



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

**URGENT: DRUG RECALL (Retail Level)**

**02/06/2019**

**Esomeprazole Magnesium DR Capsules**

**MANUFACTURED BY:  
Dr. Reddy's Laboratories Ltd.  
Telangana 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:

**Esomeprazole Magnesium DR Capsules (40mg)**

See enclosed product label.

This voluntary recall has been initiated as a result of product complaint received for the presence of brown pellets inside the capsule. The brown color is formed due to the acidic tendency of enteric coated material. Based on the Health hazard assessment, the subject lot was tested for critical attributes and the results found within the specification limits, and there is no impact on the efficacy and safety of the product because of the color change of the pellets inside the capsule.

The lot of the product to be recalled is:

Item Description	NDC	Lot	Expire Date
Esomeprazole Magnesium DR Capsules, 40mg, 90count	43598-510-90	C800589	05/2019

The product Distribution dates are: February 22<sup>nd</sup>, 2018 – March 25<sup>th</sup>, 2018

**Recall Instructions:**

Please perform the following activities:

- Examine your inventory immediately for the 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, 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 866-733-3952 Medical related questions, please contact Dr. Reddy's Laboratories/ DLSS at 888-375-3784

Sincerely,

A handwritten signature in blue ink, appearing to read "D. Forman", written over a light blue horizontal line.

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

Enclosure(s)

1. Product Label
2. Recall Return Response Form

UNCONTROLLED COPY Issued on : 31-01-2019

Unwinding Area  
40 x 20 mm

**NDC 43598-510-90**  
**Esomeprazole Magnesium**  
**Delayed-Release**  
**Capsules USP, 40 mg\***  
 Rx only  
 90 Capsules

**PHARMACIST: Dispense the Medication Guide to each patient**

**Dr.Reddy's**

For medication guide, please visit:  
[www.drreddys.com/medguide/esomeprazolecaps.pdf](http://www.drreddys.com/medguide/esomeprazolecaps.pdf)  
 Or Scan QR code to see medication guide: \*

QR Code: 435985109013

Barcode: 435985109013

150066151

M.L. 59/RR/MP/97/R  
 Dr. Reddy's Laboratories Limited  
 Bachupally - 500 090 (INDIA)  
 Mfg. By:  
 R 116  
 USP Controlled Room Temperature.  
 Store at 20°-25°C (68°-77°F); [See USP Controlled Room Temperature].  
 See package insert.  
 Keep container tightly closed.  
 USUAL ADULT DOSAGE:  
 (contains 40 mg of esomeprazole magnesium trihydrate USP)  
 \* Each delayed-release capsule contains 40 mg of esomeprazole magnesium trihydrate USP.

100% of Actual Size

Unwinding Direction

115 mm x 40 mm

	<b>Product Name:</b> Esomeprazole Mg DR Caps 40 mg	<b>Component:</b> Label
	<b>Market:</b> USA	<b>List of Colours:</b> 471 C 2091 C Black Unwinding Area
<b>Version No:</b> 02	<b>Manufacturing Location:</b> FTO-3	
<b>Date:</b> 19.12.2016	<b>SAP Code:</b> 150066151	
<b>Change History:</b> Revision Artwork Corrections done		

**RECALL STOCK RESPONSE FORM**

**RECALL of Esomeprazole Magnesium DR Capsules  
(Retail Level)  
02/06/2019**

**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
Esomeprazole Magnesium DR Capsules, 40mg, 90count	43598-510-90	C800589	

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