ABARCA

January 11, 2021

To All Network Pharmacies

Notification of Drug Recall

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

The U.S. Food and Drug Administration (FDA) provides public notices about recalls of FDA-regulated products, whenever it occurs. We are committed to our patients' health and safety. In order to keep you informed we are notifying you of the following recall.

Product	NDC Code	Batch number	Expiry Dates	Reason	Company
Paroex Chlorhexidine Gluconate Oral Rinse, 15 mL unit dose cups	68094-0028-61	502037	01/31/2021	Potential contamination with Burkholderia lata	GUM Paroex
		502040	01/31/2021		
		502043	01/31/2021		
		502494	08/31/2021		
		502757	08/31/2021		
		502677	09/30/2021		
		502693	10/31/2021		
		502728	10/31/2021		
		502771	11/30/2021		
		502784	11/30/2021		
		502824	12/31/2021		
		502925	02/28/2022		
	68094-0028-62	502037	01/31/2021		
		502040	01/31/2021		
		502043	01/31/2021		
		502494	08/31/2021		
		502759	10/31/2021		
		502771	11/30/2021		

We are including the *FDA Press Release/Announcement* for your convenience. Please refer to this document for more information.

Sincerely,
Providers Education Department
Abarca health LLC

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Company Announcement

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

- 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.