

Chlorhexidine Gluconate Oral Rinse USP Recall Alert

Date of Notice: 11/09/2020

Brief Description of Recall Alert

Lohxa, LLC is voluntarily recalling Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free (NDC:70166-027-15) products bearing an expiration date from 01/31/21 – 03/31/21 (see specific lots below) to the consumer level. This product is sourced and repackaged from Sunstar Americas Inc. who has notified us that the product may be contaminated with the bacteria *Burkholderia lata*.

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 Lohxa, LLC related to this recall.

The prescription oral rinse product, available through institutional use only, is indicated for use as part of a professional program for the treatment of gingivitis and is packaged as follows:

Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free is distributed in cases each containing 50 unit dose cups. Each case contains a colored label around the lid and body of the case.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free, 15 mL	70166-027-15	T09101A	01/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free, 15 mL	70166-027-15	T08292A	02/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free, 15 mL	70166-027-15	T10011A	02/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free, 15 mL	70166-027-15	M10193A	03/2021
Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free, 15 mL	70166-027-15	T10223A	03/2021

Prescriber Information

Pareox 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.

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.

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

Member Information

Consumers with questions regarding this recall can contact Lohxa, LLC by phone at 1-800-641-5564 or email info@lohxa.com on Monday-Friday from 8am-5pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

RxAdvance Response

Members should stop using Chlorhexidine Gluconate Oral Rinse USP and contact their physician or dentist.