COMPANY ANNOUNCEMENT

Taro Pharmaceuticals U.S.A., Inc. Issues Voluntary Nationwide Recall of Lamotrigine Tablets USP, 100 mg, 100 Count Bottles

Summary

Company Announcement Date:

January 10, 2020

FDA Publish Date:

January 10, 2020

Product Type:

Drugs

Reason for Announcement:

Cross contamination with another drug substance, Enalapril Maleate

Company Name:

Taro Pharmaceuticals U.S.A., Inc.

Brand Name:

Taro Pharmaceuticals

Product Description:

Lamotrigine Tablets, USP 100mg

Company Announcement

Taro Pharmaceuticals U.S.A., Inc. (“Taro” or the “Company”) is voluntarily recalling one (1) lot of Lamotrigine 100 mg Tablets, Lot # 331771 (expiration date June 2021) in 100 count bottles, NDC 51672-4131-1 to the consumer level. This single lot of Lamotrigine 100 mg Tablets Lot

#331771 (expiration date June 2021) was found to have been cross-contaminated with a small amount of another drug substance (Enalapril Maleate) used to manufacture another product at the same facility.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200110005522/en/ (https://www.businesswire.com/news/home/20200110005522/en/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Risk Statement: Use of Lamotrigine 100 mg Tablets could potentially result in exposure to a small amount of Enalapril Maleate, if present in the product in question. Enalapril Maleate is a drug substance indicated for hypertension and congestive heart failure. There is potential with chronic exposure to Enalapril Maleate to impact users particularly if they are small children or pregnant women. Enalapril Maleate is also associated with risk of birth defects in a developing fetus. Therefore, there is risk associated with the continued, long-term use of Lamotrigine 100 mg Tablets, Lot # 331771 (expiration date June 2021).

Taro has not received any product complaints or adverse events related to contamination of this product with Enalapril, or any complaints or adverse events that are associated specifically with this recall. Taro will continue to actively monitor for any and all adverse event reports that may be received, in compliance with FDA regulatory requirements.

Lamotrigine 100 mg Tablets are indicated for Epilepsy and Bipolar disorder. This product is packaged in white plastic bottles with screw cap closure, and each bottle contains 100 tablets. Each bottle is labeled to indicate the name of the product, Lamotrigine Tablets USP, 100 mg, the NDC #51672-4131-1 (see image of container label below), the lot number 331771 and expiration date of June 2021.

Lamotrigine 100 mg Tablets, Lot # 331771 were distributed to wholesale distributors in the US market between August 23 and August 30, 2019. These wholesale customers may have further distributed Lot # 331771 to retail pharmacies for prescription dispensing to patients who were prescribed 100 mg Lamotrigine Tablets.

Taro is notifying its distributors and customers by Phone, E-mail, and Letters via US Mail and is arranging for return of any containers or quantities of Lamotrigine 100 mg Tablets, Lot # 331771 (exp. June 2021). Consumers that have any quantities of Lamotrigine 100 mg Tablets, Lot # 331771 being recalled should stop using this product and return it to the pharmacy that dispensed it. Retailers, pharmacies and distributors should stop distributing or dispensing this product and return it to Taro.

Consumers with questions regarding this recall can contact Taro by calling 1-866-923-4914 or by e-mail at TaroPVUS@taro.com (mailto:TaroPVUS@taro.com), Monday through Friday between 7:00 AM and 7:00 PM US Central Time. 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

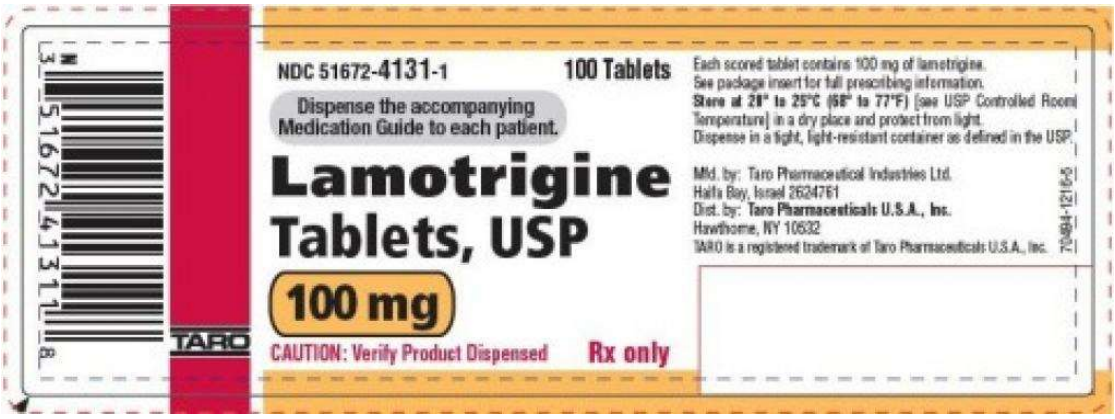
Company Contact Information

Consumers:

1-866-923-4914

TaroPVUS@taro.com (mailto:TaroPVUS@taro.com)

Product Photos



More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)