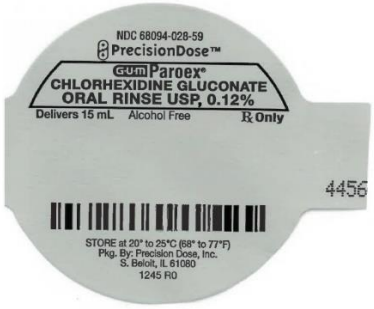
Precision Dose, Inc. Issues Voluntary Nationwide Recall of Paroex Chlorhexidine Gluconate Oral Rinse USP, 0.12%, 15mL due to Microbial Contamination

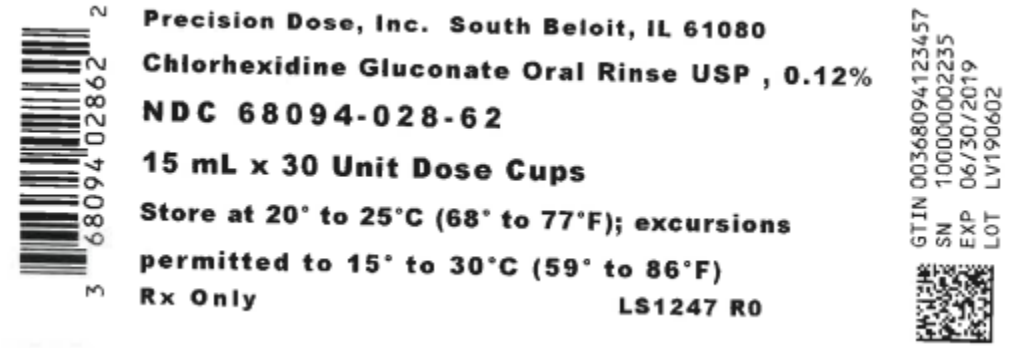


FOR IMMEDIATE RELEASE-December 31, 2020-South Beloit, IL, Precision Dose, Inc. is voluntarily recalling all lots of Chlorhexidine Gluconate Oral Rinse USP, 0.12%, 15mL Unit Dose Cups bearing an expiration date from 1/31/2021 – 02/28/2022 (see specific lots below) to the consumer level. **Precision Dose, Inc.** was notified by the manufacturer of the product, **Sunstar Americas, Inc.,** that this product may be contaminated with the bacteria *Burkholderia lata.*

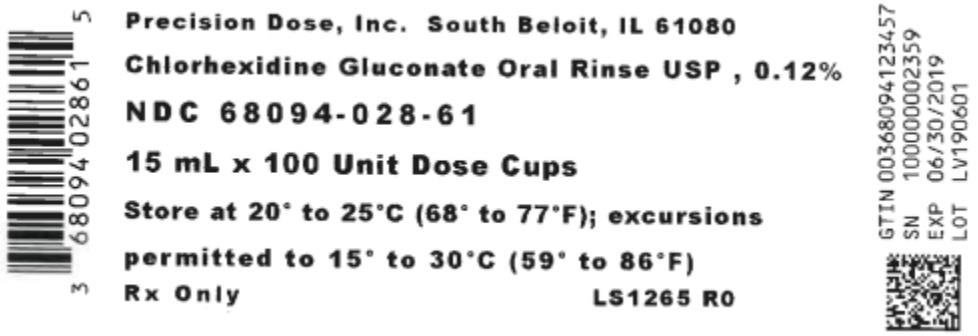
From information provided by the manufacturer, **Sunstar Americas, Inc.,** use of the defective product in the immunocompetent host may result in oral and, potentially, systemic infections requiring antibacterial therapy. In the most at-risk populations, the use of the defective product may result in life-threatening infections, such pneumonia and bacteremia. To date, no adverse events have been reported to Precision Dose, Inc. related to this recall.

The prescription oral rinse product, available through healthcare professionals only, is indicated for use as part of a professional program for the treatment of gingivitis and the product impacted is:

- Distributed in cases each containing 3 shrink-wrapped plastic trays each with 10 unit dose cups, 30-pack. NDC 68094-028-62



- Distributed in cases each containing 10 shrink-wrapped plastic trays each with 10 unit dose cups, 100-pack. NDC 68094-028-61



Chlorhexidine Gluconate Oral Rinse was distributed nationwide in the USA to pharmaceutical wholesalers.

Precision Dose, Inc. is notifying its consignees directly and is arranging for return of all recalled product. Patients, pharmacies, and healthcare facilities in possession of these products should stop using and dispensing immediately.

Consumers with questions regarding this recall can contact Precision Dose, Inc. at 1 (800) 397-9228 (Monday-Friday, 8:00 AM to 4:30 PM Central Time) or by email to customercare@precisiondose.com. Consumers should contact their physician or healthcare provider if they have experienced problems that may be related to using this drug product.

Affected products and lot numbers follow below:

AFFECTED LOTS-Chlorhexidine Gluconate Oral Rinse USP, 0.12%

LOT NUMBER	EXPIRATION DATE	NDC NUMBER
502037	01/31/2021	68094-028-61 68094-028-62
502040	01/31/2021	68094-028-61 68094-028-62
502043	01/31/2021	68094-028-61 68094-028-62
502494	08/31/2021	68094-028-61 68094-028-62
502757	08/31/2021	68094-028-61
502677	09/30/2021	68094-028-61
502693	10/31/2021	68094-028-61
502728	10/31/2021	68094-028-61
502759	10/31/2021	68094-028-62
502771	11/30/2021	68094-028-61 68094-028-62
502784	11/30/2021	68094-028-61
502824	12/31/2021	68094-028-61
502925	02/28/2022	68094-028-61

Patients should contact their physician or healthcare provider if they have additional questions or concerns. 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:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download from www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a 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 US Food and Drug Administration.

About Precision Dose, Inc.

Precision Dose, Inc. is an American company headquartered in the Midwest specializing in the commercial repackaging of unit dose products.

For more information:

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