DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Par Pharmaceutical Issues Voluntary Nationwide Recall of One Lot of Treprostinil Injection Due to Potential for Silicone Particulates in the Product Solution

03/12/2024

FOR IMMEDIATE RELEASE – March 12, 2024 – DUBLIN, Ireland – Endo International plc announced today that one of its operating companies, Par Pharmaceutical, Inc. (Par), is voluntarily recalling one lot of Treprostinil Injection 20mg/20mL (1mg/mL) to the consumer level. The product is being recalled due to the potential for the presence of silicone particulates in the product solution.

Administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Par has not received any reports of adverse events related to this recall.

Treprostinil Injection is formulated for subcutaneous or intravenous infusion. The product is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension to diminish symptoms associated with exercise and for patients who require transition from epoprostenol to reduce the rate of clinical deterioration.

Treprostinil Injection 20mg/20mL (1mg/mL) is distributed in 20mL multidose vials as sterile solutions in water for injection, individually packaged in cartons under NDC #42023-206-01. Only Lot 57014, expiration date 04/2024 is affected by this recall. The lot was distributed nationwide to wholesalers and hospitals from June 16, 2022, through October 17, 2022.

Vials from the affected lot bear this label: [see below]

Par is providing written notification to wholesale accounts and the hospital location that have received the affected lot and is arranging for return of all existing inventory of Lot 57014 through Inmar, Inc. Wholesale distributors and hospital pharmacies that have the product being recalled should immediately discontinue use and stop distribution immediately. If you have further distributed the recalled product, please notify your accounts or any additional locations which may have received the recalled product.

For information regarding the recall process, call Inmar, Inc. at 1-855-410-3565 Monday through Friday between the hours of 9 am and 5 pm EST. For medical or technical product information or to report a product complaint or adverse event please call 1-800-828-9393.

Consumers should contact their physician or healthcare provider 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

- Regular Mail or Fax: Download form 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.

Company Contact Information

Consumers:

Inmar, Inc.

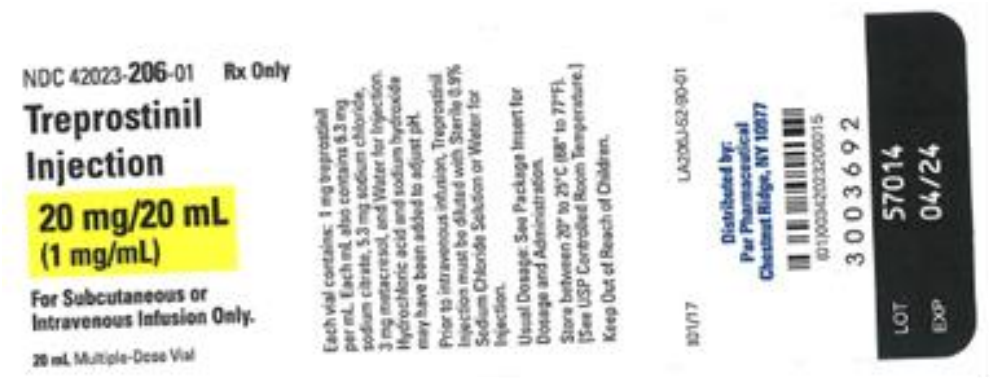
1-855-410-3565

Media:

Linda Huss

media.relations@endo.com

Product Photos:

- 

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/par-pharmaceutical-issues-voluntary-nationwide-recall-one-lot-treprostinil-injection-due-potential?utm_medium=email&utm_source=govdelivery