



January 15, 2020

URGENT: DRUG RECALL - CONSUMER LEVEL
Lamotrigine Tablets USP, 100 mg

Lot #	Exp. Date	Size	NDC	Dates Distributed
331771	June 2021	100 count bottles	51672-4131-1	August 23 to August 30, 2019

Dear Valued Customer,

This is to notify you that Taro Pharmaceuticals U.S.A., Inc. is initiating a **Voluntary Recall** of one (1) lot of Lamotrigine Tablets USP, 100 mg, 100 count bottles, Lot # 331771. This recall is being initiated because an investigation determined that Lot # 331771 was inadvertently cross-contaminated with a small quantity of another drug, Enalapril maleate, at the same facility. Enalapril maleate is indicated for hypertension and congestive heart failure. Chronic exposure may impact users, particularly small children or pregnant women. It is associated with risk of birth defects in developing fetus. This recall is being conducted with the knowledge of the FDA.

Distributors/Pharmacies/Wholesalers:

Please examine your inventory **immediately** to determine if you have units of Lot # 331771 in stock. Please discontinue distributing this lot, remove it from your stock, and promptly return all units to our distribution center according to the following instructions:

- (1) Please fill out the attached Recall Response Form completely
- (2) Return the completed form via Fax to 914-470-4946 or mail the completed form to:

Taro Pharmaceuticals U.S.A., Inc.
 3 Skyline Drive
 Hawthorne, New York 10532
 Attention: Richard Lewellyn

- (3) Taro will provide return authorization/call tag to ship any returned merchandise to our distribution center at:
 Taro Pharmaceuticals U.S.A., Inc.
 1 Commerce Drive
 Cranbury, New Jersey 08512
 Attn: RETURNED GOODS - RECALL – Lamotrigine Tablets 100 mg

- (4) Please contact all of your customers to ensure product return.

NOTE: Please return the form even if you do not have any inventory of the impacted lots.

We appreciate your prompt attention in looking through your inventory, discontinuing distribution of the affected lot and returning all units. If you have any questions about the content of this letter, please contact Richard Lewellyn at 1-800-544-1449 ext. 6334 or via email to richard.lewellyn@taro.com, or me at 914-345-9001 ext. 6216.

For any stock returned by Consumers, please contact Inmar at 866-705-1553 for product returns.

Consumers:

Please contact Inmar at 866-705-1553 for return information and reimbursement or contact the pharmacy where you purchased the product and return directly to them.

Taro apologizes for any inconvenience this may have caused.

Sincerely,

Scott Keenan
 Manager, Quality Compliance

Enclosure: Recall Response Form – Lamotrigine Tablets USP, 100 mg



RECALL RESPONSE FORM – Consumer Level

Lamotrigine Tablets USP, 100 mg

Lot #	Exp. Date	Size	NDC	Dates Distributed
331771	June 2021	100 count bottles	51672-4131-1	August 23 to August 30, 2019

Please enter the following information, completely:

Pharmacy/Retailer	
Name of Business: _____	Phone: _____
Address: _____	

Wholesale Supplier/Distributor	
Name: _____	Phone: _____
Address/Location: _____	
Wholesaler/Distributor Account Number: _____	

Please check ALL that apply:

- I have read and understood the instructions provided in the recall letter
- I have checked my inventory for any stock of lot # 331771
- Check here IF YOU DO NOT have any inventory, and please return this form
- Check here if you DO have inventory from lot #331771 and enter the quantity to be returned below:

Lot #	Exp. Date	Quantity
331771	June 2021	

Please FAX a copy of the completed response form to Richard Lewellyn at: 914-470-4946

...or return a copy of this form BY MAIL to: Taro Pharmaceuticals U.S.A., Inc.
 3 Skyline Drive
 Hawthorne, New York 10532
 Attention: Richard Lewellyn

A call tag will be issued to you for any returned merchandise, once Taro receives the response form. Please include a copy of this form with your return shipment, with the Return Authorization Number entered below.

Return Authorization Number: _____