

COMPANY ANNOUNCEMENT

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

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

October 27, 2020

FDA Publish Date:

October 28, 2020

Product Type:

Drugs

Reason for Announcement:Potential contamination with *Burkholderia lata***Company Name:**

Sunstar Americas, Inc.

Brand Name:

Paroex

Product Description:

Paroex Chlorhexidine Gluconate Oral Rinse, 4 oz and 16 oz

Company Announcement

Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% products bearing an expiration date from 6/30/22 – 9/30/22 (see specific lots below) to the consumer level. This product may be contaminated with the bacteria *Burkholderia lata*.

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. To date, no adverse events have been reported to SAI 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 is packaged as follows:

- **1789P GUM®** Paroex® 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®** Paroex® 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.

The product can be identified by as shown in the images below:

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.

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

Affected products and lot numbers follow below:

AFFECTED LOTS

Product name: Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% NDC # 052376-021-02 P/N 1789P 16 fl oz					
Lot #	Exp Date	Lot #	Exp Date	Lot #	Exp Date
C170FY	6/30/22	C191KT	7/31/22	C205BL	7/31/22
C170FZ	6/30/22	C191KU	7/31/22	C205BM	7/31/22
C170GA	6/30/22	C191KW	7/31/22	C205BN	7/31/22
C170GB	6/30/22	C191KX	7/31/22	C219DS	8/31/22

C170GC	6/30/22	C191KY	7/31/22	C240GM	9/30/22
C177GP	6/30/22	C198LJ	7/31/22	C219DK	8/31/22
C177GQ	6/30/22	C198LK	7/31/22	C219DL	8/31/22
C177GR	6/30/22	C198LL	7/31/22	C219DM	8/31/22
C240GP	9/30/22	C198LM	7/31/22	C219DN	8/31/22
C240GQ	9/30/22	C205BH	7/31/22	C219DP	8/31/22
C240GR	9/30/22	C205BJ	7/31/22	C219DQ	8/31/22
C191KS	7/31/22	C205BK	7/31/22	C219DR	8/31/22

Product name: Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% NDC # 052376-021-04 P/N 1788P 4.0 fl oz	
Lot #	Exp Date
C191KR	7/31/22

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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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

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.

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

About Sunstar Americas Inc.

Sunstar Americas, Inc., a member of the Sunstar Group of companies, is a global organization headquartered in Switzerland that is a leader in the oral care industry and the manufacturer and distributor of the GUM and Butler Brands.

For more information:

Contact us:

Phone: 1-800-528-8537

Email: us.pcr@us.sunstar.com (<mailto:us.pcr@us.sunstar.com>)

Visit us at: <https://www.gumbrand.com/news-announcements>

(<https://www.gumbrand.com/news-announcements>) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Company Contact Information

Consumers:

Sunstar Americas, Inc.

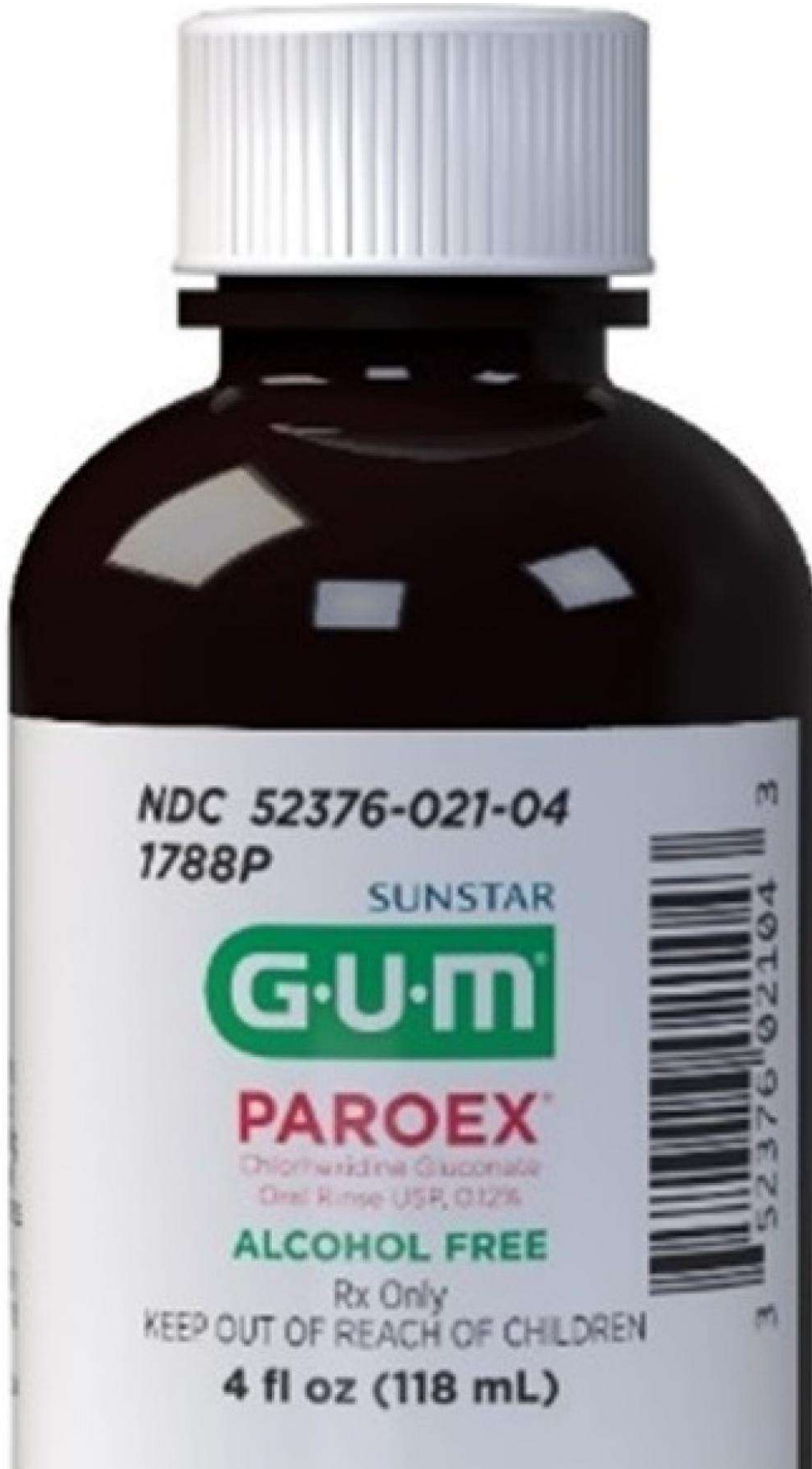
☎ 1-800-528-8537

✉ us.pcr@us.sunstar.com (<mailto:us.pcr@us.sunstar.com>)

Product Photos









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