COMPANY ANNOUNCEMENT

Lohxa LLC Issues Voluntary Nationwide Recall of Chlorhexidine Gluconate Oral Rinse USP, 0.12% Due to Microbial Contamination

Summary

Company Announcement Date:

November 09, 2020

FDA Publish Date:

November 09, 2020

Product Type:

Drugs

Reason for Announcement:

May be contaminated with Burkholderia lata

Company Name:

Lohxa, LLC

Brand Name:

Lohxa

Product Description:

Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free

Company Announcement

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 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.

The product can be identified by as shown in the images below:

Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free was distributed to Nationwide to hospital pharmacies.

Lohxa, LLC is notifying its direct customers by Fedex overnight mail, electronic mail, phone call 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.

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.

Affected products and lot numbers follow below: AFFECTED LOTS

Chlorhexidine Gluconate Oral Rinse USP, 0.12% Alcohol free, 15 mL (NDC:70166-027-15)	
LOT	**EXP**
T09101A	01/2021
T08292A	02/2021
T10011A	02/2021
M10193A	03/2021
T10223A	03/2021

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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

Lohxa, LLC is committed to delivering safe, fully compliant products of the highest quality and is taking necessary steps to prevent future occurrence of this issue.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Lohxa, LLC

1-800-641-5564

info@lohxa.com (mailto:info@lohxa.com)

Product Photos


NDC 70166-027-15
RxONLY
CHLORHEXIDINE GLUCONATE
ORAL RINSE, USP
FOR ORAL USE ONLY
0.12% (15mL)
Alcohol-Free
50 UNITS x 15mL
CHLORHEXIDINE GLUCONATE
ORAL RINSE, USP
FOR ORAL USE ONLY
0.12% (15 mL)
3 70166 02715 0
Alcohol-Free
Ingredients:
0.12% chlorhexidine gluconate in a base containing deionized water, propylene glycol, glycerin, polyoxyl 40 hydrogenated castor oil, mint flavor, potassium acesulfame, FD&C Red #40 and D&C Red #33.
[See USP Controlled Room Temperature].
See insert for dosage and administration.
For Institutional Use.
Distributed by:
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Worcester, MA 01608 U.S.A
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