November 13, 2019

COM-2019-050

Recall: Additional Voluntary Nationwide Recalls of Ranitidine: Aurobindo Pharma, American Health Packaging, Amneal Pharmaceuticals

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we are updating the information regarding additional drug recalls for ranitidine formulations. On November 6 - 12, 2019, the U.S. Food and Drug Administration (FDA) issued additional statements notifying that Aurobindo Pharma, American Health Packaging and Amneal are recalling all their ranitidine products due to the presence of NDMA (N-nitrosodimethylamine) a probable human carcinogen. The affected products are detailed in following tables.

Table 1: Affected Products of Ranitidine

Product	NDC	Exp Date
Aurobindo Pharma USA, Inc.		
Ranitidine Tablets 150mg	55910-092-79	Feb-2021
Ranitidine Capsules 150mg	59651-144-60	Jul-2020, Jul-2020
	59651-144-05	Jul-2020, Aug-2020
	59651-144-60	Aug-2020
	59651-144-05	Sep 2020, Oct 2020, Nov 2020
	59651-144-60	May-2021
	59651-144-05	May 2021
Ranitidine Capsules 300mg	59651-145-30	Jul-2020, Aug-2020, Sep-2020, Oct-2020, Jan 2021, May-2021
Ranitidine Syrup (Ranitidine Oral Solution, USP) 15 mg/mL (75 mg/5 mL)	65862-431-74	May-2021

Product	NDC	Exp Date
American Health Packaging		
Ranitidine Syrup *(Ranitidine Oral Solution USP)* *150 mg/10 mL, Liquid Unit Dose Cups*	60687-260-42	10/31/2020, 05/31/2021, 01/31/2020, 02/29/2020, 10/31/2020, 12/31/2020 03/31/2021

Product	NDC
Amneal Pharmaceuticals	
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 Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

3. Questions regarding this recall, refer to the contact information below:
    - **Aurobindo Pharma USA**, Inc: 1-866-850-2876, Option 2 or pvg@aurobindousa.com
    - **American Health Packaging**: Pharmacies: (877) 475-5864, Consumers: 800-967-595, Option 1
    - **Amneal Pharmaceuticals**, LLC**:** 866-918-8768, Monday – Friday, 8:00 am – 5:00pm orInformation@amneal.com

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

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

For additional information visit:

- Aurobindo Pharma USA: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-consumer-level-recall-38-lots-ranitidine
- American Health Packaging: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-issues-voluntary-nationwide-recall-ranitidine-syrup-ranitidine-oral
- Amneal Pharmaceuticals: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-ranitidine-tablets-usp-150mg-and-300mg

Clinical Department