

Precision Dose – Recall of Paroex® (chlorhexidine gluconate)

- On December 31, 2020, <u>Precision Dose announced</u> a voluntary, consumer level recall of <u>Paroex</u> (<u>chlorhexidine gluconate</u>) 0.12% oral rinse, labeled with expiration dates of 1/31/21 2/28/22, due to contamination with <u>Burkholderia lata</u>.
 - Precision Dose was notified by the manufacturer, Sunstar Americas, that this product may be contaminated.
- The recalled products are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Paroex (chlorhexidine gluconate) oral rinse, 0.12%, case of thirty unit dose cups	68094-028-62	Lots with expiration date from 1/31/2021 - 2/28/2022
Paroex (chlorhexidine gluconate) oral rinse, 0.12%, case of one hundred unit dose cups	68094-028-61	Lots with expiration date from 1/31/2021 - 2/28/2022

- Chlorhexidine gluconate is indicated for use between dental visits as part of a professional program
 for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including
 gingival bleeding upon probing.
- 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.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled chlorhexidine gluconate.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Precision Dose by phone at 1-800-397-9228 or by email at customercare@precisiondose.com for further information regarding this recall.



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 $\mbox{RxNews}^{\tiny{\textcircled{\tiny{\scriptsize 0}}}}$ is published by the OptumRx Clinical Services Department.

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