COMPANY ANNOUNCEMENT

MasterPharm, LLC. Issues Voluntary Nationwide Recall of Finasteride Plus 1.25mg Due to the Presence of an Undeclared Antihypertensive Drug

Summary

Company Announcement Date:

May 06, 2020

FDA Publish Date:

May 11, 2020

Product Type:

Drugs

Reason for Announcement:

Contains undeclared minoxidil

Company Name:

MasterPharm, LLC

Brand Name:

MasterPharm, LLC

Product Description:

Finasteride Plus 1.25mg, capsules

Company Announcement

MasterPharm, LLC. is voluntarily recalling 1 lot of Finasteride Plus 1.25mg, capsules to the consumer level. The Finasteride Plus capsules have been found to contain undeclared minoxidil, an antihypertensive drug, at levels greater than those found in FDA approved products. The undeclared minoxidil was found when tested with an independent testing laboratory.

Risk Statement: 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.

The product is a compounded drug for hair loss and is packaged in orange prescription bottles containing 30 capsules or blue prescription bottles containing 90 capsules. The affected Finasteride Plus 1.25mg lots include the following 02-27-2020:04@11 and a Beyond Use Date of August 25, 2020. The product can be identified by the patient-specific labeled prescription bottles with product batch labels and a patient-specific prescription label. Finasteride Plus 1.25mg was distributed Nationwide on a patient-specific prescription basis only.

MasterPharm, LLC. is notifying its customers by telephone, e-mail, and common carrier letters and is arranging for return and replacement of all recalled products. 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 (mailto: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.

FDA MedWatch Reporting

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 (/node/360543)
- Regular Mail or Fax: Download form (/node/360547) 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.

Company Contact Information

Consumers:

Lin Leung, MasterPharm, LLC

(866) 630-5600

recall@masterpharm.com (mailto:recall@masterpharm.com)

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