Paroex® (chlorhexidine gluconate) Oral Rinse USP Recall Alert

Date of Notice: 10/27/2020

Brief Description of Recall Alert

Sunstar Americas, Inc. (SAI) is voluntarily recalling Paroex® chlorhexidine gluconate oral rinse USP, 0.12% products with an expiration date from 6/30/22 – 9/30/22 (see specific lots below). These lots may be contaminated with the bacteria *Burkholderia lata*.

Use of the defective product in someone who is immunocompromised may result in oral and, potentially, systemic infections requiring antibiotic therapy. In the most at-risk populations, the use of the defective product may result in life-threatening infections, such as pneumonia and bacteremia.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	052376-021-02	C170FY C170FZ C170GA C170GB C170GC C177GP C177GQ C177GR	6/30/22
Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	052376-021-02	C240GP C240GQ C240GR	9/30/22
Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	052376-021-02	C191KS C191KT C191KU C191KW C191KX C198LJ C198LK C198LL C198LM C205BH C205BJ C205BK C205BL C205BM C205BN	7/31/22

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	052376-021-02	C219DS C219DK C219DL C219DM C219DN C219DP C219DQ C219DR	8/31/22
Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	052376-021-02	C240GM	9/30/22
Paroex® chlorhexidine gluconate oral rinse USP, 0.12%	052376-021-04	C191KR	7/31/22

Prescriber Information

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. Pharmacies and healthcare facilities in possession of these products should stop dispensing immediately. To date, no adverse events have been reported to SAI related to this recall.

Adverse reactions or quality problems 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

Members 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. Patients in possession of these products should stop using immediately. Members should contact their doctor if they have experienced any problems that may be related to using this drug product.

RxAdvance Response

Members should stop using Paroex® chlorhexidine gluconate oral rinse USP and contact their doctor or dentist. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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