

URGENT: DRUG RECALL

11/04/2015

Paricalcitol Capsules 1mcg

MANUFACTURED BY:

Dr. Reddy's Laboratories Ltd.
Bachupally - 500090 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:

Paricalcitol Capsules 1mcg

See enclosed product label.

This voluntary recall has been initiated due to high number of product complaints received for breakage and leakage of Paricalcitol capsules. In case the patient consumes the Paricalcitol capsules covered with the liquid layer of Paricalcitol around it, the patient might be receiving additional dose of Paricalcitol than expected and in case the patient consumes broken Paricalcitol capsules with the Paricalcitol content spilled off, the patient might be receiving less than expected or may be no dose (in case of empty capsules) of Paricalcitol, which could affect desired therapeutic effect in the patient. Paricalcitol can also cause hypersensitivity reactions in person who get exposed to Paricalcitol.

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

Item Description	NDC	Lot	Expire Date
Paricalcitol 1mcg, 30 count Bottle	55111-663-30	C503797	05/2017

The product Distribution dates are: August 11 – August 13, 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: recallnotice@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 11/04/2015 Paricalcitol Capsules 1mcg

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 provided 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	Lot	Qty returning
Paricalcitol Capsules 1mcg, 30 Count	55111-663-30	C503797	

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 7am to 5pm Mon thru Fri.

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

