

Mylan - Recall of nizatidine

- On January 8, 2020, <u>Mylan announced</u> a voluntary, consumer-level recall of <u>nizatidine</u> capsules due
 to detected trace amounts of N-nitrosodimethylamine (NDMA) contained in the active
 pharmaceutical ingredient (API), manufactured by Solara Active Pharma Sciences Limited.
- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA
 is a known environmental contaminant and found in water and foods, including meats, dairy
 products, and vegetables.

Product Description	NDC#	Lot# (Expiration Date)
Nizatidine 300 mg capsules	0378-5300-93	3082876 (1/2020); 3082877 (1/2020)
Nizatidine 150 mg capsules	0378-5150-91	3086746 (5/2020)

- Nizatidine is indicated for the short-term treatment (up to 8 weeks) of active duodenal ulcers and
 active benign gastric ulcers, as maintenance therapy for duodenal ulcer patients for up to one year,
 and for up to 12 weeks for the treatment of endoscopically diagnosed esophagitis and associated
 heartburn due to gastroesophageal reflux disease (GERD).
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled nizatidine.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- The FDA continues to evaluate the safety of ranitidine, including other common heartburn
 medications such as nizatidine and will provide more information as it becomes available. Updates
 can be found here.
- For more information regarding this recall, contact Stericycle (appointed company for Mylan) at 1-888-628-0727.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2020 Optum, Inc. All rights reserved.