



DR. REDDY'S

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

URGENT: DRUG RECALL

05/22/2015

Divalproex Sodium Extended-Release Tablets 250mg & 500mg

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:

Divalproex Sodium Extended-Release Tablets 250mg & 500mg

See enclosed product labels.

This voluntary recall has been initiated due to out-of-specification results for dissolution. Failed dissolution has the potential to adversely affect the efficacy of the extended-release product. Use of or consumption of this product might likely have a safety risk as per Health Hazard evaluation.

The lots of this product to be recalled are mentioned below.

Item Description	NDC	Lot	Expire Date
Divalproex Sodium Extended-Release Tablets 250mg 500 Count	55111-533-05	C307812	09/2015
Divalproex Sodium Extended-Release Tablets 250mg 100 Count	55111-533-01	C307859	09/2015
Divalproex Sodium Extended-Release Tablets 250mg 500 Count	55111-533-05	C307859	09/2015
Divalproex Sodium Extended-Release Tablets 500mg 100 Count	55111-534-01	C308195	10/2015

The product Distribution dates are: March 17, 2014 – July 16, 2014.

Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for lots listed above and immediately discontinue distribution and sales of this product being recalled. Please quarantine all 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: 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 Labels
2. Recall Return Response Form

Product Labels:

<p>DR. REDDY'S</p> <p>100 Tablets</p> <p>NDC 55111-534-01</p> <p>Divalproex Sodium Extended-Release Tablets, USP</p> <p>500 mg</p> <p>(Valproic Acid Activity)</p> <p>Rx Only</p> <p>PHARMACIST: Dispense the accompanying Medication Guide to each patient</p>	<p>Each tablet contains: Divalproex sodium USP equivalent to valproic acid500 mg.</p> <p>Do not accept if seal over bottle opening is broken or missing.</p> <p>Dispense in a USP tight, light-resistant container.</p> <p>Store at 20°-25°C (68°-77°F); [See USP Controlled Room Temperature].</p> <p>See enclosure for prescribing information.</p> <p>I 0212</p> <p>GTIN No. (01)18901148116471</p> <p>Mfd. By: Dr. Reddy's Laboratories Limited Bachupally - 500 090 INDIA</p> <p>150040354 M.L. 59/RR/AP/97/F/R</p>
<p>DR. REDDY'S</p> <p>500 Tablets</p> <p>NDC 55111-533-05</p> <p>Divalproex Sodium Extended-Release Tablets, USP</p> <p>250 mg</p> <p>(Valproic Acid Activity)</p> <p>Rx Only</p> <p>PHARMACIST: Dispense the accompanying Medication Guide to each patient</p>	<p>Each tablet contains: Divalproex sodium USP equivalent to valproic acid250 mg.</p> <p>Do not accept if seal over bottle opening is broken or missing.</p> <p>Dispense in a USP tight, light-resistant container.</p> <p>Store at 20°-25°C (68°-77°F); [See USP Controlled Room Temperature].</p> <p>See enclosure for prescribing information.</p> <p>I 0212</p> <p>GTIN: (01)08901148116399</p> <p>Mfd. By: Dr. Reddy's Laboratories Limited Bachupally - 500 090 INDIA</p> <p>150051740 M.L. 59/RR/AP/97/F/R</p>
<p>DR. REDDY'S</p> <p>100 Tablets</p> <p>NDC 55111-533-01</p> <p>Divalproex Sodium Extended-Release Tablets, USP</p> <p>250 mg</p> <p>(Valproic Acid Activity)</p> <p>Rx Only</p> <p>PHARMACIST: Dispense the accompanying Medication Guide to each patient</p>	<p>Each tablet contains: Divalproex sodium USP equivalent to valproic acid250 mg.</p> <p>Do not accept if seal over bottle opening is broken or missing.</p> <p>Dispense in a USP tight, light-resistant container.</p> <p>Store at 20°-25°C (68°-77°F); [See USP Controlled Room Temperature].</p> <p>See enclosure for prescribing information.</p> <p>I 0212</p> <p>GTIN No. (01)18901148116426</p> <p>Mfd. By: Dr. Reddy's Laboratories Limited Bachupally - 500 090 INDIA</p> <p>150040347 M.L. 59/RR/AP/97/F/R</p>



RECALL STOCK RESPONSE FORM

Product RECALL 05/22/2015 Divalproex Sodium Extended-Release Tablets 250mg & 500mg

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
Divalproex Sodium Extended-Release Tablets 250mg 500 Count	55111-533-05	C307812	
Divalproex Sodium Extended-Release Tablets 250mg 100 Count	55111-533-01	C307859	
Divalproex Sodium Extended-Release Tablets 250mg 500 Count	55111-533-05	C307859	
Divalproex Sodium Extended-Release Tablets 500mg 100 Count	55111-534-01	C308195	

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