



# Sunstar Americas Expands Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% Due to Microbial Contamination

Date: 12/28/2020

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Sunstar Americas has posted a market recall of Paroex® Chlorhexidine Gluconate Oral Rinse.

## **About this Recall:**

Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% products with an expiration date from 12/31/2020 – 9/30/2022 to the consumer level. The product may be contaminated with the bacteria *Burkholderia lata*. This is an expansion of the recall initially announced in October 2020.

## **What this means to you:**

Use of the contaminated product may lead to a mouth infection and, potentially, an infection in the body that requires antibacterial treatment. In the most at-risk populations, the use of the contaminated product may lead to life-threatening infections, such as pneumonia and bacteremia.

Consumers with questions regarding this recall can contact SAI by phone at 1-800-528-8537 or email at [us.pcr@us.sunstar.com](mailto:us.pcr@us.sunstar.com) Monday to Friday from 8 am to 5 pm CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

For more information regarding this FDA Recall Notification, please refer to the FDA website: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-expands-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse>

FDA contact information for reporting adverse events/quality complaints can be reached online at <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.