October 25, 2019

**COM-2019-046**

# Recall: Expanded Voluntary Nationwide Recall of Ranitidine

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 October 23, 2019, the U.S. Food and Drug Administration (FDA) issued a statement notifying that:

- Perrigo Company – all ranitidine products
- Sanofi – all products of Zantac OTC: Zantac 150®, Zantac 150® Cool Mint, and Zantac 75®
- Dr. Reddy's Laboratories – all ranitidine products OTC and prescription drugs with expiration dated from September 2019 to June 2021

are recalling these products following agency caution note alerting patients and health care professionals that NDMA (N-nitrosodimethylamine) was found in certain samples of ranitidine. The affected lots by the recall from Dr. Reddy's products are detailed in following table.

**Table 1:** Affected Products of Ranitidine

| NDC | Product & Pack | Type |
|---|---|---|
| 5511112960 | Ranitidine Capsules 150mg, 60 | Rx |
| 5511112905 | Ranitidine Capsules 150mg, 500 | Rx |
| 5511113030 | Ranitidine Capsules 300mg, 30 | Rx |
| 5511113001 | Ranitidine Capsules 300mg, 100 | Rx |
| 150062076 (UPC Code 078742089720) | Rantidine Tablets, USP 150mg,190(2x95) Tray (Sam's Club) | OTC |
| 0363-0010-62 | Ranitidine Tablets, USP 150mg, 95 (Walgreens) | OTC |
| 49035-404-61 | Ranitidne Tablets, USP 150mg 65 Ct Btl (Walgreens) | OTC |
| 0363-0010-01 | Ranitidine Tablets, USP 150 Tab 200Ct Btl (Walgreens) | OTC |
| 0363-0010-34 | Ranitidine Tablets, USP 150mg Tabs Btl, 24 (Walgreens) | OTC |
| 0363-0131-30 | Ranitidine Tablets, USP 75mg Tab 30Ct Btl (Walgreens) | OTC |
| 0363-0131-80 | Ranitidine Tablets, USP 75mg Tab 80Ct Btl (Walgreens) | OTC |
| 49035-404-65 | Ranitidine Tablets, USP 150 mg 220 CT Btl (Walmart) | OTC |
| 49035-404-13 | Ranitidine Tablets, USP 150 Tablet 130ct Bottle NV (Walmart) | OTC |
| 49035-404-61 | Ranitidine Tablets, USP 150 TAB 65ct BTL CP32 (Walmart) | OTC |
| 49035-404-13 | Ranitidine Tablets, USP 150 Tablet 130ct Bottle NV (Walmart) | OTC |
| 69842-871-30 | Ranitidine Tablets, USP 75 TAB 30ct Bottle NG (CVS) | OTC |



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| NDC | Product & Pack | Type |
|---|---|---|
| 69842-871-80 | Ranitidine Tablets, USP 75 TAB 80ct Bottle NG (CVS) | OTC |
| 69842-871-37 | Ranitidine Tablets, USP 75 TAB 160ct Bottle NG (CVS) | OTC |

**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:
    a. **Perrigo Company:** tel. (888) 817-2180
    b. **Sanofi: Retailers-** tel. 877-275-0993 (option 1) or via fax at 336-499-8145 or email at zantacrecall@inmar.com
    c. **Dr Reddy's laboratories:** Consumers - tel. 1-888-375-3784 (1-888-DRL-DRUG) between the hours of 8 a.m. to 8 p.m. ET, Monday through Friday

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:**

- **Perrigo Company:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n

- **Sanofi:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sanofi-provides-update-precautionary-voluntary-recall-zantac-otc-us

- **Dr. Reddy's Laboratories:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-confirms-its-voluntary-nationwide-recall-all-ranitidine-products-us-market

**Clinical Department**


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