59651-00268-01000337
SMITH DRUG HDQ
9098 FAIRFOREST RD PO Box 1779
SPARTANBURG, SC 29301

AUROBINDO
Committed to healthier life!
www.AurobindoUSA.com

March 18, 2020

URGENT DRUG RECALL

Levetiracetam Tablets USP
750mg Tablets

Dear Valued Customer:

This is to inform you of a product recall involving:

NDC	Product Description	Lot Number	Exp Date
65862-247-08	Levetiracetam 750mg Tablets	24719001A1	03/2021

Levetiracetam tablets are indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy; in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy; and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.

The affected batches can be identified by checking the product name and batch number on the respective product labeling. **See enclosed product label for ease in identifying the product.**

This recall has been initiated because this batch was manufactured in a processing area in which water leakage was observed. Although there was no direct contact of any component with the subject water during the leakage events, the subject batches are being recalled out of an abundance of caution. No other Levetiracetam batches are affected.

To date, Aurobindo has not received reports of any adverse events or identifiable safety concerns attributed to the reported water leakage.

Aurobindo began shipping these batches to customers nationwide June 6, 2019 through June 24, 2019.

Immediately examine your inventory and quarantine the product batch subject to this recall.

Aurobindo Pharma USA, Inc. · 279 Princeton Hightstown Road · East Windsor, NJ 08520-1401
(phone)866.850.2876 · (fax)732.355.9449

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This recall is being carried out to the Retail level. Your assistance is appreciated.

Recall Instructions:
Please perform the following activities:

- Immediately examine your inventory and quarantine the specified lot of Levetiracetam 750mg.
- Immediately discontinue distribution of the specific lots being recalled
- Promptly complete the business response form even if you have no product to return.

Business response forms may be completed by one of the following methods:

- E-Mail to recall@qualanex.com
- Fax to 847-737-3719
- Mail to:
  Aurobindo USA C/O Qualanex
  1410 Harris Rd
  Libertyville, IL 60048

Please complete and return the enclosed response form as soon as possible. If you need assistance in returning your product or have questions about the recall process, contact Qualanex at 800-505-9291 during the hours of 7:00am to 4:00pm CST. If you have Customer Service related questions, please contact Aurobindo Customer Service at **866-850-2876 Option 1.**

Once the business response form is received by Qualanex, a Return Goods Authorization will be sent to you. Appropriate reimbursement for product returns will be issued upon receipt of the recalled product with the Return Goods Authorization form.

This recall is being made with the knowledge of the Food & Drug Administration.

Daniel Martins
Senior Vice President, Quality Compliance
279 Princeton Hightstown Road
East Windsor, NJ 08520
dmartins@aurobindousa.com
Direct 732.823.9021

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NDC 65862-247-08

Rx only

Levetiracetam Tablets USP

750 mg

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY

AUROBINDO

120 Tablets

Each film-coated tablet contains: Levetiracetam USP 750 mg.

Usual Dosage: See package insert for complete dosage recommendations.

Pharmacist: Dispense in a tight, light-resistant container with a child-resistant closure.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Issued: 02/2019

LM-3428

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BUSINESS RESPONSE FORM

Levetiracetam Tablets USP 750mg Tablets

Product Recall – March 18, 2020

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name _____ DEA #_____

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Contact e-mail: _____

Contact Signature _____ Date_____

I have checked my stock and:

_____Do not have any stock of the withdrawn **items**.

OR

I have quarantined and listed in the box below the qty of withdrawn units I will be returning to QUALANEX, as soon as possible. Upon receipt of this Response Form, QUALANEX, will issue return authorization. Please return product using enclosed return label.

Item Description	NDC	Lot #	Sealed Qty To Be Returned	Open Qty To Be Returned
Levetiracetam 750mg Tablets	65862-247-08	24719001A1		

If you did not purchase the product directly from the Manufacturer, please complete the below section.

Purchased From: Wholesaler Name _____

City_____ State_____

Wholesaler DEA#_____

If you have any questions regarding this form or product return, please contact QUALANEX at 800-505-9291 Office hours 7am to 4pm CST Mon thru Fri.

Please fax this form to: 847-737-3719 Or E-mail recall@qualanex.com