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RECEIVED
JAN 25 2021

URGENT DRUG RECALL

January 20, 2021

Aurobindo Pharma USA Inc.
279 Princeton Hightstown Road
East Windsor, NJ 08512

Dear Valued Customer:

This is to inform you of a product recall involving:

Famotidine Tablets 40mg USP in 1000 count bottles
NDC 65862-860-99
Lot P2000467 Expiry Jul 2022

See enclosed product label for ease in identifying the product

Famotidine Tablets 40mg are white, rounded square shaped, biconvex, film-coated tablets debossed with 'CC' on one side and '61' on the other side..

This recall has been initiated due to confirmed complaints of Famotidine 20mg Tablets and one Ibuprofen 400mg tablet being present in 1000 count bottles of Famotidine 40mg Tablets Batch P2000467. A patient consuming a 20mg Famotidine tablet instead of the prescribed 40mg dose can experience reduced therapeutic efficacy A patient consuming an Ibuprofen 400mg tablet instead of Famotidine can potentially exacerbate certain gastrointestinal conditions such as a gastric ulcer.

Famotidine tablets are indicated in adult and pediatric patients 40 kg and greater for the treatment of:

- active duodenal ulcer (DU).
- active gastric ulcer (GU).
- symptomatic nonerosive gastroesophageal reflux disease (GERD).
- erosive esophagitis due to GERD, diagnosed by biopsy.

This product was shipped nationwide 09 December 2020 through 18 December 2020.

This recall is being carried out to the retail level.

Aurobindo Pharma USA, Inc. · 279 Princeton Hightstown Road · East Windsor, NJ 08520-1401
{phone}866.850.2876 · {fax}732.355.9449

Immediately examine your inventory and quarantine the product batch that is subject to this recall. In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Recall Instructions:

Please perform the following activities:

- Immediately examine your inventory and quarantine the specified lot of Famotidine 40mg Tablets.
- Immediately discontinue the distribution of the specific lot being recalled.
- Promptly complete the business response form even if you have no product to return.

Business response forms may be completed by the following methods:

- EMAIL TO RECALL@QUALANEX.COM
- Fax to 847-737-3719
- Mail to:

  Aurobindo USA C/O Qualanex
  1410 Harris Road
  Libertyville, IL 60048

Please complete and return the enclosed response form as soon as possible. If you need assistance in returning your product or have questions about the recall process, contact Qualanex at 800-505-9291 during the hours of 7:00 AM to 4:00 PM CST.

Once the business response form is received by Qualanex, a Return Goods Authorization form will be sent to you. Please return your product along with the Return Authorization using the postage paid shipping label included in your recall return packet. Appropriate reimbursement for product returns will be issued on receipt of the recalled product.

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

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Daniel Martins
Senior Vice President, Quality Compliance
279 Princeton Hightstown Road
East Windsor, NJ 08520
dmartins@aurobindousa.com
Direct 732.823.9021.

Product Label

NDC 65862-860-99

Rx only

Famotidine Tablets USP
40 mg

AUROBINDO 1,000 Tablets

Each film-coated tablet contains: Famotidine USP 40 mg.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a USP tight, light-resistant container.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

N3658628909969

P1420875

*Over printing Zone

Closing Area

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RECALL STOCK RESPONSE FORM

Famotidine Tablets 40mg USP in 1000 count bottles
VOLUNTARY Recall January 20, 2021

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.

Customer Name _____ DEA #_____

**DEA # is required, if it is not provided, the processing of your form will be delayed.*

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Contact e-mail address:_____ Fax # _____

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 withdrawn units I will be returning to QUALANEX, as soon as possible. Upon receipt of this Response Form, QUALANEX, will issue return authorization label(s) Please indicate the # of needed box labels _____.

Product Name	NDC	Batch No	Exp date	Sealed Qty To Be Returned	Open Quantity To Be Returned
Famotidine 40mg Tablets	65862-860-99	P2000467	July 2022		

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

Purchased From: Wholesaler Name _____

City _____ State _____ Wholesaler DEA# _____

If you have any questions regarding this form or product return please contact QUALANEX at 1-800-505-9291 Office hours 7am to 4pm CST Mon thru Fri.

Please fax this form to: 847-737-3719 Or E-mail recall@qualanex.com