

FDA Drug Recall

Appco Pharma LLC Issues Voluntary Nationwide Recall of Ranitidine Hydrochloride Capsules 150 mg and 300 mg Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA)

January 7, 2020

Appco Pharma LLC (Appco) is voluntarily recalling all quantities and lots, within expiry, of Ranitidine Hydrochloride Capsules to the Consumer level. Ranitidine Hydrochloride Capsules are being recalled because of the presence or potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA, based on FDA-validated tests. To date, Appco has not received any reports of adverse events related to use of the product 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 in strengths of 150 mg and 300 mg, is a prescription-only oral medication 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 products subject to recall are listed below and are packaged in bottles. The product can be identified by checking the product name, count/bottle, manufacturer details and batch or lot number on the bottle containing these products.

Description	Strength	NDC	Batch #	Counts	Expiration date
Ranitidine Capsules 300 mg	300 mg	62559-691-30	1905227UE	30's	Apr-21
	300 mg	62559-691-30	1905228UE	30's	Apr-21
Ranitidine Capsules 150 mg	150 mg	62559-690-60	1905225VN	60's	Apr-21
	150 mg	62559-690-05	1905226VD	500's	Apr-21
	150 mg	62559-690-60	1906295UN	60's	May-21



Description	Strength	NDC	Batch #	Counts	Expiration date
	150 mg	62559-690-60	1906296UN	60's	May-21
	150 mg	62559-690-60	1906297UN	60's	May-21
	150 mg	62559-690-05	1906298UD	500's	May-21

Ranitidine Capsules 150 mg & Ranitidine Capsules 300 mg were distributed nationwide.

Appco is notifying their marketing partner (ANI Pharmaceuticals, Inc.) by phone, email or other communication with recall notification communication. ANI Pharmaceuticals Inc., on behalf of Appco Pharma LLC, will be notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Appco is arranging for return of all recalled products to ANI Pharmaceuticals, Inc. Instructions for returning recalled products are given in the recall letter. Anyone with an existing inventory will be asked to immediately stop distribution and return any stock to ANI Pharmaceuticals, Inc. by contacting Stephen Bitter at stephen.bitter@anipharmaceuticals.com or 218-634-3655 (between 8 to 5PM CST). All the recalled product shall be sent to:

ANI Pharmaceuticals
 Attn: Stephen Bitter
 210 Main Street West
 Baudette, MN 56623

Consumers that have product which is being recalled should stop using/return to place of purchase and speak to their physician or pharmacist about alternate healthcare treatment options.

Consumers with questions regarding this recall can contact Appco at: (732) 253-7735 between 8 am and 6 pm (EST) (Monday-Friday) or e-mail: pv@appcopharma.com or at ANI Pharmaceuticals, Inc. at 1-800-308-6755 or PVSupport@safetycall.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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](#)
- Regular Mail or Fax: [Download form](#) 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.

Company Contact Information

Consumers:

Appco
 732-253-7735
pv@appcopharma.com

Media:

Stephen Bitter

218-634-3655

stephen.bitter@anipharma.com

Product Photos

NDC 62559-690-60

Ranitidine Capsules

150 mg

Rx Only
60 Capsules

 **ani**
Pharmaceuticals, Inc.

Each capsule contains:
Ranitidine hydrochloride USP equivalent to 150 mg ranitidine.

Usual Dosage: See accompanying prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] in a dry place. Protect from light. Replace cap securely after each opening. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

Manufactured by:
Appco Pharma LLC
Piscataway, NJ 08854
Rev. 06/2019
200353

Distributed by:
ANI Pharmaceuticals, Inc.
Baudette, MN 56623


N 3 62559 69060 7

1.15"


NO VARNISH

NDC 62559-690-05

Ranitidine Capsules

150 mg

Rx Only
500 Capsules

 **ani**
Pharmaceuticals, Inc.

Each capsule contains:
Ranitidine hydrochloride USP equivalent to 150 mg ranitidine.

Usual Dosage: See accompanying prescribing information.

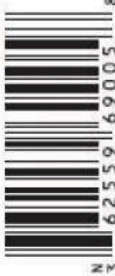
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] in a dry place. Protect from light. Replace cap securely after each opening. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

Manufactured by:
Appco Pharma LLC
Piscataway, NJ 08854

Distributed by:
ANI Pharmaceuticals, Inc.
Baudette, MN 56623

Rev. 03/2019
200256


N 3 62559 69005 8

1.00"

NO VARNISH

1.15"

NDC 62559-691-30

Ranitidine Capsules

300 mg



Rx Only
30 Capsules

Each capsule contains:
Ranitidine hydrochloride USP equivalent to 300 mg
ranitidine.

Usual Dosage: See accompanying prescribing
information.

Store at 20° to 25°C (68° to 77°F) [see USP
Controlled Room Temperature] in a dry place. Protect
from light. Replace cap securely after each opening.
Dispense in a tight, light-resistant container.

**KEEP THIS AND ALL MEDICATION OUT OF THE
REACH OF CHILDREN.**

Manufactured by:
Appco Pharma LLC
Piscataway, NJ 08854

Rev. 03/2019
200257

Distributed by:
ANI Pharmaceuticals, Inc.
Baudette, MN 56623



NO VARNISH

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/appco-pharma-llc-issues-voluntary-nationwide-recall-ranitidine-hydrochloride-capsules-150-mg-and-300?utm_campaign=Appco%20Pharma%20LLC%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Ranitidine%20Hydrochloride%20Capsules&utm_medium=email&utm_source=Eloqua