URGENT RECALL

Dear Patients

Allergy Partners has recently learned that Sandoz has issued a voluntary recall of selected lots of Ranitidine, a generic version of Zantac. You may have been prescribed Ranitidine for the treatment of heartburn or hives. The enclosed information is from the Sandoz web site. We encourage you to read this information carefully and follow the recommended steps. Please contact Sandoz at the number below for specific information regarding the recall.

Details

Company Announcement

Sandoz Inc. is voluntarily recalling all quantities and lots within expiry of Ranitidine Hydrochloride Capsules in the US to the consumer level because of confirmed contamination with N-Nitrosodimethylamine (NDMA) above levels established by the FDA in batches of Sandoz Ranitidine Hydrochloride Capsules. To date, Sandoz has not received any reports of adverse events related to use of the product as part of this recall.

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 Capsules is an oral product, 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. The affected Ranitidine Hydrochloride Capsule can be identified by NDC numbers stated on the product label.

The affected Sandoz Ranitidine includes 30 count, 60 count and 500 count bottles in the following lots:

Product Name	NDC Number	Lot Nbr.	Expiration Date	Manufacture Date
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HD1862	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9438	9/30/2020	9/5/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9439	9/30/2020	9/6/2017
RANITIDINE 150mg Capsules 500 count	0781-2855-05	HP9440	9/30/2020	9/5/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HC9266	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HD1865	4/30/2020	4/19/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	HP9441	9/30/2020	9/6/2017
RANITIDINE 150mg Capsules 60 count	0781-2855-60	JK7994	8/31/2021	8/7/2018
RANITIDINE 150mg Capsules 60 count	0781-2855-60	JK8659	8/31/2021	8/7/2018
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HD8625	4/30/2020	4/27/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HD9275	4/30/2020	4/27/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HU2207	8/31/2020	8/24/2017
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HX6676	3/31/2021	3/20/2018
RANITIDINE 300mg Capsules 30 count	0781-2865-31	HX6677	3/31/2021	3/20/2018

The product can be identified by the NDC number and lot number provided above. Sandoz Ranitidine Hydrochloride Capsules were distributed nationwide to wholesalers.

Sandoz will be notifying its distributors and customers via overnight mail and via the Sandoz web site, and will arrange for return of all recalled products. Wholesalers (direct customers) will be asked to immediately stop distribution and return any stock to Sandoz, and contact the retail pharmacies in their group to do the same. Pharmacies will be asked to immediately stop dispensing Sandoz Ranitidine Hydrochloride Capsules and return remaining stock to Sandoz by contacting Stericycle to request a recall packet. Consumers are asked to continue taking their medication and speak to their physician or pharmacist on alternate healthcare treatment options.

Consumers with questions regarding this recall can contact Sandoz at 1-800-525-8747 option # between 8:30am – 5:00pm Monday – Friday EST or www.us.sandoz.comExternal Link Disclaimer for more information. 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. This information and package photos are available at https://www.us.sandoz.com/patients-customers/product-safety-notices

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
- Regular Mail or Fax: Download form 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 Consumers: Sandoz 1-800-525-8747