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);

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		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.

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