Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

International Laboratories, LLC Issues Voluntary Nationwide Recall of One (1) Lot of Pravastatin Sodium Tablets USP, 40mg Packaged in Bottles of 30 Tablets Due to Mislabeling NDC # 54458-925-16; Lot # 115698A

For Immediate Release

August 9, 2017

Contact

Consumers

727-322-7146

Media

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Announcement

View Product Photos

International Laboratories, LLC is voluntarily recalling one (1) Lot of Pravastatin Sodium Tablets USP 40 mg **packaged in bottles of 30 tablets, to the consumer level** due to mislabeling. The product is labeled as **Pravastatin Sodium Tablets USP 40 mg but contained Bupropion Hydrochloride XL 300 mg tablets.**

If a subject mistakenly takes bupropion, common side effects include: nausea, vomiting, dry mouth, headache, constipation, sweating, sore throat, diarrhea, dizziness, restlessness, blurry vision. These are typically minor and reversible issues. However, individuals with epilepsy are at higher risk of seizure on bupropion due to it lowering the seizure threshold. Also, people on MAOIs can have a risky drug interaction with bupropion (hypertensive crisis). Finally, allergic reactions are also possible and could be life threatening.

This lot of Pravastatin Sodium Tablets USP 40 mg was recalled when International Laboratories, LLC was informed by a pharmacist that one 30ct bottle of this product was mislabeled and contained Bupropion Hydrochloride XL 300 mg tablets. International Laboratories, LLC has reported that no complaints or reports of medical illnesses or harmful effects have been received to date.

Pravastatin Sodium Tablets USP 40 mg are an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet when the response to a diet restricted in saturated fat and cholesterol and other non-pharmacologic measures alone has been inadequate. It is used to treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.

Bupropion hydrochloride extended-release tablets (XL) 300 mg are an aminoketone antidepressant, indicated for the treatment of major depressive disorder (MDD) and prevention of seasonal affective disorder (SAD) in children, adolescents, young adults and adults.

The product was delivered to distribution centers in **Arkansas, Georgia and Indiana and distributed to retail stores in Arkansas, Alabama, Florida, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Virginia and Wisconsin**.

International Laboratories, LLC is notifying its distributors and customer by letter and is arranging for return of all recalled products. Consumers who have purchased this product should not open the package or use the contents. Instead, they should return the product to the location of purchase for a full refund, or call a Customer Complaint phone number at **International Laboratories, LLC 727-322-7146** (Monday – Friday 8 AM – 5 PM EST).

Consumers with questions regarding this recall can contact International Laboratories, LLC by phone 727-322-7146 or e-mail address **sutka.veselinovic@internationallabs.com (mailto:sutka.veselinovic@internationallabs.com)** on Monday - Friday 8AM – 5PM EST. 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 **http://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.

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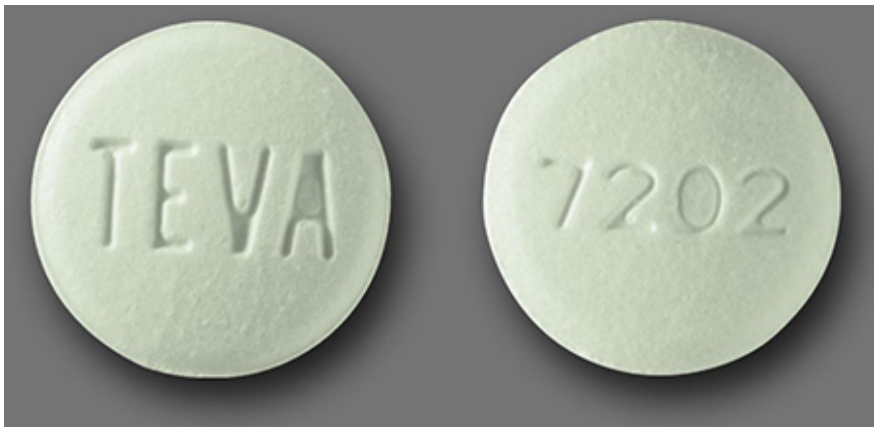
Product Photos



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