September 26, 2019

**COM-2019-041**

# Recall: Voluntary Nationwide Recall of Ranitidine Capsules and Tablets

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 inform you that on September 23 - 25, 2019, the U.S. Food and Drug Administration (FDA) issued a statement notifying that Sandoz Inc. and Apotex Corp. are recalling the products: Ranitidine Hydrochloride Capsules - Sandoz and Ranitidine 75mg and 150mg - Apotex all sizes and presentations including OTC tablets due to the presence of N-nitrosodimethylamine (NDMA) a probable human carcinogen. The affected lots by the recall are detailed in following tables by company name.

**Table Sandoz Inc:** Affected Products of Ranitidine Hydrochloride Capsules 150mg and 300mg

| NDC | Product (Sandoz) | Count | Lot # | Expiration date |
|---|---|---|---|---|
| 0781-2855-05 | RANITIDINE 150mg Capsules | 500 | HD1862<br>HP9438<br>HP9439<br>HP9440 | 4/30/2020<br>9/30/2020 |
| 0781-2855-60 | RANITIDINE 150mg Capsules | 60 | HC9266<br>HD1865<br>HP9441<br>JK7994<br>JK8659 | 4/30/2020<br>9/30/2020<br>8/31/2021 |
| 0781-2865-31 | RANITIDINE 300mg Capsules | 30 | HD8625<br>HD9275<br>HU2207<br>HX6676<br>HX6677 | 4/30/2020<br>8/31/2020<br>3/31/2021 |

**Table Apotex Corp:** Affected Products of Ranitidine Tablets 75mg and 150mg

| NDC | Product (Apotex) | Count |
|---|---|---|
| 11822-6052-1 | Ranitidine tablets, USP 150mg- acid reducer (Rite Aid) | 50 |
| 11822-6052-2 | Ranitidine tablets, USP 150mg- acid reducer (Rite Aid) | 65 |
| 11822-4727-3 | Ranitidine tablets, USP 150mg- acid reducer (Rite Aid) | 95 |
| 49035-117-06 | Ranitidine tablets, USP 150mg- acid reducer (Walmart) | 65 |
| 49035-100-00 | Ranitidine tablets, USP 150mg- acid reducer (Walmart) | 24 |
| 0363-1030-07 | Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) | 200 |



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| NDC | Product (Apotex) | Count |
|---|---|---|
| 11822-6051-8 | Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid) | 24 |
| 49035-100-07 | Ranitidine tablets, USP 150mg- acid reducer (Walmart) | 130 |
| 0363-1013-02 | Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) | 24 |
| 0363-1029-03 | Wal-Zan® 75 RANITIDINE TABLETS, USP 75 mg / ACID REDUCER (WALGREENS) | 30 |
| 11822-6107-4 | Cool mint Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid) | 24 |
| 0363-1030-06 | Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) | 65 |
| 0363-1030-09 | Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) | 95 |

**The Pharmacy must:**

1. Identify if they have the product in inventory and immediately stop using and dispensing the product. Return any stock to Sandoz and for Apotex products to the place of purchase.
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:
   **Sandoz:**
   a. Phone: 1-800-525-8747 (8:30am – 5:00pm Monday – Friday EST)
   b. Online: www.us.sandoz.com

   **Apotex:**
   a. Call: Inmar Rx Solutions at 800-967-5952 (option 1) (9:00am – 5:00-pm Monday – Friday EST)

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:

a. Online: www.fda.gov/medwatch/report.htm
b. 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:**

Sandoz: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-voluntary-recall-ranitidine-hydrochloride-capsules-150mg-and-300mg-due-elevated

Apotex: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and

**Clinical Department**



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