



Urgent Recall Notification

Please Read Immediately

October 23, 2019

Dear Valued Customer;

This is to advise that Perrigo announced today that it has initiated a voluntary product recall to the level of removing product from retail shelves of all Perrigo-produced ranitidine products (both 75mg and 150mg, in all package sizes) under the store or own brand labels listed below. The recall is being taken, out of an abundance of caution, due to possible presence of a nitrosamine impurity called N-nitrosodimethylamine (NDMA).

After the U.S. Food and Drug Administration (FDA) announced that ranitidine may potentially contain N-nitrosodimethylamine (NDMA), Perrigo promptly began testing of its externally sourced ranitidine API and samples of produced ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the combination of the current understanding of the potential for presence of variable amounts of NDMA in ranitidine materials, confirmed by limited, initial testing results, Perrigo has made the decision to conduct the voluntary recall of the following products:

- **Ranitidine 75mg Tablets**
- **Ranitidine 150mg Tablets**
- **Ranitidine 150mg Cool Mint Tablets**

This action is being taken with the knowledge of the FDA and is being issued to the retail level. We are asking for returns of the affected batches from all warehouse and retail locations.

In accordance with FDA guidelines, Perrigo must verify notifications in order to determine the effectiveness of this recall. Perrigo will begin making these Recall Effectiveness Checks by phone within three to four weeks.

Perrigo has the highest commitment to consumer safety and is taking this action in view of that commitment. We will continue to communicate with FDA on this matter, including sharing with them, ongoing results of our product testing.

We deeply regret any inconvenience and appreciate your assistance with this recall. Please contact our Recall Coordinator, Ron Hubbert, at 800-321-0105 if we can provide additional information or assistance.

Sincerely,

Paul Walker
Director Quality, Tablet Value Stream

Attachment: Recall Notification
Shipment Report

Copy: Ron Hubbert, Recall Coordinator