MAJOR PHARMACEUTICALS

URGENT: DRUG RECALL

October 28, 2019

PRODUCT

Product	NDC Number	Size	Lot Numbers
Ranitidine 75mg Tablets USP	0904-6715-46	30 Count Bottles	8JE1916, 8KE2243, 8ME2685, 9AE2785, 9CE3317, 9DE2721, 9EE2579, 9GE2785
Ranitidine 75mg Tablets USP	0904-6715-52	60 Count Bottles	8JE1917, 8KE2245, 8ME2724, 9AE2831, 9CE3339, 9DE2747, 9EE2636, 9FE2971, 9GE2793
Ranitidine 150mg Tablets USP	0904-6716-24	24 Count Bottles	8GE1833, 9EE2760
Ranitidine 150mg Tablets USP	0904-6716-51	50 Count Bottles	8GE1921, 8JE2154, 9AE2499, 9BE2863, 9CE3723, 9DE2891, 9EE2812

Distributed by: Major Pharmaceuticals
17177 N. Laurel Park Dr., Suite 233
Livonia, MI 48152

Recall Issued by:
Perrigo

REASON

We have been informed by Perrigo that they are voluntarily recalling to the **Retail Level** the products indicated in the above table. This recall was initiated because "Perrigo had learned from the U.S. Food and Drug Administration (FDA) and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contains a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels."

ACTIONS TO BE TAKEN

1. Stop distributing and quarantine the affected lot.
2. Please carry out a physical count and record this data on the Business Reply Form / Packing Slip which is included with this letter.
3. Fax the Business Reply Form, **even if you do not have the recalled product to 1-844-782-5566 or email to HarvardDrug6557@stericycle.com.**
4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to:

   Stericycle, Inc.
   2670 Executive Dr., Suite A
   Indianapolis, IN 46241
   Attn: Event # 6557

5. If you have further distributed the product, please notify your **Wholesale / Retail** customers immediately and have them return the product back to you.

OTHER INFORMATION

This recall is being carried out to the **RETAIL LEVEL** and is only for the specific products / lots listed above. No other lots, packages, or formulations are being recalled.

These products were shipped from our Indianapolis warehouse between 08/09/2018 and 10/04/2019.

For questions regarding returns, please contact Stericycle at 1-844-801-9151. For medical-related questions, please contact your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.

To ensure proper credit, please return recalled merchandise before January 31, 2020. Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.

This recall is being made with the knowledge of the FDA. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

COMPANY ANNOUNCEMENT

Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product

Summary

Company Announcement Date:

October 23, 2019

FDA Publish Date:

October 23, 2019

Product Type:

Drugs

Reason for Announcement:

Presence of N-Nitrosodimethylamine (NDMA)

Company Name:

Perrigo Company plc

Brand Name:

Perrigo Company plc

Product Description:

Ranitidine (all pack sizes)

Company Announcement

As a precautionary measure, Perrigo Company plc announced today that it has initiated a voluntary, worldwide product recall to the retail customer level of ranitidine (all pack sizes). The recall is being taken due to possible presence of a nitrosamine impurity called N-nitrosodimethylamine (NDMA).

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 is an over-the-counter (OTC) and prescription 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.

After regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall.

Perrigo has the highest commitment to consumer safety and will continue to communicate ongoing testing results with health authorities. 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.

Perrigo is notifying our retail customers by phone, email or other communication with recall notification communications to arrange for the return of all recalled 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.

About Perrigo

Perrigo Company plc is dedicated to making lives better by bringing high quality and affordable selfcare products that consumers trust everywhere they are sold. The Company is a leading provider of over-the-counter health and wellness solutions that enhance individual well-being by empowering consumers to proactively prevent or treat conditions that can be self-managed. Visit Perrigo online at http://www.perrigo.com (http://www.perrigo.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls)