RXADVANCE
2 Park Central Drive
Southborough, MA 01772

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: Download form 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.

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RxAdvance Response

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