

## COMPANY ANNOUNCEMENT

# Golden State Medical Supply, Inc. Issues a Voluntary Nationwide Recall of Ranitidine Hydrochloride 150mg and 300mg Capsules (Manufactured by Novitium Pharma LLC) Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA)

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

November 15, 2019

**FDA Publish Date:**

November 15, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

Potential presence of N-Nitrosodimethylamine (NDMA) above levels established by the FDA

**Company Name:**

GSMS, Inc.

**Brand Name:**

GSMS Incorporated

**Product Description:**


Ranitidine HCl 150mg and 300mg Capsules

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## Company Announcement

**Golden State Medical Supply, Incorporated (GSMS, Inc)** based upon a manufacturer's recall by Novitium Pharma LLC (Novitium), is voluntarily instituting a recall of all quantities and lots, within expiry, of Ranitidine HCl 150mg and 300mg Capsules to the consumer level because of potential presence of N-Nitrosodimethylamine (NDMA) above levels established by the FDA.

GSMS, Inc. received a recall notification from the manufacturer, Novitium, on October 25th, 2019 and initiated a voluntary recall on November 6th, 2019 to the consumer level for 7 lots of Ranitidine HCl 150mg and 12 lots of Ranitidine HCl 300mg Capsules.

(Novitium's press release: <http://novitiumpharma.com/products/ranitidine-recall-press-release-final/> (<http://novitiumpharma.com/products/ranitidine-recall-press-release-final/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>))

To date, GSMS, Inc. has not received any reports of adverse events related to the use of the products as part of this recall.

**Risk Statement:** NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Ranitidine Hydrochloride Capsules are indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable.

### **The Ranitidine Hydrochloride Capsules being recalled are supplied as follows:**

- **Ranitidine Hydrochloride 150mg Capsules:** Caramel colored capsules, imprinted 001 on cap and novitium 150 mg on body in white ink, filled with white to pale yellow powder.
- **Ranitidine Hydrochloride 300mg Capsules:** Caramel colored capsules, imprinted 002 on cap and novitium 300 mg on body in white ink, filled with white to pale yellow powder.

GSMS, Inc. has promptly notified its consignees via email and certified mail. Consignees, i.e., wholesale distributors and TMOPs, are instructed to immediately stop distribution, quarantine all remaining products in their control, and return the recalled product to GSMS, Inc. The consignees are also instructed to provide their customers, i.e., pharmacies and consumers, a copy of GSMS, Inc.'s recall notification, recall response form, and letter to consumers, patients, and caregivers.

The lots under GSMS, Inc.'s voluntary recall have been primarily sold to AmerisourceBergen, McKesson, and Tricare Mail Order Pharmacies (TMOP) as listed below:

Product Description	GSMS NDC	GSMS Lot #	Expiration Date
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Product Description	GSMS NDC	GSMS Lot #	Expiration Date
RANITIDINE HCl 150MG CAPSULES 500 Ct Bottle	51407-097-05	GS023970	10/31/2020
		GS026108	10/31/2020
		GS026099	10/31/2020
		GS026838	10/31/2020
		GS025702	10/31/2020
		GS027272	10/31/2020
		GS027273	05/31/2021
RANITIDINE HCl 300MG CAPSULES 100 Ct Bottle	51407-098-01	GS023971	10/31/2020
		GS025527	10/31/2020
		GS025526	10/31/2020
		GS026114	10/31/2020
		GS025813	10/31/2020
		GS026189	10/31/2020
		GS027555	07/31/2021
		GS026190	05/31/2021
		GS026220	05/31/2021
		GS026584	05/31/2021
		GS027139	05/31/2021
		GS027554	05/31/2021

Consumers taking Ranitidine HCl capsules are advised to consult with their physician, pharmacist, or healthcare provider about an alternative treatment prior to discontinuing the use of the medication. Once an alternative treatment has been prescribed, the patients are instructed to contact Novitium's recall processor to obtain instructions and kit for returning the remaining product in their possession.

**Manufacturer:** Novitium Pharma

**Recall Processor:** Stericycle Return Management Services

Phone: (866) 382-8606

Email: [Novitiumpharma6639@stericycle.com](mailto:Novitiumpharma6639@stericycle.com) (mailto:Novitiumpharma6639@stericycle.com)

Consumers with questions regarding this recall can contact GSMS, Inc, by:

Phone: (800) 284-8633, ext. 215 (Monday through Friday between 7:30 AM to 4:00 PM, Pacific)

Fax: (805) 437-7588

Email: [recalls@gsms.us](mailto:recalls@gsms.us) (mailto:Email: recalls@gsms.us)

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/forms-reporting-fda>) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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## Company Contact Information

### Consumers:

GSMS, Inc

☎ (800) 284-8633, ext. 215

✉ [recalls@gsms.us](mailto:recalls@gsms.us) (mailto:recalls@gsms.us)


### Media:

Tammy Stefanovic

☎ (805) 477-9866 ext. 287

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## Product Photos

<i>GSMS Incorporated GSMS Incorporated GSMS Incorporated GSMS Incorporated</i>			
Manufactured by Novitium Pharma LLC 70 Lake Drive, East Windsor, New Jersey 08520 Packaged by GSMS, Incorporated, Camarillo, CA 93012 USA	<ul style="list-style-type: none"> <li>• Each capsule contains: ranitidine hydrochloride, USP equivalent to 150 mg of ranitidine.</li> <li>• <b>Replace cap securely after each opening.</b></li> <li>• Store in a dry place.</li> <li>• Protect from light.</li> <li>• Dispense in a tight, light-resistant container.</li> <li>• <b>Do not use if printed safety seal under cap is broken or missing.</b></li> <li>• Keep this and all medication out of the reach of children.</li> </ul>	 5140709705	NDC 51407-097-05 <b>RANITIDINE</b> <b>CAPSULES</b> <b>150 mg</b> <b>500 capsules</b> See package insert for dosage information.
			Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

<i>GSMS Incorporated GSMS Incorporated GSMS Incorporated GSMS Incorporated GSMS Incorporated GSMS Incorporated</i>					
Manufactured by Novitium Pharma LLC 70 Lake Drive, East Windsor, New Jersey 08520 Packaged by GSMS, Incorporated, Camarillo, CA 93012 USA	<ul style="list-style-type: none"> <li>• Each capsule contains: ranitidine hydrochloride, USP equivalent to 300 mg of ranitidine.</li> <li>• <b>Replace cap securely after each opening.</b></li> <li>• Store in a dry place.</li> <li>• Protect from light.</li> <li>• Dispense in a tight, light-resistant container.</li> <li>• <b>Do not use if printed safety seal under cap is broken or missing.</b></li> <li>• Keep this and all medication out of the reach of children.</li> </ul>	 5140709801	NDC 51407-098-01 <b>RANITIDINE</b> <b>CAPSULES</b> <b>300 mg</b> <b>100 capsules</b> See package insert for dosage information.		
			Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].		<b>Rx only</b>

[↻ More Recalls, Market Withdrawals, & Safety Alerts \(/safety/recalls-market-withdrawals-safety-alerts\)](#)