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January 7, 2021 **COM-2021-001**

RECALL NOTIFICATION

FDA PUBLICATION DATE:

December 31, 2020

DRUG NAME: Paroex® Chlorhexidine Gluconate Oral Rinse

COMPANY: Precision Dose Inc.

REASON: Potential contamination with Burkholderia lata

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. For this reason, we are notifying you that on December 31, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for 13 lots of Paroex® (Chlorhexidine Gluconate) Oral Rinse USP, 0.12%, 15mL unit dose cups, manufactured by Sunstar Americas, Inc.

The voluntary recall is due to possible contamination of the products with the bacteria *Burkholderia lata*. The 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.

Affected products:

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

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Pharmacy required actions(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returning to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- Advise patients to contact their physician or healthcare provider if they have experienced any problems related to using this drug product.

Contact information: For further details, contact Precision Dose, Inc. at phone 1 (800) 397-9228 (Monday-Friday, 8:00 AM to 4:30 PM Central Time) or email customercare@precisiondose.com.

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download the FDA Form 3500 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.

Additional information can be found at:

- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/precision-dose-inc-issues-voluntary-nationwide-recall-paroex-chlorhexidine-gluconate-oral-rinse-usp
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

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Reference(s):

- U.S. Food and Drug Administration. (2021). Precision Dose, Inc. Issues Voluntary Nationwide Recall of Paroex Chlorhexidine Gluconate Oral Rinse USP, 0.12%, 15mL Due to Microbial Contamination. Retrieved January 6, 2021, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/precision-dose-inc-issues-voluntary-nationwide-recall-paroex-chlorhexidine-gluconate-oral-rinse-usp

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