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## **URGENT: DRUG RECALL**

### **Levetiracetam Extended Release Tablets, 750 mg**

**January 26, 2015**

Dear Trading Partner,

This notice is to inform you of a drug product recall involving.

Drug Product Name: Levetiracetam Extended Release Tablets, 750 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd.

NDC Number: 47335-576-86 (60 CRC)

Dosage Form: Extended Release Tablets

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/ Indications: Indicated as adjunctive therapy in the treatment of partial onset seizures in patients  $\geq 16$  years of age with epilepsy.

Package Type and Number of Doses/Sizes: 60 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC).

#### Lot Numbers

Product Name	Lot No.	Pack Size	Exp. Date
Levetiracetam Extended Release Tablets, 750 mg	JKN0249A	60 count CRC pack	02/2016

Sun Pharmaceutical Industries, Inc.  
270 Prospect Plains Road, Cranbury, NJ 08512  
Phone: (609) 495 2800 • FAX: (609) 495 2711

## **Reason for Recall**

This recall is voluntarily initiated based upon stability results. During the analysis of 6 month long term stability testing, it was noticed that the drug release results of Levetiracetam Extended Release Tablets, 750 mg, batch # JKN0249A are not meeting the specification limit.

Immediately examine your inventory and quarantine subject lots to this recall. Please stop distributing these lots immediately. This recall has been initiated to the retail level (Recall Class II). In addition, if you have further distributed this product, please notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall letter.

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


For return of affected product, please email [recallnotice@inmar.com](mailto:recallnotice@inmar.com) or call **800-967-5952**. Please complete and return the enclosed response form as soon as possible.

Affected product should be sent to:

Inmar  
4332 Empire Road  
South Dock  
Fort Worth, TX 76155

If there are any further questions, please feel free to contact me at 800-818-4555 x 4105.

Sincerely,

  
Robert Kurkiewicz  
Sr. Vice President, Regulatory Affairs



## **URGENT: DRUG RECALL – RESPONSE FORM**

**Please Complete Form and Fax to: 817-868-5362 or Email to:**  
**[recallnotice@inmar.com](mailto:recallnotice@inmar.com)**

We do not have any stock ☐

Or,

Please enter the quantity you shall be returning.

<b>Product Name</b>	<b>Lot Number</b>	<b>Pack size</b>	<b>NDC Number</b>	<b>Exp. Date</b>	<b>Quantity to be returned</b>
Levetiracetam Extended Release Tablets, 750 mg	JKN0249A	60 count	47335-576-86	02/2016	

Name\_\_\_\_\_ DEA #\_\_\_\_\_

Company\_\_\_\_\_

Address\_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code\_\_\_\_\_

Phone Number\_\_\_\_\_ Email\_\_\_\_\_

Wholesaler\_\_\_\_\_ City/State\_\_\_\_\_

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