | Yes | | | _ |
| | Туре | 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 | | | | |

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CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 |

| | _ | |
|-------|--------|---|
| Total | Pages: | 7 |
| | | |

| | Product Type(check all that apply) | OTC Compounded Generic Biosimilar | | | |
|-----|---|-----------------------------------|----------|--------|----------|
| | Event Abated After Use Stopped or Dose Reduced? | Yes | | | |
| | Event Reappeared after Reintroduction ? | Yes | | | |
| Dr | ug 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 | | | | |
| Dia | agnosis for Use (indication) | | | 1 of 1 | |
| | | | | | <u> </u> |
| D. | PRODUCT(S) | | | 2 of 4 | |
| | Concomitant | Yes | | | _ |
| | Does this report involve cosmetic, dietary supplement or food/medical food? | | | | |
| | Primary? | | | | |
| | Туре | 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 ? | | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Dose or Amount | | If Other | | |
| | | | | | |

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CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 | Total Pages: 7

| | - | | | | |
|-----|---|-----------------------------------|-------------|----------|--------|
| | Route | | If Other | | |
| | Dosage Form | | | | |
| | Start | | | | |
| | Stop | | | | |
| | Therapy Duration | | If Other | | |
| | Is therapy still on-going? | | L | I | |
| | Lot Number | | | | |
| | Expiration Date | | | | |
| Dia | agnosis for Use (indication) | <u> </u> | | | 1 of 1 |
| | | | | | |
| D. | PRODUCT(S) | | | | 3 of 4 |
| | Concomitant | Yes | | | |
| | Does this report involve cosmetic, dietary supplement or food/medical food? | | | | |
| | Primary? | | | | |
| | Туре | 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 ? | | | | |
| Dr | rug Therapy | | | <u> </u> | 1 of 1 |
| | Dose or Amount | | If Other | | |
| | Frequency | | If Other | | |
| | Route | | If Other | | |
| | Dosage Form | | | | |
| | Start | | | | |
| | Stop | | | 1 | |
| | Therapy Duration | | If Other | | |
| | Is therapy still on-going? | | | | |
| | Lot Number | | | | |
| | Expiration Date | | | | |

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1 of 1

Diagnosis for Use (indication)

CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 | Total Pages: 7

| PRODUCT(S) | | | 4 of 4 | |
|--|---|---|---|---|
| Concomitant | Yes | | | |
| Does this report involve cosmetic, dietary supplement or food/medical food? | | | | |
| Primary? | | | | |
| Туре | 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 | | | | |
| | | | | |
| Event Reappeared after | | | | |
| | | | 1 of 1 | |
| Event Reappeared after Reintroduction ? | | If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy | | If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount | | | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency | | If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route | | If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form | | If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start | | If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop | | If Other If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration | | If Other If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? | | If Other If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number | | If Other If Other | 1 of 1 | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date | | If Other If Other | | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) | | If Other If Other | | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE | | If Other If Other | | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name | | If Other If Other | | |
| Event Reappeared after Reintroduction ? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE | | If Other If Other | | |
| | Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Drug/Biologic Product Name Ievothyroxine Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Compounded Generic Biosimilar Event Abated After Use Stopped | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Drug/Biologic Product Name Ilevothyroxine Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) OTC Compounded Generic Biosimilar | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Drug/Biologic Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped |

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CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 | Total Pages: 7

| | 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) ME | EDICAL PRODUCTS | |
| | CONCOMITANT MEDICAL PROD | | |
| | | | |
| | | | |
| | | | |
| | | | |
| G. | REPORTER | 1 of 1 | |
| | Primary? | Yes | П |
| | Reporter is Patient? | | |
| | Title | | |
| П | Last Name | /1 \ / _ \ | +- |
| \vdash | Lastivanie | | |
| | Middle Name | (h) (6) | |
| | | (b) (6) | |
| | Middle Name | (b) (6) | |
| | Middle Name First Name | (b) (6) | |
| | Middle Name First Name Address | (b) (6) | |
| | Middle Name First Name Address City | (b) (6) her | |
| | Middle Name First Name Address City State/Province/Region | | |
| | Middle Name First Name Address City State/Province/Region Country | | |
| | Middle Name First Name Address City State/Province/Region Country ZIP/Postal Code | | |
| | Middle Name First Name Address City State/Province/Region Country ZIP/Postal Code Phone | | |

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CTU #: FDA-CDER-CTU-2019-40024 | Department: CDER | RCT #: RCT-287596 | CTU Triage Date: 05-Apr-2019 | AER #: 16168258 |

Total Pages: 7

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

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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- Combination Product Application #:

CTU-2019-40050 Report:

Patient Information:

Age: 64 YR Sex: Female Weight: 62.19 KG

Suspect Products:

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

Drug?

1 semaglutide 1 Mg Milligram(S) / Subcutaneous OTHER Type 2 diabetes mellitus

FREQUENCY:weekly;

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

Dose to Event

1 semaglutide Not Applicable Not Applicable Not Applicable NOVO NORDISK

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

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.



Case ID: 16168264

| Relevant Medical History | <i>y</i> : | | | | | | |
|--------------------------|----------------|------------|------------|-------------|-----------------|---------------------------|-----------------------------|
| Disease/Surgical Proced | lure | | Start Date | End Date | e Continui | ng? | |
| Medical History Product | (s) | | Start Date | End Date | e Indicatio | ons Events | |
| Relevant Laboratory Dat | a: | | | | | | |
| Test Name | | Result | Unit | N | ormal Low Range | Normal High Range | Info Avail |
| Concomitant Products: | | | | | | | |
| # Product Name: | Dose/Frequency | Route | | Dosage Text | Start Date Er | nd Date Indication(s) | Interval 1st Dose to Event |
| 1 Synjardy XR | / | | | | | | DOSC to Event |
| 2 rosuvastatin | / | | | | | | |
| 3 losartan | / | | | | | | |
| Reporter Source: | | | | | | | |
| Study report?: No | Sender orga | anization: | FDA-CTU | | | mpounding cing Facility?: | |
| Literature Text: | | | | | | | |

CTU #: FDA-CDER-CTU-2019-40050 | Department: CDER | RCT #: RCT-287648 | CTU Triage Date: 05-Apr-2019 | AER #: 16168264 |

Total Pages: 7

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

| | | red in the report are in EST(G | WI I -U5 | .00) time zone | | | |
|----------|-------------------|--|--------------------------|------------------------------------|-----------|-------------------------|--------------|
| | sic Detai | | CDI | ED CTU | 0-1-1 | nating Associat | EAEDS |
| <u> </u> | ompany U | | | ER-CTU | | nating Account | FAERS |
| | ource Med | ium | | O (Drug) | Sour | ce Form Type | E2B XML 3500 |
| | riority | to Oalandatia B.I. | Rou | tine | | | _ |
| - | | to Calculation Rule | No | | | | 05.4 05.5 |
| - | DA Receiv | | 05-4 | Apr-2019 | | Received Date | 05-Apr-2019 |
| - | TU Triage | | | | | Data Entry Date | |
| | eport Type | | | ntaneous | Repo | ort Classification | Drug |
| | ssign To | | Use | r | | | _ |
| | ser/Group | | | | | | |
| Fo | orward to [| Department | \square | CDER (CDER-OSE-RS | SS-CT | U@fda.hhs.gov) (E2B) | |
| Ca | ase Priorit | У | Dire | | | | |
| | | | | | | | |
| Сс | ntact | | | | | | |
| | ase | First Name | | Last Name | | Email Address | Phone |
| | eporter | (b) (6) | | (b) (6) | | (b) (6) | (b) (6) |
| | | _ | | | | (~) (~) | (~) (~) |
| Α. | | TINFORMATION | | (2) | | | |
| | | dentifier (In Confidence) | (b) | | | | |
| | Age | | 64 \ | /ear(s) | | | |
| | Date of E | Birth | | | | | |
| | Gender | | Fem | nale | | | |
| | Weight | | 62.1 | 9 kg | | | |
| | Ethnicity answer) | (Check single best | Not | Hispanic/Latino | | | |
| | Race (CI | neck all that apply) | | Asian | | | |
| | | | | American Indian or Alaskan Na | itive | | |
| | | | | Black or African American | | | |
| | | | $ \mathbf{\square}_{v}$ | Vhite | | | |
| | | | | Native Hawaiian or Other Pacif | ic Island | der | |
| В. | | SE EVENT, PRODUC | T PR | ROBLEM | | | |
| | Type of I apply) | Report (check all that | | Adverse Event | | | |
| | appiy) | | │∐ [ॗ] | Product Use/Medication Error | | | |
| | | | │∐ [╒] | Product Problem (e.g., defects/ | /malfunc | etions) | |
| | | | | Problem with Different Manufac | cturer of | Same Medicine | |
| | Serious | | No | | | | |
| | | Attributed to Adverse heck all that apply) | | Death | | | |
| | Lvent (O | nook all that apply) | ∐₁ | ife Threatening | | | |
| | | | Г∏ | Hospitalization (initial or prolon | ged) | | |
| | | | ାଧ୍ୟ | Other Serious or Important Med | dical Eve | ents | |
| | | | | Disability or Permanent Damag | | | |
| | | | | Congenital Anomaly/Birth Defe | | | |
| | Date of [|)eath | - F | Required Intervention to Preven | nt Perm | anent Impairment/Damage | |
| | Date Of L | Jean I | | | | | |

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CTU #: FDA-CDER-CTU-2019-40050 | Department: CDER | RCT #: RCT-287648 | CTU Triage Date: 05-Apr-2019 | AER #: 16168264 |

| Total | Pages: 7 |
|--------|----------|
| i Otai | raues. 1 |

| | Date of Event | 19-Mar-2019 | | | |
|-----|--|----------------------------|--|-------------------------|---|
| | Date of this Report | 05-Apr-2019 | | | |
| De | scribe Event, Problem or Prod | luct Use Error | | | |
| | She describes 5-day painful burni | ng sensation to upper back | ribes dysesthesias since increasing so and posterior bilateral upper arms, si d semaglutide 0.5 mg/wk without prob | milar to a sunburn. She | _ |
| Re | levant Test/Laboratory Data | | | 1 of 1 | |
| | Test Name | | Test Date | | |
| | Test Result | | Test Unit | | - |
| | Low Test Range | | High Test Range | | |
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | İ |
| | | | | | _ |
| Otl | her Relevant History, Including | Preexisting Medical Co | onditions | | ĺ |
| | | | | | |
| 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 | ı |
| | Suspect | Yes | | | |
| | Does this report involve cosmetic, dietary supplement or food/medical food? | | | | |
| | Primary? | Yes | | | |
| | Туре | 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 | | | |

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| | | 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 | 1.0 mg milligram(s) | If Other | | |
| | Frequency | Other | If Other | weekly | |
| | Route | Subcutaneous | If Other | | |
| | Dosage Form | | | <u>'</u> | |
| | Start | | | | |
| | Stop | | | | |
| | 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 4 |
| D. | Concomitant | Yes | | | 2 of 4 |
| D. | | Yes | | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or | Yes | | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? | Yes Drug/Biologic | | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? | | | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type | Drug/Biologic | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name | Drug/Biologic | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength | Drug/Biologic | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that | Drug/Biologic | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength Manufacturer/Compounder NDC# or Unique ID | Drug/Biologic Synjardy XR | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that | Drug/Biologic Synjardy XR | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that | Drug/Biologic Synjardy XR OTC Compounded | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that | Drug/Biologic Synjardy XR OTC Compounded Generic | If Other | | 2 of 4 |
| D. | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type 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 Synjardy XR OTC Compounded Generic | If Other | | 2 of 4 |
| | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type 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 Synjardy XR OTC Compounded Generic | If Other | | |
| | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type 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 Synjardy XR OTC Compounded Generic | | | 2 of 4 |
| | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type 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 Synjardy XR OTC Compounded Generic | If Other | | |
| | Concomitant Does this report involve cosmetic, dietary supplement or food/medical food? Primary? Type 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 Synjardy XR OTC Compounded Generic | | | |

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| Start | | | |
|---|-----------------------------------|----------|--------|
| Stop | | | |
| Therapy Duration | | If Other | |
| Is therapy still on-going? | | | |
| Lot Number | | | |
| Expiration Date | | | |
| Diagnosis for Use (indication) | | | 1 of 1 |
| plagificals for eac (maleation) | | | 1 01 1 |
| | | | |
| | | | |
| | | | |
| | | | |
|). PRODUCT(S) | | | 3 of 4 |
| Concomitant | Yes | | |
| Does this report involve cosmetic, dietary supplement or food/medical food? | | | |
| Primary? | | | |
| Туре | 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 ? | | | |
| orug 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) | ı | | 1 of 1 |

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| | | | | | _ |
|-----|---|---------------|--------------------|--------|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| ח | PRODUCT(S) | | | 4 of 4 | |
| D. | Concomitant | Yes | | 4014 | |
| | | res | | _ | |
| | Does this report involve cosmetic, dietary supplement or food/medical food? | | | | |
| | Primary? | | | | |
| | Туре | Drug/Biologic | | | |
| | Product Name | losartan | | | |
| | 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 | | | | |
| D. | Reintroduction ? | | | | |
| | | | | 1 ot 1 | |
| וטו | ug Therapy | | If Other | 1 of 1 | |
| וטן | Dose or Amount | | If Other | 1 of 1 | |
| וטן | Dose or Amount Frequency | | If Other | 1 of 1 | |
| וטן | Dose or Amount Frequency Route | | | 1 of 1 | |
| וטן | Dose or Amount Frequency Route Dosage Form | | If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start | | If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start Stop | | If Other If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration | | If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start Stop | | If Other If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration | | If Other If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date | | If Other If Other | | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number | | If Other If Other | 1 of 1 | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date | | If Other If Other | | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date | | If Other If Other | | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date | | If Other If Other | | |
| | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date | | If Other If Other | | |
| Di | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) | | If Other If Other | | |
| Di | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) | | If Other If Other | | |
| Di | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name | | If Other If Other | | |
| Di | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name | | If Other If Other | | |
| Di | Dose or Amount Frequency Route Dosage Form Start Stop Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name | | If Other If Other | | |

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| | 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 | FDICAL PRODUCTS | |
| | CONCOMITANT MEDICAL PROD | | |
| | | | П |
| | | | |
| | | | |
| | | | |
| G. | REPORTER | 1 of 1 | |
| | Primary? | Yes | |
| | Reporter is Patient? | | |
| | Title | | |
| | Last Name | /1 \ / (0) | |
| | Middle Name | (h) (6) | |
| | First Name | (b) (6) | |
| | Address | | |
| | City | | |
| | | | + |
| | State/Province/Region | | |
| | State/Province/Region Country | ther | |
| | <u> </u> | ther | |
| | Country | ther | |
| | Country ZIP/Postal Code | ther | |
| | Country ZIP/Postal Code Phone | ther | |

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

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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 Application #: 213051

Report:

Patient Information:

Age: 47 YR Sex: Female Weight:

Suspect Products:

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

Drug?

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 DeC ReC Lot# Exp Date NDC # MFR/Labeler OTC

Dose to Event

1 Rybelsus 14mg 28 Day No NA NOVO NORDISK

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

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



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 D | ate | Contin | uing? | | | |
| Herpes zoster | | | Nov-2019 | Nov-20 |)19 | No | | | | |
| Medical History Product(s) | | | Start Date | End D | ate | Indica | tions | | Events | |
| OZEMPIC | | | Oct-2019 | Oct-20 | 19 | Produc indicat | ct used for u ion | nknown | No advers | e event |
| Relevant Laboratory Data: | | | | | | | | | | |
| Test Name | | Result | Unit | | Normal | Low Range | Nor | mal High | Range | Info Avail |
| Concomitant Products: | | | | | | | | | | |
| # Product Name: D | Dose/Frequency | Route | | Dosage Text | St | tart Date | End Date | Indica | tion(s) | Interval 1st Dose to Event |
| Reporter Source: | | | | | | | | | | |
| Study report?: No | Sender orga | nization: | NOVO NOR | DISK | | | Compoundi urcing Faci | | | |
| Literature Text: | | | | | | | | | | |



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 Application #: 213051

Report:

Patient Information:

Age: 48 YR Sex: Male Weight:

Suspect Products:

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

Drug?

1 Rybelsus 7 Mg Milligram(S) / Oral 7 mg, qd 01-Mar-2021 Type 2 diabetes mellitus

QD

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

Dose to Event

1 Rybelsus 56 Day NA NA K082344 NOVO NORDISK

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

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



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) Indications Start Date End Date Events Relevant Laboratory Data: Test Name** Unit **Normal Low Range Normal High Range** Result Info Avail **Concomitant Products:** # Product Name: Dose/Frequency Route **Dosage Text Start Date End Date** Indication(s) Interval 1st Dose to Event **Reporter Source: 503B Compounding** Study report?: No Sender organization: **NOVO NORDISK Outsourcing Facility?:**

Literature Text:



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 Application #: 209637

Report: Yes

Patient Information:

Age: 30 YR Sex: Male Weight:

Suspect Products:

| 0 | aspect i rodacts. | | | | | | | | | |
|---|-------------------|--------------|-----|----------------|--------------|-----------------|------------|----------|---------------|---------------|
| # | Product Name: | Compoun | ded | Dose/Frequency | Route | Dosage Text | Start Date | End Date | Indication(s) |) |
| | | Drug ? | | | | | | | | |
| 1 | Ozempic | | | / | Subcutaneous | 1 mg | Oct-2021 | | Product used | d for unknown |
| | | | | | | | | | indication | |
| 2 | Ozempic | | | / | Subcutaneous | UNK (Dose Decre | eased) | | | |
| 3 | Ozempic | | | / | Subcutaneous | 2 mg | | | | |
| # | Product Name: | Interval 1st | DeC | ReC | Lot# | Exp Date | NDC # | MFR | /Labeler | ОТС |
| | | Dose to Even | t | | | | | | | |
| 1 | Ozempic | | No | NA | | | | NOV | O NORDISK | |
| 2 | Ozempic | | No | NA | | | | NOV | O NORDISK | |
| 3 | Ozempic | | No | NA | | | | NOV | O NORDISK | |

Device Products:

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



Case ID: 21901179

| 2 Ozempic | S// No | | /Other | | Event Without Device or Use | Novo Nordisk A/S |
|---|--|--|--|--|--|--|
| | | | | Problem | Device of Ose | |
| 3 Ozempic | :// No | | /Other | | Event Without | Novo Nordisk A/S |
| | | | | Identified | Device or Use | |
| | | | | Problem | | |
| Event Infor | rmation: | | | | | |
| Preferred T | Term (MedDRA Version: v.2 | .0) | | ReC | | |
| Dysaesthes | sia | | | | | |
| Arthralgia | | | | | | |
| Event/Prot | olem Narrative: | | | | | |
| ***This is and dysesthesia treated with | a)" with an unspecified onset d n Ozempic (SEMAGLUTIDE) fr | his non-serious Spontaneous c ate, "arthralgia(Arthralgia)" with om OCT-2021 and ongoing for bot Reported (| an unspecified onset date, Drug use for unknown indi | and concerned a 30 Years cation", Dosage Regimens | s old Male pations: Ozempic: ?? | ent who was -OCT-2021 to Not |
| ***This is an dysesthesia treated with Reported, N ASKU, ASK recovered. Novo-2022 | a)" with an unspecified onset d n Ozempic (SEMAGLUTIDE) fr Not Reported to Not Reported, KU, ASKU Action taken to Oze The outcome for the event "ar | ite, "arthralgia(Arthralgia)" with | an unspecified onset date, Drug use for unknown indi Dosage Regimen Ongoing reased. The outcome for the overed. References include | and concerned a 30 Years cation", Dosage Regimens); Medical history was not ne event "Skin dysesthesia ed: Reference Type: E2B I | s: Old Male pations: Ozempic: ?? provided. Batca (Skin dysesthe Report Duplicate) | ent who was -OCT-2021 to Not h Numbers: Ozempi esia)" was Not |
| ***This is andysesthesia treated with Reported, NASKU, ASK recovered. Novo-2022* | a)" with an unspecified onset don Ozempic (SEMAGLUTIDE) from Not Reported to Not Reported, KU, ASKU Action taken to Oze The outcome for the event "are 1002453 Reference Notes: N | ate, "arthralgia(Arthralgia)" with om OCT-2021 and ongoing for ' Not Reported to Not Reported (Inpic was reported as Dose Dec Inralgia(Arthralgia)" was Not rec | an unspecified onset date, Drug use for unknown indi Dosage Regimen Ongoing reased. The outcome for the overed. References include number Reference ID#: US | and concerned a 30 Years cation", Dosage Regimens); Medical history was not ne event "Skin dysesthesia ed: Reference Type: E2B I | s: Old Male pations: Ozempic: ?? provided. Batca (Skin dysesthe Report Duplicate) | ent who was -OCT-2021 to Not h Numbers: Ozempi esia)" was Not |
| ***This is an dysesthesia treated with Reported, NASKU, ASK recovered. Novo-2022* Relevant M Disease/Su | a)" with an unspecified onset don Ozempic (SEMAGLUTIDE) from Not Reported to Not Reported, KU, ASKU Action taken to Oze The outcome for the event "ar 1002453 Reference Notes: Noted Ideal History: | ate, "arthralgia(Arthralgia)" with om OCT-2021 and ongoing for Not Reported to Not Reported (Inpic was reported as Dose Dec Inralgia(Arthralgia)" was Not rec Or Reference Type: SIMS case | an unspecified onset date, Drug use for unknown indi Dosage Regimen Ongoing reased. The outcome for the overed. References include number Reference ID#: US | and concerned a 30 Years cation", Dosage Regimens); Medical history was not ne event "Skin dysesthesia ed: Reference Type: E2B I S-Novo-20221002453 Refe | s: Old Male pations: Ozempic: ?? provided. Batca (Skin dysesthe Report Duplicate) | ent who was -OCT-2021 to Not h Numbers: Ozemp esia)" was Not te Reference ID#: U |
| ***This is and dysesthesia treated with Reported, NASKU, ASK recovered. Novo-2022* Relevant M Disease/Su Medical His | a)" with an unspecified onset don Ozempic (SEMAGLUTIDE) from Not Reported to Not Reported, KU, ASKU Action taken to Ozem The outcome for the event "ar 1002453 Reference Notes: Noted Ideal History: urgical Procedure | ate, "arthralgia(Arthralgia)" with om OCT-2021 and ongoing for Not Reported to Not Reported (npic was reported as Dose Decoralgia(Arthralgia)" was Not recore Reference Type: SIMS case Start Date | an unspecified onset date, Drug use for unknown indi Dosage Regimen Ongoing reased. The outcome for the overed. References include number Reference ID#: US | and concerned a 30 Years cation", Dosage Regimens); Medical history was not ne event "Skin dysesthesia ed: Reference Type: E2B FS-Novo-20221002453 Reference Type: Continuing? | s old Male pations: Ozempic: ?? provided. Batca(Skin dysesther Report Duplications of the Notes: | ent who was -OCT-2021 to Not h Numbers: Ozemp esia)" was Not te Reference ID#: U |



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:



Case ID: 22272286

Case Information:

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

Day)

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

Report: Yes

Patient Information:

Age: 63 YR Sex: Male Weight:

Suspect Products:

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

Drug?

1 Ozempic 2 mg 2 Mg Milligram(S) // Subcutaneous 2 mg, qw 01-Feb-2023 Diabetes mellitus

WK

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

Dose to Event

1 Ozempic 2 mg 76 Day NA NA MP5D954 NOVO NORDISK

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

1 Ozempic 2 mg// No /Other Adverse Event Without Novo Nordisk A/S

Identified Device or Use

Problem

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 |

| Releva | ınt Lal | borato | rv Data: |
|--------|---------|--------|----------|
|--------|---------|--------|----------|

| Test Name | Result | Unit | Normal Low Range | Normal High Range | Info Avail |
|---------------------------------|--------|------|------------------|-------------------|------------|
| MAGNETIC RESONANCE IMAGING HEAD | | | | | Υ |

Concomitant Products:



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:



Case ID: 22333699

Case Information:

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

Day)

FDA Rcvd Date: 19-Jun-2023 Mfr Rcvd Date: 06-Jun-2023 Mfr Control #: US- Combination Product Application #: 215866

ELI_LILLY_AND_COMPANY- Report: Yes

US202305008305

Patient Information:

Age: 49 YR Sex: Male Weight: 92.1 KG

Suspect Products:

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

Drug?

1 Mounjaro //WK Subcutaneous UNK UNK, weekly (1/ 10067585

W)

2 Mounjaro 7.5 Mg Milligram(S) / / Subcutaneous 7.5 mg, weekly (1/W)

WK

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

Dose to Event

1 Mounjaro Yes NA ELI LILLY AND CO

2 Mounjaro Yes NA ELI LILLY AND CO

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

1 /TIRZEPATIDE PEN (UNKNOWN)/ No / Adverse Event Without Eli Lilly and Company

NSC Identified Device or Use

Problem



Case ID: 22333699

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

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 (Mouniaro), via pre-filled pen (autoiniector), 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:



Case ID: 22333699

Disease/Surgical Procedure Continuing? **Start Date End Date** 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** Unit **Normal Low Range Normal High Range** Result Info Avail Υ 10005809 Υ 10050318 10057434 Υ **Concomitant Products:** # Product Name: Dose/Frequency **Dosage Text End Date** Interval 1st Route Start Date Indication(s) Dose to Event 1 CRESTOR 20 Mg Milligram(S) / QD Oral 10057097 20 mg, daily 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?:



Case ID: 22333699

Literature Text:



Case ID: 22528366

Case Information:

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

Day)

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

Report:

Patient Information:

Age: 35 YR Sex: Male Weight:

Suspect Products:

| # | Product Name: | Compounded | Dose/Frequency | Route | Dosage Text | Start Date | End Date | Indication(s) |
|---|-------------------------|----------------|-----------------------|-----------------|-------------|-------------|-------------|---------------|
| | | Drug ? | | | | | | |
| 1 | Wegovy FlexTouch 1.0 mg | 9 | 0.25 Mg | Subcutaneous | 0.25 mg, qw | Dec-2022 | | Obesity |
| | | | Milligram(S) / /WK | | | | | |
| 2 | Wegovy FlexTouch 1.0 mg | 9 | 0.5 Mg Milligram(S) / | // Subcutaneous | 0.5 mg, qw | | | |
| | | | WK | | | | | |
| 3 | Wegovy FlexTouch 1.0 mg | 9 | 1.7 Mg Milligram(S) | // Subcutaneous | 1.7 mg, qw | | 17-Apr-2023 | |
| | | | WK | | | | | |
| 4 | Wegovy FlexTouch 1.0 mg | 9 | 1 Mg Milligram(S) // | Subcutaneous | 1 mg, qw | | | |
| | | | WK | | | | | |
| 5 | Wegovy FlexTouch 2.4 mg | 9 | 2.4 Mg Milligram(S) / | // Subcutaneous | 2.4 mg, qw | 17-Apr-2023 | 05-May-2023 | Obesity |
| | | | WK | | | | | |
| # | Product Name: Int | terval 1st DeC | ReC | Lot# | Exp Date | NDC # | MFR/ | Labeler OTC |
| | Do | ose to Event | | | | | | |
| 1 | Wegovy FlexTouch 1.0 | NA | NA | | | | NOVO | NORDISK |
| | mg | | | | | | | |
| 2 | Wegovy FlexTouch 1.0 | NA | NA | | | | NOVO | NORDISK |
| | mg | | | | | | | |



Case ID: 22528366

| 3 | Wegovy FlexTouch 1.0 | NA | NA | NOVO NORDISK |
|---|----------------------|-----|----|--------------|
| | mg | | | |
| 4 | Wegovy FlexTouch 1.0 | NA | NA | NOVO NORDISK |
| | mg | | | |
| 5 | Wegovy FlexTouch 2.4 | Yes | NA | NOVO NORDISK |
| | mg | | | |

Device Products:

| # | Brand Name / Common Device | Similar | Malfunction ? Device Lot# | Device Usage/ | Remedial Action | Device Problem | Manufacturer Name |
|---|----------------------------|---------|---------------------------|--------------------|-----------------|----------------|-------------------|
| | Name / Product Code | Device? | | Operator of Device | | | |
| 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 described 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 described 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

Obesity

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: 22528366

| Test Name BIOPSY KIDNEY GLOMERULAR FILTRAT PROTEIN URINE | ION RATE | Result | Unit | Normal Low Range | Normal High Range | Info Avail Y Y Y |
|--|----------------|--------------|-------------|------------------|--------------------------------|-------------------------------|
| Concomitant Products: # Product Name: | Dose/Frequency | Route | Dosage Text | Start Date Er | nd Date Indication(s) | Interval 1st Dose to Event |
| Reporter Source: Study report?: No | Sender orga | anization: N | OVO NORDISK | | ompounding rcing Facility?: | |



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- Combination Product Application #:

CTU-2023-48325 **Report**: No

Patient Information:

Age: 62 YR Sex: Male Weight: 92.25 KG

Suspect Products:

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

Drug?

1 Wegovy 2.4 Mg Milligram(S) / Subcutaneous Frequency: Weekly; 18-Jan-2023 Obesity

QW

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

Dose to Event

1 Wegovy Not Applicable Not Applicable Not Applicable NOVO NORDISK

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

1 // No /

Event Information:

Preferred Term (MedDRA Version: v.27.0) ReC

Dysaesthesia

Paraesthesia NA

Event/Problem Narrative:



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 |
|----------------------------|------------|----------|-------------|--------|
|----------------------------|------------|----------|-------------|--------|

| R | e | ev | ant | La | boı | at | ory | / Da | ta: |
|---|---|----|-----|----|-----|----|-----|------|-----|
|---|---|----|-----|----|-----|----|-----|------|-----|

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

Concomitant Products:

| C | oncomitant 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 | 1 | | | | | | |
| | | | | | | | | |

Reporter Source:



Case ID: 22655639

Study report?: No Sender organization: FDA-CTU

503B Compounding Outsourcing Facility?:

Literature Text:

CTU #: FDA-CDER-CTU-2023-48325 | Department: CDER | RCT #: RCT-1143494 | CTU Triage Date: 29-Jun-2023 | AER #: 22655639

| Total Pages: 9

| All c | dates display | red in the report are in EST(G | MT-05 | i:00) time zone | | | | | |
|---------------|----------------|--------------------------------|---|------------------------------------|--------------|---------------------|--------------|-------------|--|
| Ва | isic Detai | ils | | | | | | | |
| C | ompany U | nit | CD | ER-CTU | Origi | Originating Account | | FAERS | |
| Source Medium | | MW | /O (Drug) | Sour | ce Form Type | | E2B XML 3500 | | |
| Pı | riority | | Rou | Routine | | | | | |
| 0 | verride Au | to Calculation Rule | No | | | | | | |
| FI | DA Receiv | ed Date | 29- | Jun-2023 | CTU | Received Date | | 29-Jun-2023 | |
| C. | TU Triage | Date | | | CTU | Data Entry Date | | | |
| R | eport Type | ; | Spc | ontaneous | Repo | ort Classification | | Drug | |
| As | ssign To | | Use | er | | | , | | |
| U | ser/Group | | | | | | | | |
| Fo | orward to [| Department | | 1 | | | | | |
| C | ase Priorit | y | Dire | | | | | | |
| | | | | | | | | | |
| Сс | ntact | | | | | | | | |
| | ase eporter | First Name | | Last Name | | Email Address | | Phone | |
| V | | (b) (6) | | (b) (6) | | (b) (6) | | (b) (6) | |
| Α. | PATIEN' | T INFORMATION | | | | | | | |
| | 1 | dentifier (In Confidence) | (b) | (6) | | | | | |
| | Age | | _ | Year(s) | | | | | |
| | Date of E | Birth | | (-) | | | | | |
| | Sex | | Mal | <u> </u> | | | | | |
| | Gender | | Cisgender man/boy | | | | | | |
| | | Specify Other Gender | 0.0, | olegenus manasy | | | | | |
| | Weight | ,poony care. Conce. | 92 : | 92.25 kg | | | | | |
| | | (Check single best | Not Hispanic/Latino | | | | | | |
| | , | neck all that apply) | Asian | | | | | | |
| | | | American Indian or Alaska Native | | | | | | |
| | | | American Indian or Alaska Native Black or African American | | | | | | |
| | | | | White | | | | | |
| | | | Native Hawaiian or Other Pacific Islander | | | | | | |
| В. | ADVERS | SE EVENT, PRODUC | T PF | ROBLEM | | | | | |
| | | Report (check all that | \square | Adverse Event | | | | | |
| | apply) | | | Product Use/Medication Error | | | | | |
| | | | | Product Problem (e.g., defects | /malfund | ctions) | | | |
| | | | Problem with Different Manufacturer of Same Medicine | | | | | | |
| | Serious | | No | | | | | | |
| | | Attributed to Adverse | | Death | | | | | |
| | Event (C | heck all that apply) | | Life Threatening | | | | | |
| | | | | Hospitalization (initial or prolon | iged) | | | | |
| | | | | Other Serious or Important Me | dical Ev | ents | | | |
| | | | | Disability or Permanent Damad | ae | | | | |

Generated by: SYSTEM Generated on: 29-Jun-2023 12:45:41 Page 1 of 9

CTU #: FDA-CDER-CTU-2023-48325 | Department: CDER | RCT #: RCT-1143494 | CTU Triage Date: 29-Jun-2023 | AER #: 22655639 | Total Pages: 9

| | Congenital Anomaly/Birth Def | ects | | | | | |
|---|-------------------------------------|---------------------------------|-------------------------------|--|--|--|--|
| | Required Intervention to Prevention | ent Permanent Impairment/Damage | | | | | |
| Date of Death | | | | | | | |
| Date of Event | 28-Jun-2023 | | | | | | |
| Date of this Report | 29-Jun-2023 | | | | | | |
| Describe Event, Problem or Prod | | | | | | | |
| Describe Event, Problem, or Prod needles" sensation mostly in the t has persisted for the last 2 months | runk but also in the limbs tha | | | | | | |
| 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 Also taking atorvastatin 20 mg, mg 0.005% ou qd | | | 3 ASA, latanoprost ophthalmic | | | | |
| | | | | | | | |
| 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 | | | | | | |
| Туре | Drug/Biologic | | | | | | |
| This report involves: | Other | | | | | | |
| Name,Strength,Manufacturer/Co | mpounder (from product | label) | | | | | |
| Product Name | Wegovy | | | | | | |
| Strength | 2.4 mg milligram(s) | If Other | | | | | |
| Manufacturer/Compounder | Novo Nordisk | | | | | | |
| NDC# or Unique ID | | | | | | | |

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CTU #: FDA-CDER-CTU-2023-48325 | Department: CDER | RCT #: RCT-1143494 | CTU Triage Date: 29-Jun-2023 | AER #: 22655639

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| | 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 | 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 | | | | |
| Dia | agnosis for Use (indication) | | | 1 of 1 | |
| | | | | | _ |
| D. | PRODUCT(S) | | | 2 of 7 | |
| | Concomitant | Yes | | | |
| | Primary? | | | | |
| | Туре | Drug/Biologic | | | |
| | This report involves: | | | | |
| Na | nme,Strength,Manufacturer/Co | mpounder (from produc | ct 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 ? | | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Dose or Amount | | If Other | | |

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| | 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 | | | | |
| Dia | agnosis for Use (indication) | | | 1 of 1 | |
| | | | | | |
| | | | | | |
| D. | PRODUCT(S) | | | 3 of 7 | |
| | Concomitant | Yes | | | |
| | Primary? | | | | |
| | Туре | Drug/Biologic | | | |
| | This report involves: | <u> </u> | | | |
| Na | me,Strength,Manufacturer/Co | mpounder (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 ? | | | | |
| Dru | ug 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 | | | | |

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| | Expiration Date | | | |
|-----|---|--------------------------|----------|--------|
| Dia | agnosis for Use (indication) | | | 1 of 1 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| D. | PRODUCT(S) | | | 4 of 7 |
| | Concomitant | Yes | | |
| | Primary? | | | |
| | Туре | Drug/Biologic | | |
| | This report involves: | | | |
| Na | me,Strength,Manufacturer/Co | mpounder (from product | label) | |
| | Product Name | Atorvastatin 20 mg daily | | |
| | 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 | |
| | 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 | | | |
| Dia | agnosis for Use (indication) | | | 1 of 1 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| D. | PRODUCT(S) | | | 5 of 7 |
| | Concomitant | Yes | | |
| | Primary? | | | |

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| | Туре | Drug/Biologic | | | |
|-----|---|-----------------------------------|----------|--------|---|
| | This report involves: | | | | |
| Na | ame,Strength,Manufacturer/Co | mpounder (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 ? | | | | |
| 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) | | | 6 of 7 | |
| | Concomitant | Yes | | | |
| | Primary? | | | | |
| | Туре | Drug/Biologic | | | |
| | This report involves: | | _ | | |
| Na | me,Strength,Manufacturer/Co | mpounder (from product | label) | | |
| | Product Name | latanoprost 0.005% daily C | U | | |
| | Strength | | If Other | | |
| | Manufacturer/Compounder | | | | |
| | NDC# or Unique ID | | | | |
| | Product Type(check all that apply) | OTC Compounded | | | |

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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 | | | |
| | Stop | | | |
| | Dose Reduced | | | |
| | Therapy Duration | | If Other | |
| | Is therapy still on-going? | | • | |
| | Lot Number | | | |
| | Expiration Date | | | |
| <u> </u> | agnosis for Use (indication) | | | 1 of 1 |
| Dia | | | | |
| Dia | | | | |
| | PRODUCT(S) | | | 7 of 7 |
| | PRODUCT(S) Concomitant | Yes | | 7 of 7 |
| | | Yes | | 7 of 7 |
| | Concomitant | Yes Drug/Biologic | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: | Drug/Biologic | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: ame,Strength,Manufacturer/Co | Drug/Biologic mpounder (from pro | duct label) | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: ame,Strength,Manufacturer/Co Product Name | Drug/Biologic | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: Ime,Strength,Manufacturer/Co Product Name Strength | Drug/Biologic mpounder (from pro | duct label) | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder | Drug/Biologic mpounder (from pro | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: ame,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID | Drug/Biologic mpounder (from pro | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: me,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder | Drug/Biologic mpounder (from pro | | 7 of 7 |
| D. | 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 pro Amlodipine 2.5 mg OTC Compounded Generic | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: Ime,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 pro Amlodipine 2.5 mg OTC Compounded Generic | | |
| D. | Concomitant Primary? Type This report involves: Ime,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 pro Amlodipine 2.5 mg OTC Compounded Generic | | 7 of 7 |
| D. | Concomitant Primary? Type This report involves: Ime,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 pro Amlodipine 2.5 mg OTC Compounded Generic | | |
| D. | Concomitant Primary? Type This report involves: Ime,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 pro Amlodipine 2.5 mg OTC Compounded Generic | If Other | |

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226756630 No: RCT-1143494 FDA 3500 Form

CTU #: FDA-CDER-CTU-2023-48325 | Department: CDER | RCT #: RCT-1143494 | CTU Triage Date: 29-Jun-2023 | AER #: 22655639

| CTU #. FDA-CDER-CTU-2023-40323 | Department, CDER | NO | #. KCT- | 1143494 | CIU | Thage Date. | 29-Juli-20 |
|--------------------------------|------------------|----|---------|---------|-----|-------------|------------|
| Total Pages: 9 | | | | | | | |

| | Dosage Form | | | | |
|----|---|--|----------|---|--------|
| | Start | 01-Jan-2015 | | | |
| | Stop | | | | |
| | Dose Reduced | | | | |
| | Therapy Duration | | If Other | | |
| | Is therapy still on-going? | | | , | |
| | Lot Number | | | | |
| | Expiration Date | | | | |
| Di | agnosis for Use (indication) | | | | 1 of 1 |
| | | | | | |
| Ε. | 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

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| G. | . REPORTER | | | | 1 of 1 | |
|----|--|--------------------|----------|---|--------|--|
| | Primary? | Yes | | | | |
| | Reporter is Patient? | | | | | |
| | Title | | | | | |
| | Last Name | / \ | 101 | | | |
| | Middle Name | | | | | |
| | First Name | (b) | | | | |
| | 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/Compo | bunder | | | |
| | If you do NOT want your identity disclosed to the manufacturer | Yes | | | | |

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Case ID: 22734945

Case Information:

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

Day)

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

Report:

Patient Information:

Age: 56 YR Sex: Female Weight: 121 KG

Suspect Products:

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

Drug?

1 Wegovy FlexTouch 0.25 0.25 Mg Subcutaneous 0.25 mg, qw 20-Mar-2023 28-Mar-2023 Overweight

mg Milligram(S) / /WK

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

Dose to Event

1 Wegovy FlexTouch 7 Day No NA NOVO NORDISK

0.25 mg

Device Products:

Brand Name / Common Device Similar Malfunction ? Device Lot# Device Usage/ Remedial Action Device Problem Manufacturer Name

Name / Product Code Device? Operator of Device

1 // No

Event Information:

Preferred Term (MedDRA Version: v.27.0) ReC

Hypersensitivity

Fatigue

Ocular hyperaemia



Case ID: 22734945

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, antibhospholipid antibody syndrome and secondary si? 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)



Case ID: 22734945

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 (ioint/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 |



Case ID: 22734945

| Medical History Product(s) | | Start Date | End Date | Indicatio | ons | Events | |
|--------------------------------|----------|------------|----------|---------------|------------------|-----------------|--------------|
| Relevant Laboratory Data: | | | | | | | |
| Test Name | Result | Unit | Norn | nal Low Range | Normal High | Range | Info Avail |
| ANTIBODY TEST | | | | | | | Υ |
| BLOOD PRESSURE MEASUREMENT | | | | | | | Υ |
| C-REACTIVE PROTEIN | | | | | | | Υ |
| DERMATOLOGIC EXAMINATION | | | | | | | Υ |
| DOUBLE STRANDED DNA ANTIBODY | | | | | | | Υ |
| HAEMOGLOBIN | | | | | | | Υ |
| INVESTIGATION | | | | | | | Υ |
| INVESTIGATION | | | | | | | Υ |
| INVESTIGATION | | | | | | | Υ |
| INVESTIGATION | | | | | | | Υ |
| LYMPHOCYTE COUNT | | | | | | | Υ |
| NEUROLOGICAL EXAMINATION | | | | | | | Υ |
| OPHTHALMOLOGICAL EXAMINATION | | | | | | | Υ |
| OPHTHALMOLOGICAL EXAMINATION | | | | | | | Υ |
| PROTEIN URINE | | | | | | | Υ |
| RHEUMATOLOGICAL EXAMINATION | | | | | | | Υ |
| Concomitant Products: | | | | | | | |
| # Product Name: Dose/Frequence | cy Route | Dos | age Text | Start Date E | nd Date Indicati | on(s) | Interval 1st |
| | | | | | | | Dose to Ev |
| 1 LOSARTAN / | | UNI | (| 30-Apr-2015 | Hyperte | nsion | 2888 Day |
| 2 SIMVASTATIN / | | UNI | (| 20-Apr-2012 | Hyperch | nolesterolaemia | 3993 Day |
| 3 EUTHYROX / | | UNI | (| 10-Mar-2011 | Hypothy | /roidism | 4400 Day |



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: