Golden State Medical Supply and Aurobindo – Recall of ranitidine

- On November 8, 2019, the FDA announced a voluntary, consumer-level recalls of Aurobindo's prescription ranitidine due to unacceptable levels of N-nitrosodimethylamine (NDMA). Golden State Medical Supply has also announced a voluntary, consumer-level recall of prescription ranitidine.
    - Additionally, Aurobindo is recalling one lot of over-the-counter (OTC) ranitidine tablets to the retail level.
- The FDA has advised companies to recall their ranitidine if testing shows levels of NDMA above the acceptable daily intake (96 nanograms per day or 0.32 parts per million for ranitidine).
- 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.

Manufacturer	Product Description	NDC#	Lot# (Expiration Date)
Aurobindo	Ranitidine 150 mg tablets* *OTC product recalled to the retail level	55910-092-79	NBSB19001DA3 (Feb-21)
	Ranitidine 150 mg capsules	59651-144-60	RA1518001-A (Jul-2020)
			RA1518002-A (Jul-2020)
		59651-144-05	RA1518002-B (Jul-2020)
			RA1518003-A (Jul-2020)
			RA1518004-A (Aug-2020)
			RA1518005-A (Aug-2020)
		59651-144-60	RA1518005-B (Aug-2020)
			RA1518006-A (Aug-2020)
		59651-144-05	RA1518007-A (Sep-2020)
			RA1518008-A (Sep-2020)
			RA1518009-A (Sep-2020)
			RA1518010-A (Oct-2020)
			RA1518011-A (Nov-2020)
			RA1518012-A (Nov-2020)
			RA1518013-A (Nov-2020)
			RA1518014-A (Nov-2020)
			RA1518015-A (Nov-2020)
		59651-144-60	RA1519003-A (May-2021)
		59651-144-05	RA1519003-B (May-2021)
			RA1519004-A (May-2021)
	Ranitidine 300 mg capsules	59651-145-30	RA3018001-A (Jul-2020)
			RA3018002-A (Jul-2020)

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			RA3018003-A (Jul-2020)
			RA3018004-A (Aug-2020)
			RA3018005-A (Aug-2020)
			RA3018006-A (Aug-2020)
			RA3018007-A (Sep-2020)
			RA3018008-A (Sep-2020)
			RA3018009-A (Sep-2020)
			RA3018010-A (Oct-2020)
			RA3019001-A (Jan-2021)
			RA3019002-A (Jan-2021)
			RA3019003-A (May-2021)
	Ranitidine 15 mg/mL syrup (75 mg/5 mL)	65862-431-74	UI1519001-A (May-2021)
			UI1519002-A (May-2021)
			UI1519003-A (May-2021)
			UI1519004-A (May-2021)
Golden State Medical Supply	Ranitidine 150 mg capsule	51407-097-05	GS025702 (10/31/2020); GS026099 (10/31/2020); GS026108 (10/31/2020); GS026838 (10/31/2020); GS027272 (10/31/2020; GS027273 (5/31/2021); GS023970 (10/31/2020)
	Ranitidine 300 mg capsule	51407-098-01	GS025813 (10/31/2020); GS023971 (10/31/2020); GS025527 (10/31/2020); GS027555 (7/31/2021); GS026114 (10/31/2020); GS026189 (10/31/2020); GS026190 (5/31/2021); GS026220 (5/31/2021); GS026584 (5/31/2021); GS027139 (5/31/2021); GS027554 (5/31/2021); GS025526 (10/31/2020)

- Ranitidine is an OTC and prescription drug. Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach.

- OTC ranitidine is approved to prevent and relieve heartburn associated with acid ingestion and sour stomach. Prescription ranitidine is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.

- 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.

- Consumers may not know if the OTC ranitidine in their homes contains NDMA above the acceptable daily intake level because these recalls have been to the retail level, meaning they were only removed from store shelves. The NDMA levels the FDA found are similar to the levels a consumer would expect to be exposed to when eating common foods like grilled and smoked meats.

- Consumers taking OTC ranitidine may consider using other OTC products approved for their condition. To date, the FDA's testing has not found NDMA in alternatives such as Pepcid® (famotidine), Tagamet® (cimetidine), Nexium® (esomeprazole), Prevacid® (lansoprazole) and Prilosec® (omeprazole).

- 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 quarantine the product immediately.

- The FDA is continuing to test ranitidine products from multiple manufacturers and assessing the possible effect on patients who have been taking ranitidine. Additionally, the FDA recently released a second testing method for manufacturers and regulators to detect and quantify NDMA in ranitidine.

- The FDA will take appropriate measures based on the results of this ongoing investigation. Some manufacturers have chosen to stop distribution of ranitidine as a precautionary measure while the FDA and other international regulators conduct their investigations of the NDMA impurity.

- The FDA continues to evaluate the safety of ranitidine and will provide more information as it becomes available. Updates can be found here.

- Contact Aurobindo at **1-866-850-2876** or Golden State Medical Supply at **1-800-284-8633** for further information regarding these recalls.