

Finasteride Plus 1.25mg Capsule Recall Alert

Date of Notice: 05/06/2020

Brief Description of Recall

On May 5, 2020, MasterPharm, LLC. Issued a voluntary recall of finasteride plus 1.25mg capsules. The capsules have been found to contain undeclared minoxidil, a blood pressure drug, at levels greater than those found in the FDA approved products.

Consumption of undeclared minoxidil would be expected to result in low blood pressure, rapid heartbeat, and salt and water retention causing swelling. Consequently, patients may be at risk for developing heart failure or other heart damage. Excess fluid between the heart and the sac surrounding the heart has also been reported in association with minoxidil use. MasterPharm, LLC. has received 33 reports of increased heart rate, retention of water, dizziness and low blood pressure.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
finasteride plus 1.25mg capsules	Not available	02-27-2020:04@11	08/25/2020

Prescriber Information

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: <u>Download form</u> 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

Member Information

MasterPharm, LLC. is notifying consumers by telephone, e-mail and common carrier letters and is arranging for return and replacement of recalled product. Consumers that have finasteride plus 1.25mg which is being recalled should stop using and return the finasteride plus 1.25mg to MasterPharm, LLC. self-addressed packaging from MasterPharm, LLC. that has been sent to all customers previously.

Consumers with questions regarding this recall can contact MasterPharm, LLC. by (866) 630-5600 or recall@masterpharm.com on Monday through Friday, 9am-5pm EST/EDT. 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.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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RxAdvance Response

Finasteride plus 1.25mg capsules are considered cosmetic and are not covered on RxAdvance pharmacy benefit plans.

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