



## Par Pharmaceutical Issues Voluntary Nationwide Recall of Seven Lots of Treprostinil Injection Due to Potential for Silicone Particulates in the Product Solution

April 22, 2024

DUBLIN, April 22, 2024 /PRNewswire/ -- Endo International plc announced today that one of its operating companies, Par Pharmaceutical, Inc. (Par), is expanding its voluntary recall to include seven lots 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. The following lots are affected by this recall:

Product	NDC	Lot #	Exp. Date
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	57014	04/2024
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	56911	04/2024
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	58528	05/2024
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	58529	05/2024
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	60064	07/2024
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	60075	07/2024
Treprostinil Injection 20mg/20mL (1mg/mL)	42023-206-01	67939	03/2025

The lots were distributed nationwide to wholesalers and hospitals from June 16, 2022 through August 7, 2023.

See labels of vials from the affected lots [here](#).

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 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:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) 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.

#### **About Endo**

Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at [www.endo.com](http://www.endo.com) or connect with us on [LinkedIn](#).

#### **Cautionary Note Regarding Forward-Looking Statements**

Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation, including, but not limited to, statements with respect to the voluntary recall of Treprostinil Injection, the reasons for and the risks associated with the recall, the potential for adverse events and adverse event reporting, communications with and responses from regulators, and any other statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "outlook," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect the Company's current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of risk factors. Additional information concerning risk factors can be found in press releases issued by the Company, as well as public periodic filings with the U.S. Securities and Exchange Commission (the "SEC") and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K.

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