ASD Healthcare
AmerisourceBergen

M-F 7:00AM to 6:00PM CST
asdhealthcare.com
800.746.6273
800.547.9413

September 13, 2018

Urgent: Dr. Reddy's Laboratories issues a voluntary recall for 20 lots of Zoledronic Acid Injection, 5 mg/100 mL

Dear ASD Healthcare Customer:

Dr. Reddy's Laboratories Inc., is issuing a voluntary product recall for Zoledronic Acid Injection, 5 mg/100 mL. The affected lots are listed below for the lots distributed from February 21, 2017 to June 15, 2018.

Dr. Reddy's initiated this recall due to an out-of-specification result observed for Related Substance: Unknown Impurity. The unknown impurity has been characterized, however it is yet to be confirmed. Evaluation based on the structure of the characterized suspected impurity has no structural alerts for genotoxicity or negative for genotoxicity, and it is unlikely to pose risk to the patient safety.

This recall is being conducted with the full knowledge of the Food and Drug Administration.

Dr. Reddy's provided the following affected lot information:

Product Description	NDC	Lot	Expiry Date
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS633	09/2018
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS701	12/2018
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS702	12/2018
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS703	12/2018
Zoledronic Acid Injection, 5 mg/100 mL (Novaplus)	43598-0331-11	BS704	12/2018
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS708	03/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS709	03/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS711	03/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS712	03/2019

Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS713	03/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS714	03/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS715	03/2019
Zoledronic Acid Injection, 5 mg/100 mL (Novaplus)	43598-0331-11	BS725	06/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS726	06/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS727	06/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS728	07/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS729	07/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS730	07/2019
Zoledronic Acid Injection, 5 mg/100 mL (Novaplus)	43598-0331-11	BS745	11/2019
Zoledronic Acid Injection, 5 mg/100 mL	55111-0688-52	BS801	03/2020

We ask for your cooperation in taking the following action:

- Immediately quarantine inventory of the affected product.
- If the product was further distributed, please identify the customers and notify them immediately of this product recall.
- Promptly complete the attached recall stock response form.
- Completed recall stock response form can be submitted by any of the below methods:
  - Fax: 817-868-5362
  - Email: RXrecalls@inmar.com
  - Mail: Inmar, Attn: Recall Coordinator, Dr. Reddy's Recall
    635 Vine Street
    Winston-Salem, NC 27101

Upon receipt of your recall response for, a "Return Kit" will be sent to you. This kit will include:

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

For medical questions, please contact Dr. Reddy's Laboratories at 888.375.3784.

For the full recall notice, please view the attached documents in the following pages.

Dr.Reddy's

RECALL STOCK RESPONSE FORM

RECALL of Zoledronic Acid Injection
(Retail Level)
09/12/2018

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 #_____

Debit Memo # _____ Original Invoice # _____

DEA # and Debit Memo # is required, without it, 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 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	Quantity Returned
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS633	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS701	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS702	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS703	
Zoledronic Acid Injection, 5mg/100mL (Novaplus)	43598-331-11	BS704	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS708	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS709	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS711	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS712	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS713	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS714	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS715	
Zoledronic Acid Injection, 5mg/100mL (Novaplus)	43598-331-11	BS725	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS726	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS727	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS728	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS729	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS730	
Zoledronic Acid Injection, 5mg/100mL (Novaplus)	43598-331-11	BS745	
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS801	

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 9am to 5pm (EST) Monday through Friday.

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

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

URGENT: DRUG RECALL (Retail Level)

09/12/2018

Zoledronic Acid Injection

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 out-of-specification result observed for Related Substance: Unknown Impurity. The unknown impurity has been characterized however it is yet to be confirmed. Evaluation based on the structure of the characterized suspected impurity has no structural alerts for genotoxicity or negative for genotoxicity and it is unlikely to pose risk to the patient safety however as an abundant precaution, Dr. Reddy's has made a decision to voluntary recall all lots identified with out-of-specification results.

The recall is for the following lots:

Item Description	NDC	Lot	Expiry Date
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS633	09/2018
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS701	12/2018
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS702	12/2018
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Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS709	03/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS711	03/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS712	03/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS713	03/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS714	03/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS715	03/2019
Zoledronic Acid Injection, 5mg/100mL (Novaplus)	43598-331-11	BS725	06/2019

Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS726	06/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS727	06/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS728	07/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS729	07/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS730	07/2019
Zoledronic Acid Injection, 5mg/100mL (Novaplus)	43598-331-11	BS745	11/2019
Zoledronic Acid Injection, 5mg/100mL	55111-688-52	BS801	03/2020

The product Distribution dates are: February 21, 2017 – June 15, 2018

Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for lots listed above and immediately discontinue distribution and sales of the product lots being recalled. Please quarantine the affected lots 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, Dr. Reddy's Recall
635 Vine Street,
Winston Salem, NC 27101

For questions regarding return of the recalled product please call Inmar at 800-967-5952.
Office hours 9am to 5pm (EST) Monday through Friday.

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 at 866-733-3952. For Medical related questions, please contact Dr. Reddy's Laboratories at 888-375-3784

Sincerely,

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

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