October 29, 2020 **COM-2020-085**

RECALL NOTIFICATION

FDA PUBLICATION DATE:

October 28, 2020

DRUG NAME: Paroex®

COMPANY: Sunstar Americas Inc.

REASON: Due to Microbial Contamination

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on October 28, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for 36 lots of Paroex® oral rinse 16 fl oz products and 1 lot of the 4 fl oz product (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) manufactured by Sunstar Americas, Inc. (SAI).

The voluntary recall is due to possible contaminated products with the bacteria *Burkholderia lata*. The 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.

See the complete list of the recalled products here.
(https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-issues-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse)

Pharmacy required actions(s):

- Identify if the product is inventory and immediately stop using and dispensing it. The product should be returning to the place of purchase or as directed in the recall notification.

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- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- For further information: Contact SAI by phone at 1-800-528-8537 or email us.pcr@us.sunstar.com. Consumers should contact their physician or healthcare provider if they have experienced any problems related to using this drug product.

Contact information:

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download the FDA Form 3500 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.

Additional information can be found at:

- FDA Recall for Paroex
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. Also, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2020). Sunstar Americas Inc. Issues Voluntary Nationwide Recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12% Due to Microbial Contamination. (2020). Retrieved October 28 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunstar-americas-inc-issues-voluntary-nationwide-recall-paroexr-chlorhexidine-gluconate-oral-rinse

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