

URGENT: DRUG RECALL

Date: 12/28/2015

Allopurinol Tablets 100mg

MANUFACTURED BY:

**Dr. Reddy's Laboratories Louisiana LLC
Shreveport, LA 71106**

RECALLED BY:

**Dr. Reddy's Laboratories, Inc.
107 College Road East,
Princeton, NJ- 08540 USA**

Dear Valued Customer:

This is to inform you of a product recall involving:

Allopurinol tablets 100mg, 100Ct Bottles, Lot L401555

See enclosed product label.

This voluntary recall has been initiated due to failure to do assessment of issue related to out of target limits in-process results for hardness testing. While the out of target limit hardness results encountered during the production are not expected to impact safety or efficacy of the product, it is Dr. Reddy's intent, in an abundance of precaution, to conduct a voluntary recall of this specific lot L401555.

The lot of this product to be recalled is mentioned below.

Item Description	NDC	Lot	Expire Date
Allopurinol Tablets 100mg, 100Ct Bottles	55111-729-01	L401555	10/2017

The product Distribution dates are: May 19 – July 10, 2015

Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for lot listed above and immediately discontinue distribution and sales of this product lot being recalled. Please quarantine the affected lot of this product.
- In addition, if the listed product was further distributed, please identify the customers and notify them immediately of this product recall. The notification to the customers may be expedited by including a copy of this recall notification letter
- Promptly complete the attached recall stock response form even if you have no product to return.

Completed Recall Stock Response form can be submitted by any of the below methods:

Fax: 817-868-5362

E-mail: RXrecalls@inmar.com

Mail: Inmar, Attn: Recall Coordinator,
4332 Empire Road Suite 200,
Fort Worth, TX 76155

For questions regarding return of the recalled product please call Inmar at 800-967-5952.

Upon receipt of your Recall Response Form a "Return Kit" will be sent to you. This kit will include:

- Pre-paid shipping label(s)
- Processing labels
- Shipping instructions

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

Your cooperation and prompt response to this notice is much appreciated. If you have Customer Service related questions, please contact Dr. Reddy's Laboratories 866-733-3952 Medical related questions, please contact Dr. Reddy's Laboratories/ DLSS at 888-375-3784

Sincerely,



Douglas Forman
Associate Director, Quality
Dr. Reddy's Laboratories, Inc.

Enclosure(s)

1. Product Label
2. Recall Return Response Form



RECALL STOCK RESPONSE FORM

Product RECALL 12/28/2015 Allopurinol Tablets 100mg

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

Company Name _____ DEA # _____
DEA # is required, if not provide the processing of your form will be delayed.

Address _____

City _____ State _____ Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

I have checked my stock and:

_____ Do not have any stock of the recalled items.

OR

I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) and will need _____
of box labels

Item Description	NDC	Lot	Qty returning
Allopurinol Tablets 100mg, 100Ct Bottle	55111-729-01	L401555	

Wholesalers and Distributors only

☐ I have identified my customers that were shipped or may have been shipped this product. Attached is a list of customers with their contact details who received/may have received this product.

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

Purchased From: Wholesaler Name _____ DEA # _____

City _____ State _____

If you have any questions regarding this form or product return please contact Inmar at 1-800-967-5952
Office hours 8am to 5pm (EST) Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail: RXrecalls@inmar.com,