RXADVANCE
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# Paroex® Chlorhexidine Gluconate Oral Rinse Recall Alert

Date of Notice: 12/28/2020

## Brief Description of Recall Alert

Sunstar Americas, Inc. (SAI) Schaumburg, Illinois, 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.

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.

## Affected Products

| Drug Name & Strength | NDC | Lot | Expiration Date |
|---|---|---|---|
| Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% 16 fl. oz. | 052376-021-02 | All lots | 12/31/2020 to 09/30/2022 |
| Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% 4 fl. oz. | 052376-021-04 | All lots | 12/31/2020 to 09/30/2022 |

## Prescriber Information

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.

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.

Adverse reactions or issues experienced with the use of this drug 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

## Member Information

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.

## RxAdvance Response

RxAdvance recommends that members should stop using Chlorhexidine Gluconate Oral Rinse USP and contact their physician or dentist.