American Health Packaging – Recall of ranitidine

- On February 27, 2020, American Health Packaging announced a voluntary, consumer-level recall of prescription ranitidine tablets because of the potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA.
    - This recall was initiated in response to the recall by Amneal Pharmaceuticals which included affected lots that were repackaged by American Health Packaging.
- 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
Ranitidine 150 mg tablets, 100 count unit dose blisters	Carton NDC: 60687-322-01 Individual dose NDC: 60687-322-11	179516	12/31/19
		179745	12/31/19
		180712	02/29/20
		180819	04/30/20
		181403	05/31/20
		182544	05/31/20
		183155	05/31/20
		183236	05/31/20
		185739	12/31/20
		186600	12/31/20
		186702	12/31/20

- Prescription ranitidine is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of gastroesophageal reflux disease, and treatment of endoscopically diagnosed erosive esophagitis.
- Patients taking prescription ranitidine who wish to stop should talk to their healthcare provider about other treatment options. Multiple drugs are approved for the same or similar uses as ranitidine.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled ranitidine.
- 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 and will provide more information as it becomes available. Updates can be found here.

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- Contact Inmar (appointed company for American Health Packaging) at **1-800-967-5952** for further information regarding this recall.

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