Mylan Initiates Voluntary Nationwide Recall of Three Lots of Nizatidine Capsules, USP, Due to the Detection of Trace Amounts of NDMA (N-Nitrosodimethylamine) Impurity Found in the Active Pharmaceutical Ingredient Manufactured by Solara Active Pharma Scien

January 8, 2020

HERTFORDSHIRE, England, and PITTSBURGH, Jan. 8, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced that its U.S. based Mylan Pharmaceuticals business is conducting a voluntary nationwide recall, to the consumer level, of three lots of Nizatidine Capsules, USP (including the 150mg and 300mg strengths). While Mylan has not received any reports of adverse events related to these batches to date, this product is being voluntarily 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 (a substance that could cause cancer) according to the International Agency for Research on Cancer (IARC).

The finished products are manufactured by Mylan Pharmaceuticals Inc. These batches were distributed nationwide to wholesalers, mail order pharmacies, retail pharmacies, and a distributor between June 2017 and August 2018. The recalled batches are as follows:

NDC	Product Description	Strength	Size	Lot Number	Expiry
0378-5150-91	Nizatidine Capsules, USP	150mg	Bottles of 60	3086746	May 2020
0378-5300-93	Nizatidine Capsules, USP	300mg	Bottles of 30	3082876	Jan 2020
0378-5300-93	Nizatidine Capsules, USP	300mg	Bottles of 30	3082877	Jan 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).

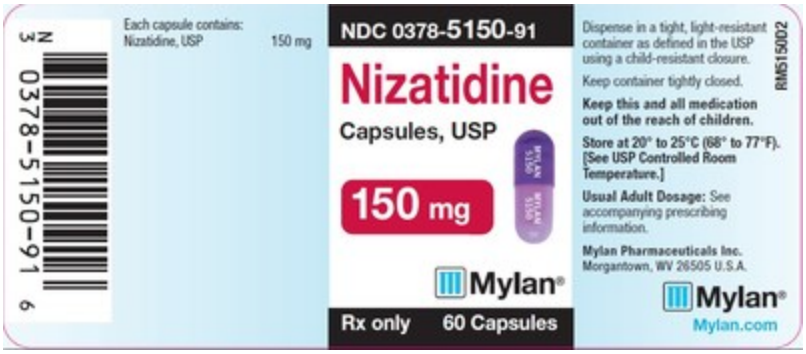
Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. Wholesalers, retailers and consumers that are in possession of recalled product should contact Stericycle at 888-628-0727 for the return of the recalled product. Normal business hours are Monday through Friday 8 a.m. to 5 p.m. EST.

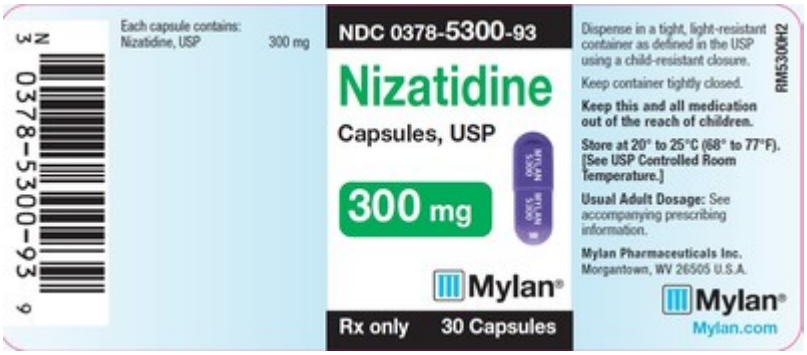
Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.





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SOURCE Mylan N.V.

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