

## Appco Pharma – Recall of ranitidine

- On January 7, 2020, [Appco Pharma announced](#) a voluntary, consumer-level recall of prescription [ranitidine](#) capsules because of the presence or potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA.
- 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 300 mg capsules	62559-691-30	1905227UE (4/2021); 1905228UE (4/2021)
Ranitidine 150 mg capsules	62559-690-60	1905225VN (4/2021); 1906295UN (5/2021); 1906296UN (5/2021); 1906297UN (5/2021);
	62559-690-05	1905226VD (5/2021) 1906298UD (5/2021);

- 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](#).
- Contact Appco or ANI pharmaceuticals by phone or email for more information regarding this recall.
  - Appco: 1-732-253-7735; [pv@appcopharma.com](mailto:pv@appcopharma.com)
  - ANI Pharmaceuticals: 1-800-308-6755; [PVSupport@safetycall.com](mailto:PVSupport@safetycall.com)