Dr.Reddy's

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

URGENT: DRUG RECALL

08/29/2016

Zenatane (Isotretinoin Capsules USP), 20mg

MANUFACTURED BY:
Cipla Limited
Pune – 413802, India

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:

Zenatane (Isotretinoin Capsules USP), 20mg

See enclosed product label.

This voluntary recall has been initiated due to an out-of-specification result for Dissolution obtained during stability testing. Based on toxicological study performed, if the patient consumes Isotretinoin capsules of the below mentioned batch, the capsules may not be effective in controlling the acne for which it is indicated. Also if the patient takes Isotretinoin capsules from the below mentioned batch during initial dose adjustment phase then it may lead to wrong dose adjustment.

The lot of the product to be recalled is:

Item Description	NDC	Bulk Lot Number (as on the blister)	Finished Good Lot Number (as on the carton)	Expiration Date
Zenatane (Isotretinoin Capsules USP), 20mg, 30 Capsules, (3x10 Prescription Packs)	55111-136-81	KB60205	79KB60205	02/2018

The product Distribution dates are: May 13, 2016 – May 24, 2016

Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for lot listed above and immediately discontinue distribution and sales of the 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,

08/29/2016

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

Enclosure(s)
1. Product Label
2. Recall Return Response Form

Dr.Reddy's

RECALL STOCK RESPONSE FORM

RECALL of Zenatane (Isotretinoin Capsules USP), 20mg
08/29/2016
VOLUNTARY RECALL – Class TBD

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 qty of recalled units 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	Bulk Lot Number (as on the blister)	Finished Good Lot Number (as on the carton)	Quantity returning
Zenatane (Isotretinoin Capsules USP), 20mg, 30 Capsules, (3x10 Prescription Packs)	**55111-136-81**	**KB60205**	**79KB60205**	

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 Monday through Friday.

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