



Sunstar Americas – Recall of Paroex® (chlorhexidine gluconate)

- On October 28, 2020, the [FDA announced](#) a voluntary, consumer level recall of [Sunstar America's Paroex \(chlorhexidine gluconate\)](#) 0.12% oral rinse, labeled with expiration dates of 6/30/22 – 9/20/22, due to contamination with *Burkholderia lata*.
- Paroex was distributed nationwide to dental offices, dental distributors, pharmaceutical wholesalers, dental schools, and pharmacies.

Product Description	NDC#	Lot# (Expiration Date)
Paroex (chlorhexidine gluconate) oral rinse, 0.12%	52376-021-04	C191KR (7/31/2022)
	52376-021-02	C170FY (6/30/2022); C170FZ (6/30/2022); C170GA (6/30/2022); C170GB (6/30/2022); C170GC (6/30/2022); C177GP (6/30/2022); C177GQ (6/30/2022); C177GR (6/30/2022); C240GP (9/30/2022); C240GQ (9/30/2022); C240GR (9/30/2022); C191KS (7/31/2022); C191KT (7/31/2022); C191KU (7/31/2022); C191KW (7/31/2022); C191KX (7/31/2022); C191KY (7/31/2022); C198LJ (7/31/2022); C198LK (7/31/2022); C198LL (7/31/2022); C198LM (7/31/2022); C205BH (7/31/2022); C205BJ (7/31/2022); C205BK (7/31/2022); C205BL (7/31/2022); C205BM (7/31/2022); C205BN (7/31/2022); C219DS (8/31/2022);

Continued . . .

		C240GM (9/30/2022); C219DK (8/31/2022); C219DL (8/31/2022); C219DM (8/31/2022); C219DN (8/31/2022); C219DP (8/31/2022); C219DQ (8/31/2022); C219DR (8/31/2022)
--	--	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

- Paroex is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing.
- 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 Sunstar America related to this recall.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled Paroex.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Sunstar by phone at **1-800-528-8537** or by email at **us.pcr@us.sunstar.com** for further information regarding this recall.



OptumRx<sup>®</sup> specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum<sup>®</sup> company — a leading provider of integrated health services. Learn more at [optum.com](http://optum.com).

All Optum<sup>®</sup> trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews<sup>®</sup> is published by the OptumRx Clinical Services Department.

©2020 Optum, Inc. All rights reserved.