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January 2020 **COM-2020-005**

RECALL NOTIFICATION

DATE:
January 8, 2020

DRUG NAME:
Nizatidine Capsules 150mg and 300mg

COMPANY:
Mylan N.V.

REASON:
NDMA (Nitrosodimethylamine) impurity detected

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

Affected products:

NDC	Product description	Lot #	Expiration date
0378-5150-91	**Nizatidine 150mg Capsules x 60**	3086746	May 2020
0378-5300-93	**Nizatidine 300mg Capsules x 30**	3082876	Jan 2020
0378-5300-93	**Nizatidine 300mg Capsules x 30**	3082877	Jan 2020

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.

Contact information:

- Wholesalers, retailers, and consumers:
  - Stericycle: Phone: 888-628-0727, Monday - Friday 8 a.m. to 5 p.m. EST

Safety Note:

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- 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

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Expires 12/01/2022

Additional information // Reference:

- Center for Drug Evaluation and Research, F. D. A. (2020, January 8). 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 Sciences Limited. Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-initiates-voluntary-nationwide-recall-three-lots-nizatidine-capsules-usp-due-detection-trace

Best regards,

PharmPix Clinical Department

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