Par Issues Voluntary Nationwide Recall of One Lot of Treprostinil Injection Due to Potential for Silicone Particulates

Date: 03/12/2024

About this recall:
Par is voluntarily recalling one lot of Treprostinil injection 20 mg/20 mL (1 mg/mL) to the consumer level. The product is being recalled due to the potential for silicone particulates in the solution. Treprostinil injection 20 mg/20 mL is supplied in 20 mL 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 impacted by this recall. This lot was distributed nationwide to wholesalers and hospitals from June 16, 2022 through October 17, 2022.

Treprostinil injection can be given under the skin or as an intravenous (IV) infusion. The product is a prostacyclin vasodilator FDA-approved for the treatment of pulmonary arterial hypertension (PAH) to decrease symptoms associated with exercise as well as for patients who require transition from epoprostenol to reduce the rate of clinical deterioration.

What this means to you:
Administration of an injectable product that contains particulates may result in local irritation or swelling due to the foreign material. If the particulate reaches the blood vessels, it can travel to various organs and block blood flow in the heart, lungs, or brain which can lead to stroke and could result in death. Consumers should contact their healthcare provider if they have experienced any problems that may be related to using this drug product.

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

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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/par-pharmaceutical-issues-voluntary-nationwide-recall-one-lot-treprostinil-injection-due-potential

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.