

March 12, 2024



Par issues voluntary nationwide recall of 1 lot of treprostinil injection due to potential for silicone particulates

At Prime Therapeutics Management, we want to help you receive the best possible care. Visit **[PrimeTherapeutics.com/DrugRecalls](https://www.PrimeTherapeutics.com/DrugRecalls)** to review the latest FDA drug recalls.

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 number 57014 (expiration date 04/2024) is impacted by this recall. This lot was distributed nationwide to wholesalers and hospitals from June 16, 2022, through Oct. 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 health care 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 **855.410.3565**, Monday–Friday, 9 a.m.–5 p.m. Eastern Standard Time (EST). For medical product information or to report a product complaint or adverse event, please call **800.828.9393**.