COMPANY ANNOUNCEMENT

Viatrexx Bio Incorporated Issues Voluntary Nationwide Recall of Sterile Injectables due to a Lack of Sterility Assurance

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Summary

Company Announcement Date:
October 15, 2019

FDA Publish Date:
October 15, 2019

Product Type:
Drugs

Reason for Announcement:
Lack of sterility assurance

Company Name:
Viatrexx Bio Incorporated

Brand Name:
Viatrexx

Product Description:
Sterile injectable products

Company Announcement

Viatrexx Bio Incorporated, Newark, Delaware is voluntarily recalling 10 mL sterile injectable vials of products, listed in the table below with lot numbers, to the consumer level. The products were sold exclusively to practitioners for office use. The products were manufactured in a manner that cannot guarantee its sterility.
Administration of a non-sterile product, intended to be sterile, may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity, or a fatal outcome. To date, Viatrexx has not received any reports of adverse events related to this recall.

The products are used as sterile injectables and packaged in a 10 mL vial. The affected lots are included in the table.

<table>
<thead>
<tr>
<th>Lot #</th>
<th>Exp</th>
<th>Product</th>
<th>NDC #</th>
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<td>19-S00026</td>
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<td>Facial</td>
<td>73069-164-4Z</td>
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</table>

These products have a very limited distribution to less than 32 US practitioners. They are only for the 10mL sterile injectable products.
Viatrexx is notifying its customers by email and phone and is arranging for the return and replacement of all recalled products. Practitioners that have any of the 10 mL sterile injectable product which is being recalled should stop using/return to Viatrexx or discard.

Consumers with questions regarding this recall can contact Viatrexx by calling 450-536-1295 or info@viatrexx.com, from Monday to Friday, between 9 am to 3 pm EST (closed between 1 and 2 pm EST). Consumers should contact their physician if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/forms-reporting-fda) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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**Company Contact Information**

**Consumers:**
Viatrexx

tel 450-536-1295

email info@viatrexx.com

**Media:**
Stephen Emond or Barry Saunders

tel 450-536-1295

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**Product Photos**
Viatrexx Bio Incorporated Issues Voluntary Nationwide Recall of Sterile Injectables due to a Lack of Sterility Assurance

Viatrexx-Articula
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC, & Parenteral Use
Preserved with Benzyl Alcohol
Osmolarity around 0.3mOsmol/mL
See insert for product details.
Monograph at www.viatrexx.com

Date opened: ________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 88 F) and dry place. Refrigerate after first use (38 to 46 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8852

Viatrexx-Arthros
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral Use
Preserved with Benzyl Alcohol
Osmolarity around 0.3mOsmol/mL
See insert for product details.
Monograph at www.viatrexx.com

Date opened: ________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 88 F) and dry place. Refrigerate after first use (38 to 46 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8852

Viatrexx-Adipose
Rx 10 ml Sterile multi-dose Injectable. For IV, ID, IM, SC & Parenteral Use
Preserved with Benzyl Alcohol
Osmolarity around 0.3mOsmol/mL
See insert for product details.
Monograph at www.viatrexx.com

Date opened: ________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 88 F) and dry place. Refrigerate after first use (38 to 46 F).

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**Viatrexx-Collagen**

Rx 10 ml
Sterile multi-dose injectable
For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol
Osmolarity around 0.3 mOsm/Lml.
See insert for product details.
Monograph at [www.viatrexx.com](http://www.viatrexx.com)

Date opened: __________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 88 F) and dry place. Refrigerate after first use (36 to 46 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

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**Viatrexx-Connectissue**

Rx 10 ml Sterile multi-dose injectable. IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol
Osmolarity around 0.3 mOsm/Lml.
See insert for product details.
Monograph at [www.viatrexx.com](http://www.viatrexx.com)

Date opened: __________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 88 F) and dry place. Refrigerate after first use (36 to 46 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

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**Viatrexx-Facial**

Rx 10 ml Sterile multi-dose injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol
Osmolarity around 0.3 mOsm/Lml.
See insert for product details.
Monograph at [www.viatrexx.com](http://www.viatrexx.com)

Date opened: __________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 88 F) and dry place. Refrigerate after first use (36 to 46 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652
Date opened: __________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 68 F) and dry place. Refrigerate after first use (36 to 48 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

NDC: 73069-189-41  Item: VSPC0211
Viatrexx-GI
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/ml.
See insert for product details.
Monograph at www.viatrexx.com

Date opened: __________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 68 F) and dry place. Refrigerate after first use (36 to 48 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

NDC: 73069-249-41  Item: VSPC0279
Viatrexx-Infla
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/ml.
See insert for product details.
Monograph at www.viatrexx.com

Date opened: __________
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 68 F) and dry place. Refrigerate after first use (36 to 48 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

NDC: 73069-250-41  Item: VSPC0280
Viatrexx-Intra-Cell
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/ml.
See insert for product details.
Monograph at www.viatrexx.com
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Viatrexx-Ithurts
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/mL
See insert for product details.
Monograph at www.viatrexx.com

Date opened: 
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 68 F) and dry place. Refrigerate after first use (36 to 46 F).

Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

Viatrexx-Immunexx
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/mL
See insert for product details.
Monograph at www.viatrexx.com

Date opened: 
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 68 F) and dry place. Refrigerate after first use (36 to 46 F).

Viatrexx Bio Incorporated
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info@viatrexx.com
Phone: 1-888-743-8652

Viatrexx-Lymph 1
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/mL
See insert for product details.
Monograph at www.viatrexx.com

Date opened: 
Discard 10 days after first puncture or sooner if signs of contamination.
Store in a cool (50 to 68 F) and dry place. Refrigerate after first use (36 to 46 F).

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Viatrexx Bio Incorporated
Newark, DE, USA, 19713
info@viatrexx.com
Phone: 1-888-743-8652

Lot #:  
Expiry Date:  

Viatrexx-Ouch
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/mL
See insert for product details. Monograph at www.viatrexx.com

Viatrexx-Prolo
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/mL
See insert for product details. Monograph at www.viatrexx.com

Viatrexx-Relief +
Rx 10 ml Sterile multi-dose Injectable. For IV, IM, SC & Parenteral use
Preserved with Benzyl Alcohol Osmolarity around 0.3mOsmol/mL
See insert for product details. Monograph at www.viatrexx.com
