

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

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Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex<sup>®</sup> 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 on October 27, 2020.

Use of the contaminated product in an immunocompetent host may lead to oral and, potentially, systemic infections requiring antibacterial therapy. In the most at-risk populations, the use of the contaminated product may result in life-threatening infections, such as pneumonia and bacteremia.

To date, 29 adverse events have been reported to the manufacturer related to this recall. Affected patients tested positive for *Burkholderia lata* infections, usually found in sputum cultures, while under treatment for other serious medical conditions. Use of the contaminated product in patients with pre-existing respiratory conditions, including in those with coronavirus disease 2019 (COVID-19), is particularly unsafe.

The prescription oral rinse product, available through healthcare professionals (HCPs) only, is indicated for use as part of a professional program for the treatment of gingivitis and is packaged as follows:

- 1789P GUM<sup>®</sup> Paroex<sup>®</sup> is distributed in cases each containing 6 amber bottles of 16 fluid ounce (473 mL) chlorhexidine rinse. The bottle has a childproof cap and a 15 mL metered dosage cup, is safety sealed, and is decorated with a multiple-panel wrap-around label.
- 1788P GUM<sup>®</sup> Paroex<sup>®</sup> is distributed in cases each containing 24 amber bottles of 4 fluid ounce (118.25 mL) chlorhexidine rinse. The bottle has a childproof cap, is safety sealed, and is decorated with a multiple-panel wrap-around label.

Paroex was distributed nationwide to dental offices, dental distributors, pharmaceutical wholesalers, dental schools, and pharmacies.

SAI is notifying its direct distributors and customers by USPS Priority mail and is arranging for return of all recalled products. Patients, pharmacies, and healthcare facilities in possession of these products should stop using and dispensing immediately. Sunstar is committed to delivering safe, fully compliant products of the highest quality and is taking necessary steps to prevent future occurrence of this issue.

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 through Friday from 8 am to 5 pm CST. Consumers should contact their physician or HCP if they have experienced any problems that may be related to using this drug product.

Affected products and lot numbers follow below:

- **Product name:** Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12%
  - **Size/ Form:** 16 fl.oz. amber bottles
  - **NDC #:** 052376-021-02
  - **Product Code:** 1789P
  - **Lots Recalled:** all lots with expiration date from December 31, 2020 through September 30, 2022
  
- **Product name:** Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12%
  - **Size/ Form:** 4 fl.oz. Amber Bottles
  - **NDC #:** 052376-021-04
  - **Product Code:** 1788P
  - **Lots Recalled:** all lots with expiration date from December 31, 2020 through September 30, 2022

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 United States (US) Food and Drug Administration (FDA).

Link to FDA recall notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-expands-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse>

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## Company Contact Information

### Consumers:

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## Product Photos

Click [here](#) for product photos.