Urgent: Product Recall

Nizatidine Capsules, USP

Recall initiated by the Manufacturer: Mylan Pharmaceuticals Inc.
Product Distributed by: Mylan Pharmaceuticals Inc.

January 7, 2020

PRODUCT	NDC	Name and Strength	Size	Lot number	Expiry
	0378-5150-91	Nizatidine Capsules, USP 150 mg	Bottles of 60	3086746	May 2020
	0378-5300-93	Nizatidine Capsules, USP 300 mg	Bottles of 30	3082876	January 2020
	0378-5300-93	Nizatidine Capsules, USP 300 mg	Bottles of 30	3082877	January 2020

REASON

Mylan Pharmaceuticals Inc. is conducting a voluntary nationwide recall to the consumer level of select lots of Nizatidine Capsules, USP (including the 150 mg and 300 mg strengths). This product is being recalled due to detected trace amounts of an impurity, N-nitrosodimethylamine (NDMA) contained in the API Nizatidine, USP, manufactured by Solara Active Pharma Sciences Limited. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products and vegetables. NDMA has been classified as a probable human carcinogen according to the International Agency for Research on Cancer (IARC). These batches were distributed in the U.S. between June 2017 and August 2018. To date, Mylan has not received any adverse events related to these batches.

Nizatidine capsules are indicated for up to 8 weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within 4 weeks. Nizatidine capsules are indicated for maintenance therapy for duodenal ulcer patients, after a reduced dosage of 150 mg at bedtime (h.s.) after healing of an active duodenal ulcer. The consequences of continuous therapy with nizatidine for longer than one year are not known. Nizatidine is indicated for up to 12 weeks for the treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis and associated heartburn due to gastroesophageal reflux disease (GERD). Nizatidine is indicated for up to 8 weeks for the treatment of active benign gastric ulcer. Before initiating therapy, care should be taken to exclude the possibility of malignant gastric ulceration.

ACTION

Wholesaler: Immediately examine your inventory, quarantine and discontinue distribution of these lots. In addition, if you have further distributed the product, please identify your retail level customers and notify them of this product recall. Please provide a list of customers via Microsoft excel file to mylan3408@stericycle.com within 10 business days. Stericycle will notify your retail level customers that received the affected batches.
Retailer: Immediately examine your inventory, quarantine and discontinue distribution of these lots. Additionally, if you have further distributed the product, please identify the consumer and notify them immediately of this product recall. The consumer should be instructed to contact Stericycle at 1-888-628-0727 for the documentation packet to return the product to Stericycle.
Consumer: Please contact Stericycle at 1-888-628-0727 for the documentation packet to return the product to Stericycle.
Wholesaler, Retailer and Consumer: Please proceed to items 1, 2, and 3 listed below.

1. Carry out a physical count and record this data on the Business Reply Card and Packing Slip which are included.
2. Mail the postage paid Business Reply Card to the address provided.
3. Return the recalled product with the Packing Slip using the prepaid UPS Return Service shipping label and limited quantity sticker to:

Stericycle
Event # 3408
2670 Executive Drive, Suite A
Indianapolis, IN 46241

OTHER

This recall extends to the consumer level.
Credit/check will be issued for return of recalled product only.
This recall is being conducted with the knowledge of the Food and Drug Administration.
For questions regarding the recall, please call Stericycle at 1-888-628-0727.
Any other product returned that is not involved with this recall will be destroyed and credit will not be issued.
We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.