



Review

Lamotrigine and Phenytoin indicated for epilepsy recalled by the manufacturer in America**Aslam Pathan***Department of Pharmacology, College of Medicine, Shaqra University, Shaqra-11961, Saudi Arabia***ARTICLE INFO***Article history:*

Received 26 Feb 2020

Received in revised form
15 March 2020

Accepted 29 March 2020

Available online
30 April 2020*Keywords:*

Lamotrigine

Phenytoin

Epilepsy

Bipolar disorder

Manufacturing defects

ABSTRACT

On 10 January 2020 Taro Pharmaceuticals U.S.A., Inc. Issues voluntary nationwide recall of Lamotrigine tablets USP, 100 mg, 100 count bottles and on 20 February 2020 Taro Pharmaceuticals U.S.A. Issues voluntary nationwide recall of Phenytoin oral suspension USP, 125 Mg/5 Ml due to possible underdosing or overdosing. The reason for the recall of Lamotrigine 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 reason for the recall of Phenytoin is that products from these two lots of Phenytoin oral suspension may not re-suspend when shaken, as instructed for administration, which could result in under or overdosing. This recall is being conducted with the knowledge of the FDA.

Lamotrigine:

Taro Pharmaceuticals U.S.A., Inc. 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.

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 the risk of birth defects in a developing fetus. Therefore, there is a 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

Corresponding author at: Department of Pharmacology, College of Medicine, Shaqra University, Shaqra-11961, Saudi Arabia

E-mail address: dr.aslam@su.edu.sa

<https://orcid.org/0000-0002-6569-2306>

<https://doi.org/10.37881/1.513>

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 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, the lot number 331771 and the 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 have 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.¹

Phenytoin:

Taro Pharmaceuticals U.S.A., Inc. is voluntarily recalling two lots of Phenytoin oral suspension USP, 125 mg/5 mL both in 237 mL bottles, to the consumer level. Phenytoin oral suspension USP, 125 mg/5 mL is indicated for the treatment of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures and is packaged in amber plastic bottles with an inner seal and a white childproof closure, and each bottle contains 237 mL. The reason for the recall is that products from these two lots of Phenytoin oral suspension may not re-suspend when shaken, as instructed for

administration, which could result in under or overdosing. This recall is being conducted with the knowledge of the FDA.

The population at risk is primarily infants and young children. In those patients, there is a reasonable probability that inaccurate dosing might result in a serious adverse effect such as intoxication or breakthrough seizures requiring medical intervention. For a small minority of patients, who might have severe or repeated breakthrough seizures, a drop in their phenytoin blood levels could result in life-threatening status epilepticus requiring immediate emergency room treatment.

Each bottle is labeled to indicate the name of the product, Phenytoin Oral Suspension USP, 125 mg/5 mL and the NDC #51672-4069-1. Lot 327874 was distributed to wholesale distributors, long-term care providers, a repackager and mail-order customers in the U.S. market between May 3 and July 5, 2019. Lot 327876 was distributed to wholesale distributors, long-term care providers and mail-order customers in the U.S. market between July 1 and August 21, 2019. These customers may have further distributed these lots to retail pharmacies for prescription dispensing to patients who were prescribed Phenytoin Oral Suspension.

Taro is notifying its distributors and retail customers by phone, e-mail, and letters via U.S. Mail and is arranging for return of any containers or quantities of Phenytoin oral suspension lots # 327874 and 327876 (both with an expiration date of December 2020). Retail customers that have any quantities of these two lots which are being recalled, should stop distribution and return any unsold units to their wholesaler.²

Discussion:

Cross-contamination in drug manufacturing has become a huge concern not only to experts involved in the therapeutic market and pharma industry as a whole but to the average person as well. It becomes a major topic of discussion among various communities. But what exactly is this? In essence,

that is the 'infection', so to speak, of any material in the process (starting material or intermediate product) or a finished drug with another material in process or pharmaceutical. Manufacturers must have appropriate procedures in place to prevent risks of contamination and to prove that no contamination has occurred by delivering detailed documentation. The dangers and negative effects of this process may cause are many. Taking measures against cross-contamination, then, becomes something of extreme importance. It is crucial as such preventive actions can retain the quality of products. But what is even more significant, they can minimize any life-threatening reactions which may result from the potential consumption of cross-contaminated medicaments.

Oral suspension may not re-suspend when shaken, as instructed for administration, which could result in under or overdosing resulting in dangerous life-threatening effects. Pharmaceutical companies should strictly follow the good manufacturing practices which will prevent manufacturing defects and life-threatening adverse reactions to human beings.

References:

1. Recalls, Market Withdrawals, & Safety Alerts. Available from: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-lamotrigine-tablets-usp-100-mg-100#recall-photos>
2. Recalls, Market Withdrawals, & Safety Alerts. Available from: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall-phenytoin-oral-suspension-usp-125-mg5-ml#recall-photos>

Copyright

© 2020 NeuroPharmac J. This is an open-access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License.

Cite this article: Pathan A. Lamotrigine and Phenytoin indicated for epilepsy recalled by the manufacturer in America. *NeuroPharmac J.* 2020; 5(1): 118-120.

DOI: 10.37881/1.513
