



Updated Version: 01

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RA&QA  
DEC 06 2021  
BY: *n/q* 12-06-2021

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

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

(Note: This letter is a revised letter to the previously released 'Wholesale level Drug Recall' issued on October 01, 2021 for the subject lot. Please note the depth of the recall has been changed to the 'Retail Level').

**11/30/2021**

**Ezetimibe & Simvastatin Tablets**

**MANUFACTURED BY:**

**Dr. Reddy's Laboratories Louisiana, LLC.  
Shreveport, Louisiana, United States**

**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:

**Ezetimibe & Simvastatin Tablets**

See enclosed product label.

This voluntary recall is being initiated as a precautionary measure due to out of specification (OOS) results for the conductivity test for one of the excipients, Microcrystalline Cellulose (Avicel pH 102), NF supplied by DuPont. MCC is used as a tableting agent during the manufacturing of Ezetimibe/Simvastatin tablets. In addition to the above reason, lot# L100208 is also being recalled due to a product complaint received for comingling, where five (5) Ezetimibe and Simvastatin 10mg/10mg tablets found in a bottle of Ezetimibe and Simvastatin 10mg/40mg tablets.

The lots of the product to be recalled are in the table below:



Batch #	Description (Name, Strength, count)	Expiry Date	NDC
L100158	Ezetimibe & Simvastatin Tablets 10mg/40mg, 30 count	12/2022	43598-743-30
L100159	Ezetimibe & Simvastatin Tablets 10mg/40mg, 90 count	12/2022	43598-743-90
L100160	Ezetimibe & Simvastatin Tablets 10mg/80mg, 30 count	01/2023	43598-745-30
L100185	Ezetimibe & Simvastatin Tablets 10mg/40mg, 30 count	12/2022	43598-743-30
L100208	Ezetimibe & Simvastatin Tablets 10mg/40mg, 500 count	01/2023	43598-743-05
L100235	Ezetimibe & Simvastatin Tablets 10mg/20mg, 90 count	01/2023	43598-744-90
L100249	Ezetimibe & Simvastatin Tablets 10mg/80mg, 90 count	01/2023	43598-745-90
L100250	Ezetimibe & Simvastatin Tablets 10mg/80mg, 500 count	01/2023	43598-745-05
L100256	Ezetimibe & Simvastatin Tablets 10mg/10mg, 90 count	01/2023	43598-742-90
L100257	Ezetimibe & Simvastatin Tablets 10mg/10mg, 1000 count	01/2023	43598-742-10
L100298	Ezetimibe & Simvastatin Tablets 10mg/20mg, 30 count	01/2023	43598-744-30
L100304	Ezetimibe & Simvastatin Tablets 10mg/20mg, 30 count	01/2023	43598-744-30

**Risk Assessment: The OOS in conductivity in Microcrystalline cellulose was detected because of the presence of moderately higher additional ammonium chloride salt. Based on the safety and exposure assessment, the elevated levels of ammonium Chloride are not expected to pose any human health hazard.**

**There is a possibility of under dosing when the comingled tablet (10mg/10mg) is consumed by a patient. Considering the chronic nature of the indication, frequent monitoring of lipid profile and dose adjustment in patients receiving Ezetimibe and Simvastatin tablets, the possibility of harm due to such under dosing is very low.**

The Product Distribution Dates: March 30, 2021 to June 17, 2021

## Recall Instructions:

**Please perform the following activities:**

- Examine your inventory immediately for the lots listed above and immediately discontinue distribution and sales of the product lots 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 855-806-2523  
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 at 888-375-3784.

Sincerely,

For

DocuSigned by:  
**Naga Veluri**  
 Signer Name: Naga Veluri  
Signing Reason: I approve this document  
Signing Time: 01-Dec-21 | 12:41:11 AM IST  
6E040730C77C44BF858BCC47B4A296D7

Subbareddy Inta  
Sr. Director Quality  
Dr. Reddy's Laboratories, Inc.

Enclosure(s)

1. Product Label
2. Recall Return Response Form

NDC 43598-742-90

**Ezetimibe and Simvastatin Tablets**  
**10 mg/10 mg**

Rx only  
**90 Tablets** Dr.Reddy's 

Each tablet contains 10 mg ezetimibe and 10 mg simvastatin.  
**Usual Dosage:** See package insert for full prescribing information.  
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
 Keep container tightly closed.  
 Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
 Manufactured by:  
 Dr. Reddy's Laboratories LA LLC  
 Shreveport, LA 71106 USA  
 Distributed by:  
 Dr. Reddy's Laboratories Inc. 150072953-00  
 Princeton, NJ 08540 USA Issued: 05/18

GTIN: 00343598742908  
 43598742908  
 N M

NDC 43598-742-10

**Ezetimibe and Simvastatin Tablets**  
**10 mg/10 mg**

Rx only  
**1000 Tablets** Dr.Reddy's 

Each tablet contains 10 mg ezetimibe and 10 mg simvastatin.  
**Usual Dosage:** See package insert for full prescribing information.  
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
 Keep container tightly closed.  
 Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
 Manufactured by:  
 Dr. Reddy's Laboratories LA LLC  
 Shreveport, LA 71106 USA  
 Distributed by:  
 Dr. Reddy's Laboratories Inc. 150072973-00  
 Princeton, NJ 08540 USA Issued: 05/18

GTIN: 00343598742106  
 43598742106  
 N M

NDC 43598-744-30

**Ezetimibe and Simvastatin Tablets**  
**10 mg/20 mg**

Rx only  
**30 Tablets** Dr.Reddy's 

Each tablet contains 10 mg ezetimibe and 20 mg simvastatin.  
**Usual Dosage:** See package Insert for full prescribing information.  
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
 Keep container tightly closed.  
 Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Manufactured by:  
 Dr. Reddy's Laboratories LA LLC  
 Shreveport, LA 71106 USA  
 Distributed by:  
 Dr. Reddy's Laboratories Inc. 150072918-00  
 Princeton, NJ 08540 USA Issued: 05/18

  
 4359874430  
 NDC  
 GTIN: 00343598744308

NDC 43598-744-90

**Ezetimibe and Simvastatin Tablets**  
**10 mg/20 mg**

Rx only  
**90 Tablets** Dr.Reddy's 

Each tablet contains 10 mg ezetimibe and 20 mg simvastatin.  
**Usual Dosage:** See package Insert for full prescribing information.  
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
 Keep container tightly closed.  
 Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Manufactured by:  
 Dr. Reddy's Laboratories LA LLC  
 Shreveport, LA 71106 USA  
 Distributed by:  
 Dr. Reddy's Laboratories Inc. 150072974-00  
 Princeton, NJ 08540 USA Issued: 05/18

  
 4359874490  
 NDC  
 GTIN: 00343598744902



NDC 43598-743-30

**Ezetimibe and Simvastatin Tablets**  
10 mg/40 mg


Rx only  
30 Tablets 

Each tablet contains 10 mg ezetimibe and 40 mg simvastatin.  
Usual Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Keep container tightly closed.  
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
Manufactured by:  
Dr. Reddy's Laboratories LA LLC  
Shreveport, LA 71106 USA  
Distributed by:  
Dr. Reddy's Laboratories Inc. 150072916-00  
Princeton, NJ 08540 USA Issued: 05/18


  
43598-74330-1  
N3  
GTIN: 0034358743301

NDC 43598-743-90

**Ezetimibe and Simvastatin Tablets**  
10 mg/40 mg

Rx only  
90 Tablets 

Each tablet contains 10 mg ezetimibe and 40 mg simvastatin.  
Usual Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Keep container tightly closed.  
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
Manufactured by:  
Dr. Reddy's Laboratories LA LLC  
Shreveport, LA 71106 USA  
Distributed by:  
Dr. Reddy's Laboratories Inc. 150072984-00  
Princeton, NJ 08540 USA Issued: 05/18

  
43598-74390-5  
N3  
GTIN: 0034358743905

NDC 43598-743-05

**Ezetimibe and Simvastatin Tablets**  
10 mg/40 mg

Rx only  
500 Tablets 

Each tablet contains 10 mg ezetimibe and 40 mg simvastatin.  
Usual Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Keep container tightly closed.  
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
Manufactured by:  
Dr. Reddy's Laboratories LA LLC  
Shreveport, LA 71106 USA  
Distributed by:  
Dr. Reddy's Laboratories Inc. 150072917-00  
Princeton, NJ 08540 USA Issued: 05/18

  
43598-74305-9  
N3  
GTIN: 0034358743059



NDC 43598-745-30

**Ezetimibe and Simvastatin Tablets**  
10 mg/80 mg

Rx only  
30 Tablets 

Each tablet contains 10 mg ezetimibe and 80 mg simvastatin.  
Usual Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Keep container tightly closed.  
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
Manufactured by:  
Dr. Reddy's Laboratories LA LLC  
Shreveport, LA 71106 USA  
Distributed by:  
Dr. Reddy's Laboratories Inc. 150072919-00  
Princeton, NJ 08540 USA Issued: 05/18

  
4359874530  
N 3  
GTIN: 004339874530

NDC 43598-745-90

**Ezetimibe and Simvastatin Tablets**  
10 mg/80 mg

Rx only  
90 Tablets 

Each tablet contains 10 mg ezetimibe and 80 mg simvastatin.  
Usual Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Keep container tightly closed.  
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
Manufactured by:  
Dr. Reddy's Laboratories LA LLC  
Shreveport, LA 71106 USA  
Distributed by:  
Dr. Reddy's Laboratories Inc. 150072955-00  
Princeton, NJ 08540 USA Issued: 05/18


  
4359874590  
N 9  
GTIN: 004339874590

NDC 43598-745-05

**Ezetimibe and Simvastatin Tablets**  
10 mg/80 mg

Rx only  
500 Tablets 

Each tablet contains 10 mg ezetimibe and 80 mg simvastatin.  
Usual Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Keep container tightly closed.  
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).  
**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**  
Manufactured by:  
Dr. Reddy's Laboratories LA LLC  
Shreveport, LA 71106 USA  
Distributed by:  
Dr. Reddy's Laboratories Inc. 150072954-00  
Princeton, NJ 08540 USA Issued: 05/18

  
4359874505  
N 3  
GTIN: 004339874505



## RECALL STOCK RESPONSE FORM

### RECALL of Ezetimibe & Simvastatin Tablets (Retail Level) 11/30/2021

**(Note: This letter is a revised letter to the previously released 'Wholesale level Drug Recall' issued on October 01, 2021 for the subject lot. Please note the depth of the recall has been changed to the 'Retail Level').**

**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 and will be returning to Inmar. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) and will need \_\_\_\_\_ # of box labels.

Batch #	Description (Name, Strength, count)	NDC	Quantity Returned
L100158	Ezetimibe & Simvastatin Tablets 10mg/40mg, 30ct	43598-743-30	
L100159	Ezetimibe & Simvastatin Tablets 10mg/40mg, 90ct	43598-743-90	
L100160	Ezetimibe & Simvastatin Tablets 10mg/80mg, 30ct	43598-745-30	
L100185	Ezetimibe & Simvastatin Tablets 10mg/40mg, 30ct	43598-743-30	
L100208	Ezetimibe & Simvastatin Tablets 10mg/40mg, 500ct	43598-743-05	
L100235	Ezetimibe & Simvastatin Tablets 10mg/20mg, 90ct	43598-744-90	





## RECALL STOCK RESPONSE FORM

### RECALL of Ezetimibe & Simvastatin Tablets (Retail Level)

**11/30/2021**

**(Note: This letter is a revised letter to the previously released 'Wholesale level Drug Recall' issued on October 01, 2021 for the subject lot. Please note the depth of the recall has been changed to the 'Retail Level').**

Batch #	Description (Name, Strength, count)	NDC	Quantity Returned
L100249	Ezetimibe & Simvastatin Tablets 10mg/80mg, 90ct	43598-745-90	
L100250	Ezetimibe & Simvastatin Tablets 10mg/80mg, 500ct	43598-745-05	
L100256	Ezetimibe & Simvastatin Tablets 10mg/10mg, 90ct	43598-742-90	
L100257	Ezetimibe & Simvastatin Tablets 10mg/10mg, 1000ct	43598-742-10	
L100298	Ezetimibe & Simvastatin Tablets 10mg/20mg, 30ct	43598-744-30	
L100304	Ezetimibe & Simvastatin Tablets 10mg/20mg, 30ct	43598-744-30	

#### 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.

Any adverse events associated with recalled product?  Yes  No

If yes, please explain: \_\_\_\_\_

**If you did not purchase the product directly from the Manufacturer, please complete the below section.**

Purchased from: Wholesaler Name \_\_\_\_\_ DEA # \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_



**RECALL STOCK RESPONSE FORM**

**RECALL of Ezetimibe & Simvastatin Tablets  
(Retail Level)**

**11/30/2021**

**(Note: This letter is a revised letter to the previously released 'Wholesale level Drug Recall' issued on October 01, 2021 for the subject lot. Please note the depth of the recall has been changed to the 'Retail Level').**

If you have any questions regarding this form or product return, please contact Inmar at 855-806-2523, 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)**