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

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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, Inc. (SAI) has posted a lot recall of Paroex.

About this Recall:
SAI is voluntarily recalling specific lots of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% with an expiration date from 6/30/2022 to 9/30/2022 to the consumer level. This product is being recalled as it may be contaminated with the bacteria *Burkholderia lata*.

What this means to you:
Use of the contaminated product in a person with a normal immune response may result in 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, no adverse events have been reported related to this recall.

The prescription oral rinse product, available through healthcare providers (HCPs) 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 linked here.

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 at 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.

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

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 US Food and Drug Administration (FDA).

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-issues-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.