Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-013-CG
March 18, 2024

FDA announced that 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.

RECOMMENDATIONS

1. 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.

2. 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**.

3. 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.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

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

SUMMARY:

Company Announcement Date:	March 12, 2024
FDA Publish Date:	March 12, 2024
Product Type:	Drugs
Reason for Announcement:	Potential Presence of Silicone Particulate Matter
Company Name:	Endo International, Par Pharmaceutical
Brand Name:	Par Pharmaceutical
Product Description:	Treprostinil 20mg/20mL Injection

COMPANY ANNOUNCEMENT

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.

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Vials from the affected lot bear the label shown below:

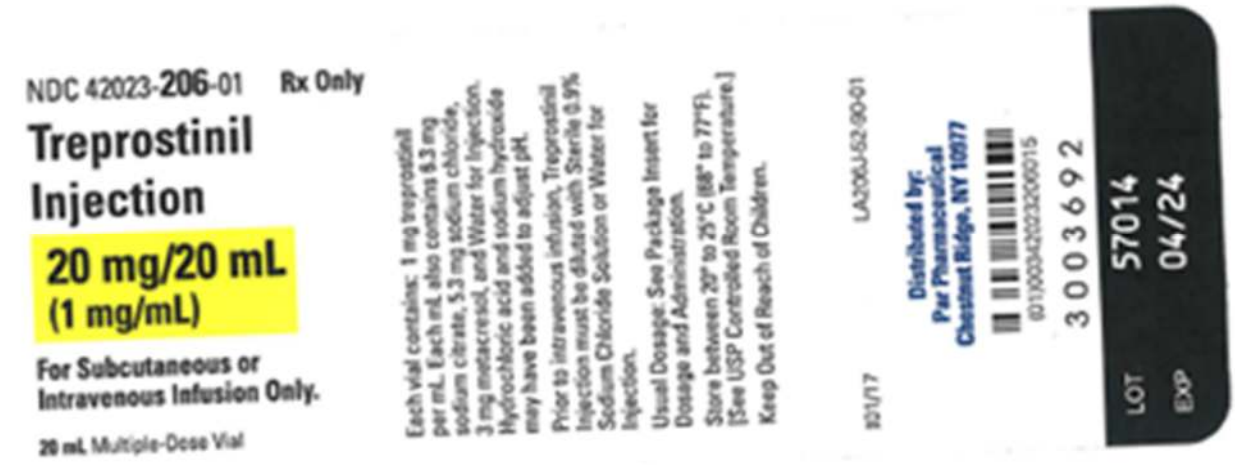
Par is providing written notification to wholesale accounts and the hospital location that have received the affected lot and is arranging for return of all existing inventory of Lot 57014 through Inmar, Inc. Wholesale distributors and hospital pharmacies that have the product being recalled should immediately 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**



T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com