APOTEX
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Public Communication
Important Safety Information on
Apo-Ranitidine / Acid Reducer (Tablets and Oral Solution)

Date: 09/24/2019

Subject: Precautionary Recall of Apo-Ranitidine / Acid Reducer (Ranitidine Tablets and Oral Solution)

Apotex has initiated a voluntary **Type I** recall on a precautionary basis to the **Retail Level** for all products of "**Apo-Ranitidine / Acid Reducer (Ranitidine Tablets and Oral Solution)**". Apotex has learned from the Health Canada 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. 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. Although NDMA may cause harm in large amounts, NDMA at low levels barely exceed amounts you might expect to find in common foods. Please see the table below for potentially impacted products and further information:

PRODUCT	DIN #	UPC #
Apo-Ranitidine (Ranitidine Tablets USP)	00733059	771313007580
Apo-Ranitidine (Ranitidine Tablets USP)	00733059	771313007597
Apo-Ranitidine (Ranitidine Tablets USP)	00733059	771313007634
Apo-Ranitidine (Ranitidine Tablets USP)	00733059	771313055314
Apo-Ranitidine (Ranitidine Tablets USP)	00733067	771313007665
Apo-Ranitidine (Ranitidine Tablets USP)	00733067	771313007658
Apo-Ranitidine (Ranitidine Tablets USP)	00733067	771313007672
APO- RANITIDINE (Ranitidine Oral Solution USP)	02280833	771313170819
Acid Reducer (Ranitidine Tablets USP 150 mg)	02296160	059749956178
Acid Reducer (Ranitidine Tablets USP)	02296160	628915165852
Acid Reducer (Ranitidine Tablets USP)	02296160	628915165869

APO-RANITIDINE (ranitidine hydrochloride) is indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable.

To report a suspected adverse reaction associated with the use of **Apo-Ranitidine / Acid Reducer (Ranitidine Tablets and Oral Solution)** patients may contact Apotex by calling 1**-800-667-4708** (select prompt 2), by email at drugsafety@apotex.com or by fax at **1-866-429-9133** or **416-401-3819**.

Patients may also report any suspected adverse reactions associated with the use of health products to Health Canada by calling toll free at **1-866-234-2345** or by visiting MedEffect Canada's Web page on Adverse Reaction Reporting to https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html for information on how to report online, by mail or by fax.