Taro Pharmaceuticals – Recall of lamotrigine

- On January 10, 2020, Taro Pharmaceuticals announced a voluntary, consumer-level recall of lamotrigine tablets because one lot 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.

- The recalled lot of lamotrigine was distributed in the U.S. between August 23 and August 30, 2019.

Product Description	NDC#	Lot# (Expiration Date)
Lamotrigine 100 mg tablets, 100 count bottles	51672-4131-1	331771 (June 2021)

- Lamotrigine is indicated as adjunctive therapy for the following seizure types in patients aged 2 years and older: partial-onset seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome. Lamotrigine is also indicated for conversion to monotherapy in adults (aged 16 years and older) with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug.

- In addition, lamotrigine is indicated for the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes (depression, mania, hypomania, mixed episodes) in patients treated for acute mood episodes with standard therapy.

- Use of the recalled lamotrigine tablets could potentially result in exposure to a small amount of enalapril. Enalapril is a drug substance indicated for hypertension and congestive heart failure. There is potential with chronic exposure to enalapril to impact users particularly if they are small children or pregnant women. Enalapril is also associated with risk of birth defects in a developing fetus. Therefore, there is risk associated with the continued, long-term use of the recalled lamotrigine tablets.

- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled lamotrigine.

- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.

- Consumers with questions regarding this recall can contact Taro by calling **1-866-923-4914** or by e-mail at **TaroPVUS@taro.com**.

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