DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Amneal Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Ranitidine Tablets, USP, 150mg and 300mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL, Due to Possible Presence of N-nitrosodimethylamine (NDMA) Impurity

November 12, 2019

Amneal Pharmaceuticals, LLC. Bridgewater, New Jersey is voluntarily recalling Ranitidine Tablets, 150 mg and 300 mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL to the consumer level. A listing of the recalled lots is identified below.

Ranitidine Tablets, USP, 150 mg and 300 mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL, are being recalled because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA.

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.

Amneal Pharmaceuticals, LLC. has not received any reports of adverse events that have been confirmed to be directly related to this recall. Ranitidine Tablets, USP and Ranitidine Syrup (Ranitidine Oral Solution, USP), manufactured by Amneal, are prescription oral products. Ranitidine is a histamine-2 blocker, which decreases the amount of acid created by the 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.

The Ranitidine Tablets, USP and Ranitidine Syrup (Ranitidine Oral Solution, USP) subject to the recall can be identified by NDC numbers stated on the product label:

Product	Strength	Pack Size	NDC Number
Ranitidine Tablets, USP	150 mg	60 count	65162-253-06
Ranitidine Tablets, USP	150 mg	100 count	65162-253-10
Ranitidine Tablets, USP	150 mg	180 count	65162-253-18
Ranitidine Tablets, USP	150 mg	500 count	65162-253-50
Ranitidine Tablets, USP	150 mg	1000 count	65162-253-11
Ranitidine Tablets, USP	300 mg	30 count	65162-254-03
Ranitidine Tablets, USP	300 mg	100 count	65162-254-10
Ranitidine Tablets, USP	300 mg	250 count	65162-254-25
Ranitidine Tablets, USP	300 mg	1000 count	65162-254-11
Ranitidine Tablets, USP	150 mg	500 count	53746-253-05
Ranitidine Tablets, USP	150 mg	1000 count	53746-253-10
Ranitidine Syrup (Ranitidine Oral Solution, USP)	15 mg/mL; 16 fl. oz.	473 mL	65162-664-90

The affected Ranitidine Tablets, USP and Ranitidine Syrup (Ranitidine Oral Solution, USP) were distributed directly to Wholesalers, Distributors, Retailers and Repackagers.

Amneal is notifying its direct customers via mail (UPS Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

Customers who purchased the impacted product directly from Amneal can call Stericycle at 866-918-8768, Monday – Friday, 8:00 am – 5:00 pm, EST to arrange for product return.

Consumers who have **Ranitidine Tablets, USP and Ranitidine Syrup (Ranitidine Oral Solution, USP)** which are being recalled should **stop using the product and can call Stericycle at** 866-918-8768, Monday – Friday, 8:00 am – 5:00 pm, EST for further information.

Consumers who would like to report adverse reactions or quality problems experienced with the use of this product can contact Amneal Drug Safety by phone at 1-877-835-5472, Monday thru Friday, 8:00 am – 6:00 pm, EST, or e-mail at DrugSafety@amneal.com.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of 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

The following lot numbers of Ranitidine Tablets, USP, 150 mg & 300 mg and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL are included in this recall.

Ranitidine Tablets, USP, 150 mg		
Description	**Lot#**	**Expiration Date**
Ranitidine Tablets, USP 150mg	AR180483B	3/31/2020
Ranitidine Tablets, USP 150mg	AR180559A	3/31/2020
Ranitidine Tablets, USP 150mg	AR180560A	3/31/2020
Ranitidine Tablets, USP 150mg	AR180594A	3/31/2020
Ranitidine Tablets, USP 150mg	AR180595A	3/31/2020
Ranitidine Tablets, USP 150mg	AR180675A	4/30/2020
Ranitidine Tablets, USP 150mg	AR180829A	4/30/2020
Ranitidine Tablets, USP 150mg	AR180831A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180832A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180868A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180868B	5/31/2020
Ranitidine Tablets, USP 150mg	AR180869A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180870A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180871A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180872A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180995A	5/31/2020

Ranitidine Tablets, USP, 150 mg		
Ranitidine Tablets, USP 150mg	AR180996A	5/31/2020
Ranitidine Tablets, USP 150mg	AR180997A	6/30/2020
Ranitidine Tablets, USP 150mg	AR180998A	6/30/2020
Ranitidine Tablets, USP 150mg	AR181158A	7/31/2020
Ranitidine Tablets, USP 150mg	AR181159A	7/31/2020
Ranitidine Tablets, USP 150mg	AR181160A	7/31/2020
Ranitidine Tablets, USP 150mg	AR181161A	7/31/2020
Ranitidine Tablets, USP 150mg	AR181690A	10/31/2020
Ranitidine Tablets, USP 150mg	AR181691A	10/31/2020
Ranitidine Tablets, USP 150mg	AR181692A	10/31/2020
Ranitidine Tablets, USP 150mg	AR181693A	10/31/2020
Ranitidine Tablets, USP 150mg	AR181694A	10/31/2020
Ranitidine Tablets, USP 150mg	AR181709A	10/31/2020
Ranitidine Tablets, USP 150mg	AR181710A	11/30/2020
Ranitidine Tablets, USP 150mg	AR181711A	11/30/2020
Ranitidine Tablets, USP 150mg	AR181806A	11/30/2020
Ranitidine Tablets, USP 150mg	AR181807B	11/30/2020
Ranitidine Tablets, USP 150mg	AR181807C	11/30/2020
Ranitidine Tablets, USP 150mg	AR181808A	11/30/2020
Ranitidine Tablets, USP 150mg	AR190004A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190005A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190006A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190007A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190008A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190008B	12/31/2020
Ranitidine Tablets, USP 150mg	AR190085A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190086A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190087A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190088A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190089A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190090A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190121A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190122A	12/31/2020

Ranitidine Tablets, USP, 150 mg		
Ranitidine Tablets, USP 150mg	AR190123A	12/31/2020
Ranitidine Tablets, USP 150mg	AR190124A	1/31/2021
Ranitidine Tablets, USP 150mg	AR190125B	1/31/2021
Ranitidine Tablets, USP 150mg	AR190181A	1/31/2021
Ranitidine Tablets, USP 150mg	AR190182A	1/31/2021
Ranitidine Tablets, USP 150mg	AR190183A	1/31/2021
Ranitidine Tablets, USP 150mg	AR190184A	1/31/2021
Ranitidine Tablets, USP 150mg	AR190364A	2/28/2021
Ranitidine Tablets, USP 150mg	AR190365A	2/28/2021
Ranitidine Tablets, USP 150mg	AR190366A	2/28/2021
Ranitidine Tablets, USP 150mg	AR190366B	2/28/2021
Ranitidine Tablets, USP 150mg	AR190509A	3/31/2021
Ranitidine Tablets, USP 150mg	AR190510A	3/31/2021
Ranitidine Tablets, USP 150mg	AR190542B	3/31/2021
Ranitidine Tablets, USP 150mg	AR190609A	3/31/2021
Ranitidine Tablets, USP 150mg	AR190610A	3/31/2021
Ranitidine Tablets, USP 150mg	HD03119A	3/31/2021
Ranitidine Tablets, USP 150mg	HD03219A	3/31/2021
Ranitidine Tablets, USP 150mg	HE03119A	4/30/2021
Ranitidine Tablets, USP 150mg	HE03219A	4/30/2021
Ranitidine Tablets, USP, 300 mg		
Description	**Lot#**	**Expiration Date**
Ranitidine Tablets, USP 300mg	AR180519A	3/31/2020
Ranitidine Tablets, USP 300mg	AR180613A	3/31/2020
Ranitidine Tablets, USP 300mg	AR180615A	3/31/2020
Ranitidine Tablets, USP 300mg	AR180638A	3/31/2020
Ranitidine Tablets, USP 300mg	AR180640A	4/30/2020
Ranitidine Tablets, USP 300mg	AR180641A	4/30/2020
Ranitidine Tablets, USP 300mg	AR181156A	7/31/2020
Ranitidine Tablets, USP 300mg	AR181157A	7/31/2020
Ranitidine Tablets, USP 300mg	AR181795A	11/30/2020
Ranitidine Tablets, USP 300mg	AR181920A	12/31/2020
Ranitidine Tablets, USP 300mg	AR181921A	12/31/2020

Ranitidine Tablets, USP, 150 mg		
Ranitidine Tablets, USP 300mg	AR181921B	12/31/2020
Ranitidine Tablets, USP 300mg	AR190414B	2/28/2021
Ranitidine Tablets, USP 300mg	AR190415A	2/28/2021
Ranitidine Tablets, USP 300mg	AR190416A	2/28/2021
Ranitidine Tablets, USP 300mg	AR190417A	2/28/2021
Ranitidine Tablets, USP 300mg	AR190418A	2/28/2021
Ranitidine Tablets, USP 300mg	AR190418B	2/28/2021
Ranitidine Tablets, USP 300mg	AR190543A	3/31/2021
Ranitidine Tablets, USP 300mg	AR190544A	3/31/2021
Ranitidine Tablets, USP 300mg	AR190545A	3/31/2021
Ranitidine Tablets, USP 300mg	AR190705A	4/30/2021

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

Description	Lot#	Expiration Date
Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL	06648001A	11/2019
Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL	06648003A	04/2020
Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL	06649001A	01/2021

Company Contact Information

Consumers:

Stericycle

866-918-8768

Media:

Ms. Candis Edwards

Information@amneal.com

Product Photos

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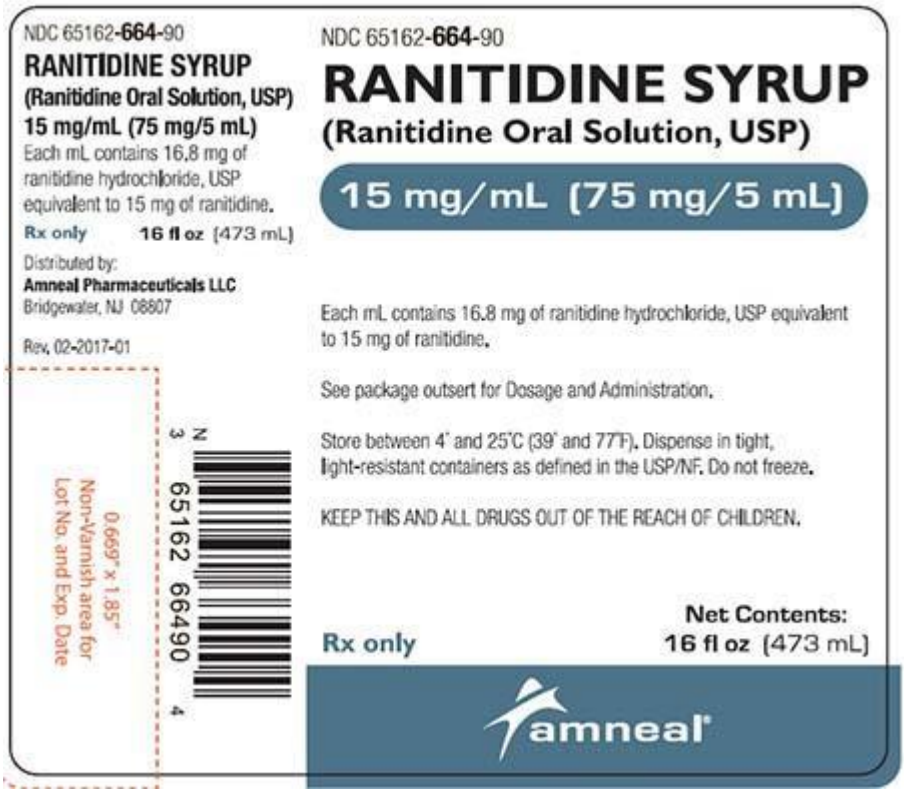
- 

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Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-ranitidine-tablets-usp-150mg-and-300mg?utm_campaign=FDA%20MedWatch%20%7E%20Ranitidine%20Tablets%2C%20Syrup%20and%20Oral%20Solution%20by%20Amneal%20Pharmaceuticals&utm_medium=email&utm_source=Eloqua