

FDA Drug Recall- Expansion

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 22, 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	150 mg	1000 count	53746-253-10
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

Product	Strength	Pack Size	NDC Number
Ranitidine Tablets, USP	300 mg	250 count	53746-254-02
Ranitidine Syrup (Ranitidine Oral Solution, USP)	15 mg/mL; 6 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, 150mg			
NDC No.	Description	Lot	Expiration Date
53746-253-10	Ranitidine Tablets, USP 150mg	HB03718A	3/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HB03818A	3/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HB03918A	3/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HB04018A	3/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HC01618A	3/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HC14618A	5/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HC14718A	5/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HC14818A	5/2020

NDC No.	Description	Lot	Expiration Date
53746-253-10	Ranitidine Tablets, USP 150mg	HC14918A	5/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HC15018A	5/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HK02318A	9/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HK02418A	9/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HK02518A	9/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HK02618A	9/2020
53746-253-10	Ranitidine Tablets, USP 150mg	HD03119A	3/2021
53746-253-10	Ranitidine Tablets, USP 150mg	HD03219A	3/2021
53746-253-10	Ranitidine Tablets, USP 150mg	HE03119A	4/2021
53746-253-10	Ranitidine Tablets, USP 150mg	HE03219A	4/2021

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NDC No.	Description	Lot	Expiration Date
65162-253-06	Ranitidine Tablets, USP 150mg	AR171764A	11/2019
65162-253-06	Ranitidine Tablets, USP 150mg	AR171875A	11/2019
65162-253-06	Ranitidine Tablets, USP 150mg	AR171876A	11/2019
65162-253-06	Ranitidine Tablets, USP 150mg	AR171981A	11/2019
65162-253-06	Ranitidine Tablets, USP 150mg	AR180020C	1/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180206A	1/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180207A	1/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180208A	1/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180438A	2/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180439A	2/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180481A	3/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR180482A	3/2020

NDC No.	Description	Lot	Expiration Date
65162-253-06	Ranitidine Tablets, USP 150mg	AR180483A	3/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR181690A	10/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR181691A	10/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR181806A	11/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR190058A	12/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR190059A	12/2020
65162-253-06	Ranitidine Tablets, USP 150mg	AR190183A	1/2021
65162-253-06	Ranitidine Tablets, USP 150mg	AR190184A	1/2021

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NDC No.	Description	Lot	Expiration Date
65162-253-10	Ranitidine Tablets, USP 150mg	AR171984A	12/2019
65162-253-10	Ranitidine Tablets, USP 150mg	AR180020B	1/2020
65162-253-10	Ranitidine Tablets, USP 150mg	AR180675A	4/2020
65162-253-10	Ranitidine Tablets, USP 150mg	AR180868B	5/2020
65162-253-10	Ranitidine Tablets, USP 150mg	AR181807A	11/2020
65162-253-10	Ranitidine Tablets, USP 150mg	AR190366B	2/2021

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NDC No.	Description	Lot	Expiration Date
65162-253-11	Ranitidine Tablets, USP 150mg	AR171986A	12/2019
65162-253-11	Ranitidine Tablets, USP 150mg	AR171987A	12/2019
65162-253-11	Ranitidine Tablets, USP 150mg	AR180255A	1/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180441A	2/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180442A	2/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180559A	3/2020

NDC No.	Description	Lot	Expiration Date
65162-253-11	Ranitidine Tablets, USP 150mg	AR180560A	3/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180594A	3/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180595A	3/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180829A	4/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180831A	5/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180832A	5/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR180868A	5/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR181807C	11/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR190085A	12/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR190086A	12/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR190087A	12/2020
65162-253-11	Ranitidine Tablets, USP 150mg	AR190124A	1/2021
65162-253-11	Ranitidine Tablets, USP 150mg	AR190542B	3/2021
65162-253-11	Ranitidine Tablets, USP 150mg	AR190609A	3/2021
65162-253-11	Ranitidine Tablets, USP 150mg	AR190610A	3/2021

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NDC No.	Description	Lot	Expiration Date
65162-253-18	Ranitidine Tablets, USP 150mg	AR171875B	11/2019
65162-253-18	Ranitidine Tablets, USP 150mg	AR180483B	3/2020
65162-253-18	Ranitidine Tablets, USP 150mg	AR181807B	11/2020
65162-253-18	Ranitidine Tablets, USP 150mg	AR190008B	12/2020

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NDC No.	Description	Lot	Expiration Date
65162-253-50	Ranitidine Tablets, USP 150mg	AR171763A	11/2019

NDC No.	Description	Lot	Expiration Date
65162-253-50	Ranitidine Tablets, USP 150mg	AR171764B	11/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171874A	11/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171875C	11/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171877B	11/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171878B	11/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171982A	11/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171983A	12/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR171985A	12/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR180016A	12/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR180017A	12/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR180018A	12/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR180019A	12/2019
65162-253-50	Ranitidine Tablets, USP 150mg	AR180020A	1/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180208B	1/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180256A	1/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180291A	1/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180292A	1/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180293A	1/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180294A	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180295A	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180364A	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180365A	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180366A	2/2020

NDC No.	Description	Lot	Expiration Date
65162-253-50	Ranitidine Tablets, USP 150mg	AR180367A	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180368A	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180440B	2/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180484A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180485A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180556A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180557A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180558A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180596A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180597A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180598A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180599A	3/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180675B	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180676A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180677A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180678A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180679A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180801A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180802A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180803A	4/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180869A	5/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180870A	5/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180871A	5/2020

NDC No.	Description	Lot	Expiration Date
65162-253-50	Ranitidine Tablets, USP 150mg	AR180872A	5/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180994A	5/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180995A	5/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180996A	5/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180997A	6/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR180998A	6/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181158A	7/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181159A	7/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181160A	7/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181161A	7/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181692A	10/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181693A	10/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181694A	10/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181709A	10/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181710A	11/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181711A	11/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181808A	11/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR181809A	11/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190004A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190005A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190006A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190007A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190008A	12/2020

NDC No.	Description	Lot	Expiration Date
65162-253-50	Ranitidine Tablets, USP 150mg	AR190088A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190089A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190090A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190121A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190122A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190123A	12/2020
65162-253-50	Ranitidine Tablets, USP 150mg	AR190125B	1/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190181A	1/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190182A	1/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190364A	2/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190365A	2/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190366A	2/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190509A	3/2021
65162-253-50	Ranitidine Tablets, USP 150mg	AR190510A	3/2021

Ranitidine Tablets, USP, 300mg

NDC No.	Description	Lot	Expiration Date
53746-254-02	Ranitidine Tablets, USP 300mg	HB04118A	2/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HB04218A	2/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HB04318A	2/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HB04418A	2/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HF13518A	6/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HF13618A	6/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HF13718A	6/2020

NDC No.	Description	Lot	Expiration Date
53746-254-02	Ranitidine Tablets, USP 300mg	HF13818A	6/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HK02818A	9/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HK02918A	9/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HK03018A	9/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HK03118A	9/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HL08418A	11/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HL08518A	11/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HL08618A	11/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HL08718A	11/2020
53746-254-02	Ranitidine Tablets, USP 300mg	HB01419A	1/2021
53746-254-02	Ranitidine Tablets, USP 300mg	HB05619A	1/2021
53746-254-02	Ranitidine Tablets, USP 300mg	HB05719A	1/2021
53746-254-02	Ranitidine Tablets, USP 300mg	HB05819A	1/2021
53746-254-02	Ranitidine Tablets, USP 300mg	HB05919A	1/2021
53746-254-02	Ranitidine Tablets, USP 300mg	HB06019A	1/2021
53746-254-02	Ranitidine Tablets, USP 300mg	HB06119A	1/2021

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NDC No.	Description	Lot	Expiration Date
65162-254-03	Ranitidine Tablets, USP 300mg	AR172033B	11/2019
65162-254-03	Ranitidine Tablets, USP 300mg	AR180024A	12/2019
65162-254-03	Ranitidine Tablets, USP 300mg	AR180025A	12/2019
65162-254-03	Ranitidine Tablets, USP 300mg	AR180118A	12/2019
65162-254-03	Ranitidine Tablets, USP 300mg	AR180119A	12/2019
65162-254-03	Ranitidine Tablets, USP 300mg	AR180519A	3/2020

NDC No.	Description	Lot	Expiration Date
65162-254-03	Ranitidine Tablets, USP 300mg	AR180615A	3/2020
65162-254-03	Ranitidine Tablets, USP 300mg	AR181795A	11/2020
65162-254-03	Ranitidine Tablets, USP 300mg	AR181921B	12/2020
65162-254-03	Ranitidine Tablets, USP 300mg	AR190705A	4/2021

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NDC No.	Description	Lot	Expiration Date
65162-254-10	Ranitidine Tablets, USP 300mg	AR172029A	11/2019
65162-254-10	Ranitidine Tablets, USP 300mg	AR172030A	11/2019
65162-254-10	Ranitidine Tablets, USP 300mg	AR180021A	12/2019
65162-254-10	Ranitidine Tablets, USP 300mg	AR180022A	12/2019
65162-254-10	Ranitidine Tablets, USP 300mg	AR180023A	12/2019
65162-254-10	Ranitidine Tablets, USP 300mg	AR180123A	12/2019
65162-254-10	Ranitidine Tablets, USP 300mg	AR180144A	1/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180145A	1/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180146A	1/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180147A	1/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180402A	2/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180465A	2/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180466A	2/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180467A	2/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180468A	2/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR180613A	3/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR181156A	7/2020
65162-254-10	Ranitidine Tablets, USP 300mg	AR181157A	7/2020

NDC No.	Description	Lot	Expiration Date
65162-254-10	Ranitidine Tablets, USP 300mg	AR190418B	2/2021

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NDC No.	Description	Lot	Expiration Date
65162-254-25	Ranitidine Tablets, USP 300mg	AR171800A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171801A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171802A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171803A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171804A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171931A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171932A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171933A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171934A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171935A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171936A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR171937A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172026A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172027A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172028A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172031A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172032A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172033A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172034A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR172035A	11/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180030A	12/2019

NDC No.	Description	Lot	Expiration Date
65162-254-25	Ranitidine Tablets, USP 300mg	AR180031A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180032A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180033A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180034A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180113A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180114A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180115A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180117A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180120A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180121A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180122A	12/2019
65162-254-25	Ranitidine Tablets, USP 300mg	AR180148A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180198A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180199A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180200A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180201A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180202A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180257A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180258A	1/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180335A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180336A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180337A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180338A	2/2020

NDC No.	Description	Lot	Expiration Date
65162-254-25	Ranitidine Tablets, USP 300mg	AR180339A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180374A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180375A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180376B	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180403A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180404A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180405A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180406A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180424A	2/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180486A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180487A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180488A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180515A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180516A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180517A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180518A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180638A	3/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180640A	4/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR180641A	4/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR181920A	12/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR181921A	12/2020
65162-254-25	Ranitidine Tablets, USP 300mg	AR190414B	2/2021
65162-254-25	Ranitidine Tablets, USP 300mg	AR190415A	2/2021

NDC No.	Description	Lot	Expiration Date
65162-254-25	Ranitidine Tablets, USP 300mg	AR190416A	2/2021
65162-254-25	Ranitidine Tablets, USP 300mg	AR190417A	2/2021
65162-254-25	Ranitidine Tablets, USP 300mg	AR190418A	2/2021
65162-254-25	Ranitidine Tablets, USP 300mg	AR190543A	3/2021
65162-254-25	Ranitidine Tablets, USP 300mg	AR190544A	3/2021
65162-254-25	Ranitidine Tablets, USP 300mg	AR190545A	3/2021

Ranitidine Syrup (Ranitidine Oral Solution, USP)

NDC No.	Description	Lot	Expiration Date
65162-664-90	Ranitidine Syrup 15mg/mL	06648001A	11/2019
65162-664-90	Ranitidine Syrup 15mg/mL	06648003A	4/2020
65162-664-90	Ranitidine Syrup 15mg/mL	06649001A	1/2021

Product Photos



NDC 65162-664-90

RANITIDINE SYRUP
(Ranitidine Oral Solution, USP)
15 mg/mL (75 mg/5 mL)
Each mL contains 16.8 mg of ranitidine hydrochloride, USP equivalent to 15 mg of ranitidine.
Rx only 16 fl oz (473 mL)

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 02-2017-01

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65162 66490
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0.669" x 1.85"
Non-Markish area for
Lot No. and Exp. Date

NDC 65162-664-90

RANITIDINE SYRUP
(Ranitidine Oral Solution, USP)

15 mg/mL (75 mg/5 mL)

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


See package insert for Dosage and Administration.

Store between 4° and 25°C (39° and 77°F). Dispense in tight, light-resistant containers as defined in the USP/NF. Do not freeze.

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

Rx only

Net Contents:
16 fl oz (473 mL)



H4140_RXRECALLPROV_C

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=Amneal%20Pharmaceuticals%2C%20LLC.%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Ranitidine%20Tablets&utm_medium=email&utm_source=Eloqua