

## Pareox Chlorhexidine Gluconate Oral Rinse Recall Alert

Date of Notice: 12/31/2020

### Brief Description of Recall Alert

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 as 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. The product impacted is shown in the table below.

NDC	Description
68094-028-62	Distributed in cases each containing 3 shrink-wrapped plastic trays each with 10-unit dose cups, 30-pack.
68094-028-61	Distributed in cases each containing 10 shrink-wrapped plastic trays each with 10-unit dose cups, 100-pack.

### Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502037	01/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-62	502037	01/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502040	01/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-62	502040	01/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502043	01/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-62	502043	01/31/2021

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502494	08/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-62	502494	08/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502757	08/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502677	09/30/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502693	10/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502728	10/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-62	502759	10/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502771	11/30/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-62	502771	11/30/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502784	11/30/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502824	12/31/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12%	68094-028-61	502925	02/28/2022

## Prescriber Information

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.

Adverse reactions or issues experienced with the use of this drug 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

## Member Information

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 [customer care@precisiondose.com](mailto:customer care@precisiondose.com). Consumers should contact their physician or healthcare provider if they have experienced problems that may be related to using this drug product.

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## RxAdvance Response

RxAdvance recommends that members should stop using chlorhexidine gluconate oral rinse USP and contact their physician or dentist.

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