AvKare – Recall of ranitidine

- On November 14, 2019, AvKare announced a voluntary, consumer-level recall of prescription ranitidine due to potential N-nitrosodimethylamine (NDMA) amounts above 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.
- AvKare's recall is due to the recent consumer level recall of Amneal's prescription ranitidine products.

Product Description	NDC#	Lot# (Expiration Date)
Ranitidine 150 mg tablets	42291-0724-10	HH04918A (08/31/20); HG02319A (06/30/21); HG02419A (06/30/21); HG02619A (06/30/21); HH04518A (08/31/20); HH04618A (08/31/20); HL07518A (11/30/20); HH04818A (08/31/20); HE03319A (04/30/21); HK06918A (10/31/20); HK02718A (10/31/20); HK16617A (11/30/19); HL03917A (11/30/19); HL04017A (11/30/19); HA00419A (12/31/20); HH04718A (08/31/20); HC14018A (04/30/20); HA00519A (12/31/20); HA2719A (12/31/20); HA02819A (12/31/20); HB03518A (03/31/20); HB03618A (03/31/20); HC05019A (03/31/21); HE05419A (04/30/21); HC05911A (03/31/21); HE03419A (04/30/21); HC14118A (04/30/20); HC14218A (04/30/20); HC14318A (04/30/20); HC14418A (04/30/20); HC14518A (05/31/20); HM06017A (11/30/19); HC05119A (03/31/21); HM06117A (11/30/19); HL07418A (11/30/20)

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	42291-0724-18	21570 (03/01/20); 21571 (03/01/20); 22190 (03/31/20); 22192 (05/31/20); 22497 (05/31/20); 22620 (05/31/20); 22999 (09/30/20); 23000 (09/30/20); 24158 (03/31/21); 24159 (04/30/21)
	42291-0724-60	22657 (03/31/20); 24157 (04/30/21); 23001 (09/30/20); 22193 (03/31/20); 21680 (03/01/20); 21241 (03/01/20); 23002 (09/30/20)
Ranitidine 300mg tablets	42291-0725-25	22247 (06/30/20); 24289 (01/31/21); 24199 (01/31/21); 24198 (01/31/21); 23244 (11/30/20); 23214 (09/30/20); 21528 (02/01/20); 21527 (02/01/20); 21309 (02/01/20); 21307 (02/01/20); 23243 (09/30/20)
	42291-0725-30	23776 (01/31/21); 22291 (06/30/20); 23215 (09/30/20)

- 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 GERD 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 AvKare at **1-931-908-2199** for further information regarding this recall.