



Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL

### Montelukast Sodium Oral Granules USP, 4 mg 30 packets/carton

March 27, 2023

Lot #	Exp. Date	Strength	Size	Carton NDC	Packet NDC
3007556A	05/2023	4 mg	30 (individual foil) packets/carton	0093-7487-56	0093-7487-19

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is initiating a voluntary nationwide recall of one lot of **Montelukast Sodium Oral Granules USP, 4 mg** to the **RETAIL LEVEL**. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is test results for known Organic Impurities were above approved product specifications for the subject lot. Teva's toxicological and health hazard assessments determined that the level of the organic impurities pose a low risk to patient health.

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

***Please take the following actions upon receipt of this letter:***

- Immediately examine your inventory for the specified recall lot.
- Immediately discontinue distribution of the specific lot being recalled.
- Our records indicate we commercially distributed/shipped this product from 04/25/2022 through 05/23/2022.
- **If you have further distributed the recalled lot, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Stock Response Form as a basis for your recall notification.**
- Even if you have no product to return, promptly complete the attached Recall Business Reply Form (BRF) and return the BRF to Inmar, Attn: Recall Coordinator by any one of these means:

MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101

EMAIL: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com).

FAX: 817-868-5362.

Inmar will send labels for Return Goods Authorization (RGA) and shipping labels after receipt of your BRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
<b>Product Returns:</b> Contact Inmar at 855-246-5053 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from <a href="http://clsnetlink.com">clsnetlink.com</a>
<b>Medical-related Questions or to report an Adverse Event:</b> Contact Teva Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at <a href="mailto:druginfo@tevapharm.com">druginfo@tevapharm.com</a>
<b>Product Quality Complaint-related Questions:</b> Contact Teva Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at <a href="mailto:QAS@tevapharm.com">QAS@tevapharm.com</a>
<b>Customer Service-related Questions:</b> Contact Teva Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
<b>FDA contact information for reporting adverse events/quality complaints:</b> Online at <a href="http://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a> or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.



Teva Pharmaceuticals USA, Inc.

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Montelukast Sodium Oral Granules USP, 4 mg  
30 packets/carton

March 27, 2023

RECALL BUSINESS REPLY FORM

Date Form Completed \_\_\_\_\_

Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator  
MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) FAX: 817-868-5362

Section 1 – Customer Information

Check One

This Stock Response is for:

☐ Teva Direct Account

☐ Non-Direct Customer

Customer/Store Name:

\*DEA #:

\*Debit Memo #

*\*DEA # is required; in order to process your form.*

Address:

City/State/Zip

Contact Name (please print):

Telephone #:

Please mark your answer - I have checked my stock and):

☐ I do have stock of the recalled item(s) (complete section 2) OR ☐ I do not have stock of the recalled item(s).

Teva Direct Accounts

Does your response include **all** your DC locations?

☐ YES

☐ NO

Non-Direct Customer

The product(s) in this recall were purchased from:

Name of the Wholesaler/Distributor and Location: \_\_\_\_\_

Section 2 – Quantity of Product to Return

Enter the information of the recalled product(s) to be returned in the table below. If additional space is needed, please make copies of this form.

Montelukast Sodium Oral Granules USP, 4 mg 30 packets/carton					
Lot #	Exp. Date	Carton NDC	# of Cartons to Return	Packet NDC	# of Packets to Return
3007556A	05 2023	0093-7487-56		0093-7487-19	

Please indicate the number of shipping labels that you need to return the recalled product(s): \_\_\_\_\_

Inmar/MedTurn Use Only:

Scan

Labels

Store

Kit

D.B