

**URGENT: DRUG RECALL**

**03/30/2016**

**Ondansetron Tablets USP, 4mg**

**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:

**Ondansetron Tablets USP, 4mg**

See enclosed product label.

**This voluntary recall has been initiated due to an out-of-specification result for Related Substance; Maximum Unknown Impurity obtained during stability testing.**

The lot of the product to be recalled is mentioned below:

Item Description	NDC	Lot	Expire Date
Ondansetron Tablets USP, 4mg, 30ct bottles	55111-153-30	C500691	12/2016

The product Distribution dates are: March 12, 2015 – August 19, 2015

**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](mailto: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**

**RECALL of Ondansetron Tablets USP, 4mg  
03/30/2016**

### **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	Lot	Qty returning
Ondansetron Tablets USP, 4mg	55111-153-30	C500691	

**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](mailto:RXrecalls@inmar.com)**