COMPANY ANNOUNCEMENT

Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All pack sizes and Formats) due to the potential for Detection of an Amount of Unexpected Impurity,N-nitrosodimethylamine (NDMA) Impurity in the product

Summary

Company Announcement Date:

September 25, 2019

FDA Publish Date:

September 25, 2019

Product Type:

Drugs

Reason for Announcement:

Contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)

Company Name:

Apotex Corp.

Brand Name:

Apotex Corp.

Product Description:

Ranitidine Tablets 75mg and 150mg

Company Announcement

Apotex Corp. is voluntarily, on a precautionary basis, recalling Ranitidine Tablets 75mg and 150mg (All pack sizes and Formats) to the **Retail level**. Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. To date, Apotex has not received any reports of adverse events related to use of the product.

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

Ranitidine Hydrochloride Tablet is an over the counter (OTC) oral product indicated for the relief of heartburn associated with acid indigestion and sour stomach and prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages. The affected Ranitidine Hydrochloride Tablets can be identified by NDC numbers stated on the product label.

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

Product	Strength	Pack Size	NDC Number
Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid)	150 mg	24's Bottle	11822-6051-8
Ranitidine tablets, USP 150mg- acid reducer (Walmart)	150 mg	130's Bottle	49035-100-07
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	24's Bottle	0363-1013-02

Product	Strength	Pack Size	NDC Number
Wal-Zan® 75 RANITIDINE TABLETS, USP 75 mg / ACID REDUCER (WALGREENS)	75 mg	30's Bottle	0363-1029-03
Cool mint Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid)	150 mg	24's Bottle	11822-6107-4
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	65's Bottle	0363-1030-06
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS)	150 mg	95's Bottle	0363-1030-09

The affected Ranitidine Hydrochloride Tablets were distributed Nationwide to Warehousing Chains. Apotex Corp. has notified its affected direct account Warehousing Chains via mail (FedEx Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product.

Wholesalers, Distributors and Retailers return the impacted product to place of purchase. Anyone with an existing inventory of the product should quarantine the recalled lots immediately. Customers who purchased the impacted product directly from Apotex can call **Inmar Rx Solutions at 800-967-5952 (option 1) (9:00am – 5:00-pm, EST Monday thru Friday), to arrange for their return.**

Consumers with questions regarding this recall can contact Apotex corp. by phone-number 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address **UScustomerservice@Apotex.com** (mailto:UScustomerservice@Apotex.com). **Consumers should contact their physician or healthcare provider** if they have experienced any problems that may be related to taking or using this drug product.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/forms-reporting-fda) 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.

Company Contact Information

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