Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Consumer Level Recall of 38 Lots of Ranitidine Tablets 150mg, Ranitidine Capsules 150mg, Ranitidine Capsules 300mg and Ranitidine Syrup 15mg/mL due to the detection of NDMA (Nitrosodimethylamine) Impurity

Aurobindo Pharma USA, Inc. contact {1-866-850-2876 option 2}

Recall being handled by:

Qualanex: Contact 1-888-504-2014

FOR IMMEDIATE RELEASE November 6, 2019: Aurobindo Pharma USA, Inc. is conducting a voluntary recall of 1 lot of **Ranitidine Tablets 150mg to the retail level and 37 lots of Ranitidine Capsules 150mg, Ranitidine Capsules 300mg and Ranitidine Syrup 15mg/mL to the consumer level due to the detection of NDMA (Nitrosodimethylamine) Impurity in the finished product**. The impurity detected is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall.

Ranitidine is a competitive, reversible inhibitor of the action of histamine at the histamine H2 receptors found in gastric parietal cells. This results in decreased gastric acid secretion and gastric volume, and reduced hydrogen ion concentration. Uses are:

- Relieves heartburn associated with acid indigestion and sour stomach.
- Prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages.

Patients who prescribed or are taking **Ranitidine Tablets 150mg, Ranitidine Capsules 150mg, Ranitidine Capsules 300mg and Ranitidine Syrup 15mg/mL** should continue taking their medication. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The products subject to recall are listed below and are packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

Product Name	NDC	Batch Number	Exp. Date
Ranitidine Tablets 150mg	55910-092-79	NBSB19001DA3	Feb-2021
Ranitidine Capsules 150mg	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 Capsules 300mg	59651-145-30	RA3018001-A	Jul-2020
		RA3018002-A	Jul-2020
		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 Syrup (Ranitidine Oral Solution, USP) 15 mg/mL (75 mg/5 mL)	65862-431-74	UI1519001-A	May-2021
		UI1519002-A	May-2021
		UI1519003-A	May-2021
		UI1519004-A	May-2021

Ranitidine Tablets 150mg, Ranitidine Capsules 150mg, Ranitidine Capsules 300mg and Ranitidine Syrup 15mg/mL were distributed nationwide to Aurobindo Pharma USA, Inc. and AuroHealth wholesale and distributor customers 28 September 2018 through 19 September 2019. Qualanex, on behalf of Aurobindo Pharma USA, Inc. 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. Aurobindo Pharma USA, Inc. is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Aurobindo Pharma USA, Inc. at:

- 1-866-850-2876 Option 2
- pvg@aurobindousa.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

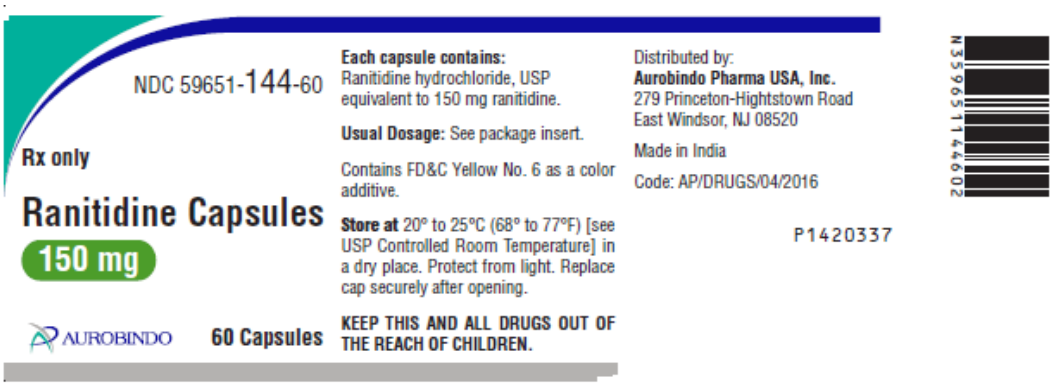
Any general **questions regarding the return of this product** please contact Qualanex at 1-888-504-2014 or email recall@qualanex.com (live calls received 7:00 am to 4:00 pm M-F CST).

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**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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.

The product labels are as shown below:



AUROBINDO
Committed to healthier life!
www.AurobindoUSA.com

NDC 59651-144-05

Rx only

Ranitidine Capsules
150 mg

AUROBINDO **500 Capsules**

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

Usual Dosage: See package insert.

Contains FD&C Yellow No. 6 as a color additive.

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 opening.

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

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

N3596511440 5 3

P1420338

NDC 59651-145-30

Rx only

Ranitidine Capsules
300 mg

AUROBINDO **30 Capsules**

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

Usual Dosage: See package insert.

Contains FD&C Yellow No. 6 as a color additive.

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 opening.

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

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

N3596511453 0 2

P1420339

NDC 65862-431-74

Rx only

Ranitidine Syrup (Ranitidine Oral Solution, USP)
15 mg/mL (75 mg/5 mL)

Contains 7.5% alcohol.

AUROBINDO **474 mL**

Each mL contains:
16.8 mg of ranitidine hydrochloride USP equivalent to 15 mg of ranitidine.

Usual Dosage: See package insert for Dosage and Administration.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not freeze.

Dispense in tight, light-resistant containers as defined in the USP/NF.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/19/1993

N3658624317 4 5

P1423175

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AUROBINDO
Committed to healthier life!
www.AurobindoUSA.com

DG™ health

Maximum Strength

Acid Reducer

Ranitidine Tablets 150 mg
Acid Reducer

PREVENTS & RELIEVES HEARTBURN
Associated with
Acid Indigestion
and Sour Stomach

8 Tablets
(8 Doses)

TAMPER EVIDENT: Do Not Use If The Printed Foil Under Cap Is Open or Torn.

Warnings

Do not use

■ if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ with other acid reducers ■ if you have kidney disease, except under the advice and supervision of a doctor. **Ask a doctor before use if you have** ■ had heartburn over 3 months. ■ heartburn with **lightheadedness, sweating or dizziness** ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent **chest pain** ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain. **Stop use and ask a doctor if** ■ your heartburn worsens or you need to take this product for more than 14 days. **If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

■ adults and children 12 years and over: ■ to **relieve** symptoms, swallow 1 tablet with a glass of water ■ to **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn ■ can be used up to twice daily (do not take more than 2 tablets in 24 hours) ■ children under 12 years: ask a doctor

Questions? call **1-888-309-9030**

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