

Provider Memorandum

RE: Amneal Pharmaceuticals, LLC. Recalls Ranitidine Tablets and Syrup

Effective November 8, 2019, **Amneal Pharmaceuticals, LLC**. Recalled **Ranitidine Tablets** (150 mg, 300 mg) and Ranitidine Syrup (15 mg/mL) to the consumer level due to the presence of Nitrosodimethylamine (NDMA) above the levels recently established by the U.S. Food and Drug Administration (FDA).

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 found in water and foods, including meats, dairy products and vegetables. 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.

Please immediately check your medical supplies, quarantine any drug products impacted, and do not administer them. The NDC numbers associated with Amneal Pharmaceuticals, LLC. recalled products are as follows:

Ranitidine 150 mg tablets (NDC 65162-0253-06, 65162-0253-10, 65162-0253-18, 65162-0253-50, 65162-0253-11, 53746-0253-05, 53746-0253-10), Ranitidine 300 mg tablets (NDC 65162-0254-03, 65162-0254-10, 65162-0254-25, 65162-0254-11), and Ranitidine 15 mg/mL syrup (NDC 65162-0664-90).

Providers can review the FDA's full press release by visiting:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-ranitidine-tablets-usp-150mg-and-300mg>

For questions or concerns, please reach out to Envolve Pharmacy Solutions' Pharmacy Department by calling 1.800.782.2221.

NextLevel Health is committed to improving the health of our Members and providing access to necessary medication.

Sincerely,

Provider Services Department
Nextlevel Health