# Amneal Pharmaceuticals, LLC. Issues a Voluntary Nationwide Recall of Ranitidine Tablets, USP, 150mg and 300mg

**Amneal Pharmaceuticals, LLC** has initiated a voluntary recall to the patient level of all unexpired lots of prescription Ranitidine Tablets, USP 150mg and 300mg because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA.

## What does this mean?

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. To date, Amneal has not received any reports of adverse events related to this issue.

## What you should do:

**Patients who have the recalled product should stop using the medication and contact their prescriber to obtain a prescription for a different therapy as replacement medication is currently not available.**

Patients may also contact **Stericycle at 1-866-918-8768, Monday – Friday, 8:00am – 5:00 pm, EST** for further information.

Patients who would like to report an adverse event or quality problem can contact **Amneal Drug Safety by phone at 1-877-835-5472, Monday – Friday, 8:00 am – 6:00 pm, EST, or email at** DrugSafety@amneal.com.

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

## The affected Ranitidine products include:

| Product Description | NDC# | Lot# | Expiry Date |
|---|---|---|---|
| RANITIDINE 300MG TAB 30 | 65162-0254-03 | AR180519A | 033120 |
| | | AR180615A | 033120 |
| | | AR181795A | 113020 |
| | | AR181921B | 123120 |
| | | AR190705A | 043021 |
| RANITIDINE 300MG TAB 100 | 65162-0254-10 | AR180613A | 033120 |
| | | AR181156A | 073120 |
| | | AR181157A | 073120 |
| | | AR190418B | 022821 |
| RANITIDINE 300MG TAB 25 | 65162-0254-25 | AR180638A | 033120 |
| | | AR180640A | 033120 |
| | | AR180641A | 043020 |
| | | AR181920A | 123120 |
| | | AR181921A | 123120 |
| | | AR190414B | 022821 |
| | | AR190415A | 022821 |
| | | AR190416A | 022821 |
| | | AR190417A | 022821 |
| | | AR190418A | 022821 |
| | | AR190543A | 033121 |
| | | AR190544A | 033121 |
| | | AR190545A | 033121 |

| Product Description | NDC# | Lot # | Expiry Date |
|---|---|---|---|
| RANITIDINE 150 MG TAB | 65162-0253-06 | AR181690A | 103120 |
| | | AR181691A | 103120 |
| | | AR181806A | 113020 |
| | | AR190183A | 013121 |
| | | AR190184A | 013121 |
| RANITIDINE 150MG TAB | 65162-0253-10 | AR180675A | 043020 |
| | | AR180868B | 053120 |
| | | AR190366B | 022821 |
| RANITIDINE 150MG TAB | 65162-0253-18 | AR180483B | 033120 |
| | | AR181807B | 113020 |
| | | AR190008B | 123120 |
| RANITIDINE 150MG TAB | 65162-0253-50 | ALL | ALL |
| RANITIDINE 150MG TAB | 65162-0253-11 | ALL | ALL |

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 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.

Thank you for choosing Walmart Pharmacy.

Sincerely,

Your Local Sam’s Club Pharmacy