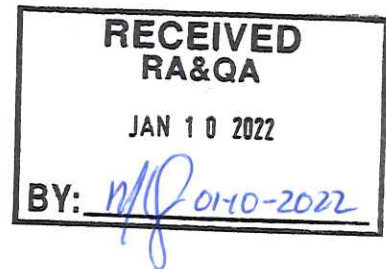




**Dr. Reddy's Laboratories, Inc.**  
107 College Road East,  
Princeton, NJ 08540



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

**01/04/2022**

**Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg**

**MANUFACTURED BY:**  
**Dr. Reddy's Laboratories Ltd.**  
**Malkajgiri District/ 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:

**Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg ER Tablets**

See enclosed product labels.

This extended voluntary recall for the thirty-nine (39) finished product lots of the above-mentioned product is based on the investigation root cause and impact assessment of the dissolution failure of one bulk lot C2103329.

There is no dissolution failure observed in the 39 subject finished product lots. However, this recall is being initiated as an abundant caution and is an extension to the initial recall. The initial recall notification was issued on November 12, 2021.

Refer to the attachment for the product lot details to be recalled.

**Risk Assessment:** Due to initial low dissolution results for the bulk lot, which was attributed to set-up during compression, the desired therapeutic concentration may fluctuate marginally. Because the subject thirty-nine (39) lots share the similar set-up which may lead to low dissolution, it was concluded to recall the lots mentioned in the attachment.

The product Distribution Dates: August 10, 2020 – October 25, 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)

For questions regarding return of the recalled product please call Inmar at 855-868-7082 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

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

DocuSigned by:  
Naga Veluri  
 Signer Name: Naga Veluri  
Signing Reason: I approve this document  
Signing Time: 05-Jan-22 | 4:31:28 AM IST  
6E040730C77C44BF858BCC47B4A296D7

Enclosure(s)

1. Product Labels
2. Recall Return Response Form



**Attachment - Extension Recall Notification - Fexofenadine 60mg / Pseudoephedrine 120mg Tablets**

S.No.	Label NDC#	UPC Number	Product Description	Lot Number	Expiry Date
1	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg/Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	79C002624A	4/30/2022
2	69842-249-30	50428290538	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	79C002624B	4/30/2022
3	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	79C002624C	4/30/2022
4	63868-729-10	635515998049	QC QUALITY CHOICE® Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg Extended-Release Tablets, 10ct (CDMA)	79C002624D	4/30/2022
5	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	79C002625A	4/30/2022
6	70000-0518-1	96295138627	LEADER™ Cardinal Health Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	79C002625B	4/30/2022
7	63868-729-10	635515998049	QC QUALITY CHOICE® Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg Extended-Release Tablets, 10ct (CDMA)	79C002625C	4/30/2022
8	69842-249-20	50428436189	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2000968A	8/31/2022
9	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2000968B	8/31/2022
10	43598-823-14	343598823140	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 20ct	AC2000968C	8/31/2022
11	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2000968D	8/31/2022
12	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2000968E	8/31/2022
13	69842-249-20	50428436189	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2000968F	8/31/2022
14	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2103328A	1/31/2023
15	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103328B	1/31/2023
16	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103328C	1/31/2023
17	43598-823-35	343598823355	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 10ct	AC2103328D	1/31/2023



**Attachment - Extension Recall Notification - Fexofenadine 60mg / Pseudoephedrine 120mg Tablets**

S.No.	Label NDC#	UPC Number	Product Description	Lot Number	Expiry Date
18	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	AC2103328E	1/31/2023
19	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2103328F	1/31/2023
20	70000-0518-1	96295138627	LEADER™ Cardinal Health Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2103328G	1/31/2023
21	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330A	1/31/2023
22	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330B	1/31/2023
23	43598-823-31	343598823317	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 30ct	AC2103330C	1/31/2023
24	11822-7388-5	11822738873	Rite Aid® Fexofenadine HCl 60mg & Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2103330D	1/31/2023
25	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2103330E	1/31/2023
26	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	AC2103330F	1/31/2023
27	69842-249-30	50428290538	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330G	1/31/2023
28	69842-249-30	50428290538	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330H	1/31/2023
29	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2103330I	1/31/2023
30	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2103330J	1/31/2023
31	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2106452A	3/31/2023
32	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2106452B	3/31/2023
33	70000-0518-1	96295138627	LEADER™ Cardinal Health Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2106452C	3/31/2023
34	43598-823-31	343598823317	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 30ct	AC2106452D	3/31/2023

**Attachment - Extension Recall Notification - Fexofenadine 60mg / Pseudoephedrine 120mg Tablets**

S.No.	Label NDC#	UPC Number	Product Description	Lot Number	Expiry Date
35	11822-7388-5	11822738873	Rite Aid® Fexofenadine HCl 60mg & Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2106452E	3/31/2023
36	0536-1242-07	305361242077	Rugby® Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg Extended-Release Tablets, 30ct	AC2106452F	3/31/2023
37	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	AC2106452G	3/31/2023
38	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2106452H	3/31/2023
39	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2106452I	3/31/2023



**RECALL STOCK RESPONSE FORM**

**RECALL of Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg  
(Retail Level)  
01/04/2022**

**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. **If this form is not filled out correctly and in its entirety, you may not be eligible for credit.**

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 attachment 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.

**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.**





**RECALL STOCK RESPONSE FORM**

**RECALL of Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg  
(Retail Level)  
01/04/2022**

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

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

If you have any questions regarding this form or product return, please contact Inmar at 855-868-7082, 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)**

Attachment Stock Response Form - Fexofenadine 60mg / Pseudoephedrine 120mg Tablets Recall <input type="checkbox"/>						
S.No.	Label# NDC#	UPC Number	Product Description	Lot Number	Expiry Date	Quantity returned
1	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg/Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	79C002624A	4/30/2022	
2	69842-249-30	50428290538	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	79C002624B	4/30/2022	
3	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	79C002624C	4/30/2022	
4	63868-729-10	635515998049	QC QUALITY CHOICE® Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg Extended-Release Tablets, 10ct (CDMA)	79C002624D	4/30/2022	
5	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	79C002625A	4/30/2022	
6	70000-0518-1	96295138627	LEADER™ Cardinal Health Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	79C002625B	4/30/2022	
7	63868-729-10	635515998049	QC QUALITY CHOICE® Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg Extended-Release Tablets, 10ct (CDMA)	79C002625C	4/30/2022	
8	69842-249-20	50428436189	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2000968A	8/31/2022	
9	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2000968B	8/31/2022	
10	43598-823-14	343598823140	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 20ct	AC2000968C	8/31/2022	
11	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2000968D	8/31/2022	
12	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2000968E	8/31/2022	
13	69842-249-20	50428436189	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2000968F	8/31/2022	
14	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2103328A	1/31/2023	



Attachment Stock Response Form - Fexofenadine 60mg / Pseudoephedrine 120mg Tablets Recall						
S.No	Label# NDC#	UPC Number	Product Description	Lot Number	Expiry Date	Quantity returned
15	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103328B	1/31/2023	
16	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103328C	1/31/2023	
17	43598-823-35	343598823355	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 10ct	AC2103328D	1/31/2023	
18	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	AC2103328E	1/31/2023	
19	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2103328F	1/31/2023	
20	70000-0518-1	96295138627	LEADER™ Cardinal Health Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2103328G	1/31/2023	
21	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330A	1/31/2023	
22	0363-1606-30	311917209739	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330B	1/31/2023	
23	43598-823-31	343598823317	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 30ct	AC2103330C	1/31/2023	
24	11822-7388-5	11822738873	Rite Aid® Fexofenadine HCl 60mg & Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2103330D	1/31/2023	
25	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2103330E	1/31/2023	
26	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	AC2103330F	1/31/2023	
27	69842-249-30	50428290538	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330G	1/31/2023	
28	69842-249-30	50428290538	CVS Health™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 30ct	AC2103330H	1/31/2023	

Attachment Stock Response Form - Fexofenadine 60mg / Pseudoephedrine 120mg Tablets Recall <input type="checkbox"/>						
S.No.	Label NDC#	UPC Number	Product Description	Lot Number	Expiry Date	Quantity returned
29	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2103330I	1/31/2023	
30	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2103330J	1/31/2023	
31	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2106452A	3/31/2023	
32	30142-611-14	41260004346	Kroger Allergy Relief-D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2106452B	3/31/2023	
33	70000-0518-1	96295138627	LEADER™ Cardinal Health Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2106452C	3/31/2023	
34	43598-823-31	343598823317	Dr. Reddy's Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets, 30ct	AC2106452D	3/31/2023	
35	11822-7388-5	11822738873	Rite Aid® Fexofenadine HCl 60mg & Pseudoephedrine HCl 120mg Extended-Release Tablets, 20ct	AC2106452E	3/31/2023	
36	0536-1242-07	305361242077	Rugby® Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg Extended-Release Tablets, 30ct	AC2106452F	3/31/2023	
37	49035-273-30	681131366298	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 30ct	AC2106452G	3/31/2023	
38	0363-1606-20	311917209722	Wal-Fex® D Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended Release Tablets, 20ct	AC2106452H	3/31/2023	
39	49035-273-20	681131366281	equate™ Fexofenadine HCl 60mg / Pseudoephedrine HCl 120mg Extended-Release Tablets USP, 20ct	AC2106452I	3/31/2023	