



## **RECALL STOCK RESPONSE FORM**

**RECALL of Zoledronic Acid Injection, 5mg/100mL  
03/03/2016**

### **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
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS523	

**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 Mon thru Fri.

**Please fax this form to: 1-817-868-5362 or E-mail: [RXrecalls@inmar.com](mailto:RXrecalls@inmar.com)**

**URGENT: DRUG RECALL**

**03/03/2016**

**Zoledronic Acid Injection, 5mg/100mL**

**MANUFACTURED BY:**  
**Gland Pharma Limited.**  
**Telangana - 500043 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:

**Zoledronic Acid Injection 5mg/100mL**

See enclosed product label.

The voluntary recall has been initiated due to product complaints received for defective seals where the metal silver ring was not attached tightly to the vial which makes the vial unusable. If a patient is not administered Zoledronic Acid Injection as a result of defective seal, the medical condition for which the Zoledronic Acid Injection is indicated may not be controlled or may worsen.

The recall is for the following lots:

Item Description	NDC	Lot	Expire Date
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS523	10/2017

The product Distribution dates are: December 21, 2015 – January 12, 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](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