COMPANY ANNOUNCEMENT

Sunstar Americas Inc. Expands 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:

December 28, 2020

FDA Publish Date:

December 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

Schaumburg, Illinois, Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% products bearing an expiration date from 12/31/2020 – 9/30/2022 to the consumer level. This 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 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, 29 adverse events have been reported to SAI related to this recall. Affected patients tested positive for *Burkholderia lata* infections, typically found in sputum cultures while under treatment for other serious medical conditions. Use of the contaminated product on patients with pre-existing respiratory conditions, including those infected with Covid-19, is particularly unsafe.

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 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 (mailto: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:

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 Dec. 31, 2020 through Sep. 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 Dec. 31, 2020 through Sep. 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 (/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.

Original Press Release (/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-issues-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse)

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Product Photos


NDC 52376 - 021-02
17689
SUNSTAR
G·U·M
PAROEX
ALCOHOL FREE
Rx Only
KEEP OUT OF REACH OF CHILDREN
PLACE PHARMACY
LABEL HERE


Dispense in bottle as
provided or in amber glass
1 Pint
(473 mL)


NDC 52376-021-04
1788P
SUNSTAR
G·U·M
PAROEX
ALCOHOL FREE
Rx Only
KEEP OUT OF REACH OF CHILDREN
4 fl oz (118 mL)

More Recalls, Market
Withdrawals, &
Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)