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## **URGENT: DRUG RECALL**

### **Alendronate Sodium Tablets USP, 70 mg**

**February 11, 2016**

Dear Trading Partner:

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

Drug Product Name: Alendronate Sodium Tablets USP, 70 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd.

NDC Number: 47335-638-68 (Blister of 4 Tablets)

Dosage Form: Tablets

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/ Indications: Indicated for treatment and prevention of osteoporosis in postmenopausal women.

Package Type and Number of Doses/Sizes: 4 tablets packed in aluminium blister.

Lot Numbers

Product name	Batch No.	Mfg. Date	Exp. Date
Alendronate Sodium Tablets USP, 70 mg	JKP2234A	05/2015	04/2017
	JKP2235A	05/2015	04/2017

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 3 month long term stability testing, it was noticed that observed levels of highest unknown impurity was exceeding specification limit.

These lots were distributed during September 2015 to November 2015.

Immediately examine your inventory and quarantine subject lots to this recall. Please stop distributing these lots immediately. This recall is being initiated to the retail level. In addition, if you have further distributed this product, please notify your customers at once of this product recall. Your notification 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 [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call **800-967-5952**, during Monday to Friday, from 8:00 am to 5:00 pm (EST). Please complete and return the enclosed response form along with your affected customer list as soon as possible.

Affected product should be sent to:

Inmar  
4332 Empire Road  
South Dock  
Fort Worth, TX 76155

Sincerely,



Blynda B. Masters  
Director, Customer Service

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

**Please Complete This Form and A Provide Return Invoice and Fax to: 817-868-5362 or Email to: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)**

We do not have any stock ☐

Or,

Please enter the quantity you shall be returning.

Product Name	Lot Number	Pack size	NDC Number	Exp. Date	Quantity to be returned
Alendronate Sodium Tablets USP, 70 mg	JKP2234A	Blister of 4 Tablets	47335-638-68	04/2017	
	JKP2235A	Blister of 4 Tablets	47335-638-68	04/2017	

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

Company \_\_\_\_\_

Address \_\_\_\_\_

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

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

Email Address \_\_\_\_\_

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

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