COMPANY ANNOUNCEMENT

Precision Dose Inc. Issues Voluntary Nationwide Recall of Ranitidine Oral Solution, USP 150 mg/10 mL Due to Possible Presence of N-nitrosodimethylamine (NDMA) Impurity.

Summary

Company Announcement Date:

November 19, 2019

FDA Publish Date:

November 19, 2019

Product Type:

Drugs

Reason for Announcement:

Potential presence of N-Nitrosodimethylamine (NDMA) above levels established by the FDA

Company Name:

Precision Dose Inc.

Brand Name:

PrecisionDose

Product Description:

Ranitidine Oral Solution, USP 150 mg/10 mL

Company Announcement

Precision Dose Inc. is voluntarily recalling 5 lots of Ranitidine Oral Solution, USP 150 mg/10 mL to the consumer level. Ranitidine Oral Solution, USP 150 mg/10 mL, is being recalled because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA. This recall is being initiated in response to the recall by the manufacturer (Amneal Pharmaceuticals. LLC), which included lots that were repackaged by Precision Dose Inc.

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. Precision Dose Inc. has not received any reports of adverse events related to this recall to date.

Ranitidine is a histamine-2 blocker, which decreases the amount of acid created by the stomach. Prescription Ranitidine is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.

Ranitidine Oral Solution, USP 150 mg/10 mL is packaged in unit dose cups (NDC 68094-204-59) and sold in 30-pack cartons (68094-204-62) or 100-pack cartons (68094-204-61). The affected Ranitidine Oral Solution, USP 150 mg/10 mL lots are:

Lot	Expiry
501290	30-Nov-2019
501326	30-Nov-2019
501501	30-Nov-2019
501592	30-Apr-2020
501679	30-Apr-2020

The lot number and expiration date are printed on each unit dose cup and carton label. Ranitidine Oral Solution, USP 150 mg/10 mL was distributed Nationwide to Wholesalers, Distributors and Hospitals.

Precision Dose Inc. is notifying its distributors and direct customers by certified mail and is arranging for return of all recalled products. Customers, who purchased the impacted product directly from Precision Dose Inc., can call us at 815-624-8523, Monday – Friday, 8:00 am – 4:30 pm, CST to arrange for product return. Consumers, distributors and retailers that have Ranitidine Oral Solution, USP 150 mg/10 mL, which is being recalled, should stop using and call Precision Dose Inc. at 815-624-8523 to obtain a return packet.

Consumers with questions regarding this recall can contact Precision Dose Inc. by phone (815-624-8523), Monday through Friday 8 am to 4:30 pm CST or e-mail us at: druginfo@precisiondose.com (mailto:druginfo@precisiondose.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 (/node/360543)
- Regular Mail or Fax: Download form (/node/360547) 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

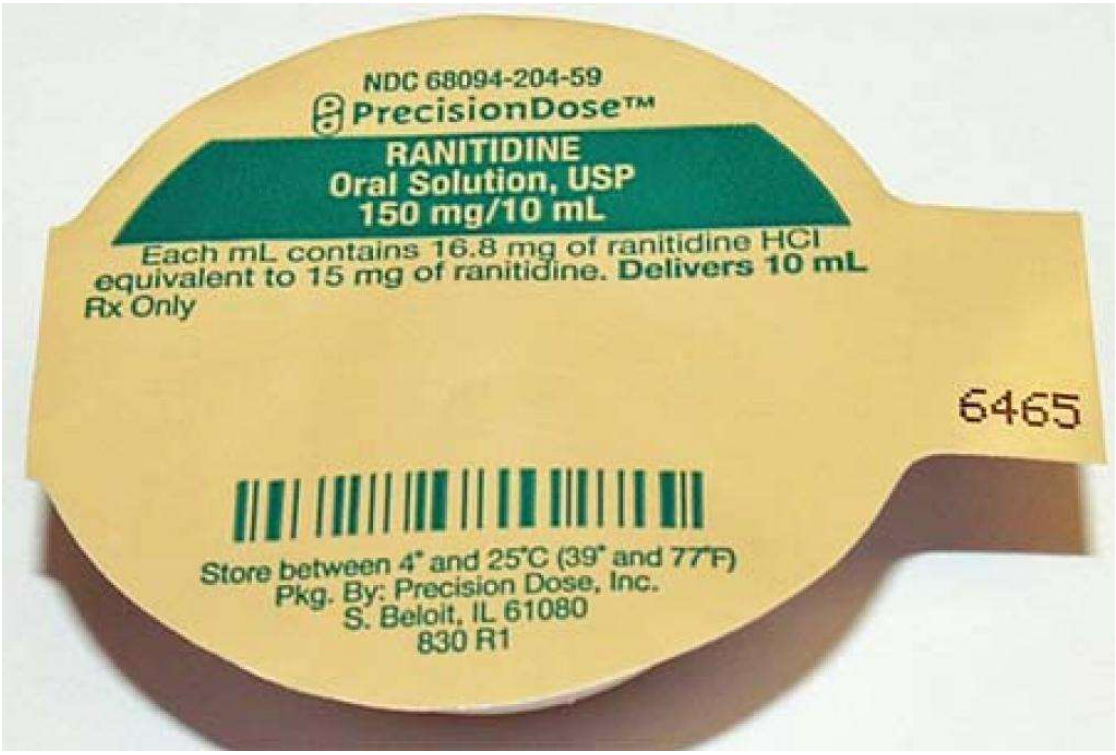
Consumers:

Robert Koopman

815-624-8523

druginfo@precisiondose.com (mailto:druginfo@precisiondose.com)

Product Photos



More Recalls, Market
Withdrawals, &
Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)