

# **Lamotrigine Tablets Recall Alert**

Date of Notice: 01/10/2020

### **Brief Description of Recall**

On January 10, 2020, Taro Pharmaceuticals USA, Inc. issued a voluntary recall for one lot of lamotrigine 100mg tablets. The drug was found to be cross-contaminated with a small amount of another drug (enalapril maleate) manufactured in the same facility.

Use of lamotrigine 100mg 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.

#### **Affected Products**

Drug Name & Strength	NDC	Lot	Expiration Date
lamotrigine 100mg tablets	51672-4121-1	331771	06/2021

#### **Prescriber Information**

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.

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**

Members with questions regarding this recall can contact Taro by calling 1-866-923-4914 or by e-mail at TaroPVUS@taro.com, Monday through Friday between 7:00 AM and 7:00 PM US Central Time.

Members should contact their prescriber 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**

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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