AKORN

Sterile Ophthalmics and Injectables

1925 West Field Court, Suite 300 • Lake Forest, Illinois 60045 • PHONE (800) 932-5676 • FAX (800) 943-3694 • www.akorn.com

March 18, 2016

RE: URGENT PRODUCT RECALL – ALL MARKETED LOTS

Chlorhexidine Gluconate Oral Rinse, 0.12% (16 oz)

Manufactured/Distributed by

Hi-Tech Pharmacal Co., Inc.
369 Bayview Avenue
Amityville, NY 11701, USA
NDC# 50383-720-16

PerioRx® (Chlorhexidine Gluconate Oral Rinse, 0.12%) (16 oz)

Distributed by:
Discus Dental LLC
Ontario, CA 91761, USA

ORIS® (Chlorhexidine Gluconate Oral Rinse, 0.12%) (16 oz)

Distributed by:
Dentsply Professional
1301 Smile Way
York, PA 17404, USA

Affected Drug Batches:

Chlorhexidine Gluconate Oral Rinse, 0.12% - 16 oz Bottle (1 of 3)
Distributed by Hi-Tech Pharmacal Co. LTD
NDC # 50383-720-16

Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
626537	3/2016	626853	3/2016	627343	4/2016	627953	5/2016
626540	3/2016	626856	3/2016	627346	4/2016	627956	5/2016
626543	3/2016	626859	3/2016	627528	5/2016	627959	5/2016
626570	3/2016	627043	4/2016	627763	5/2016	628040	5/2016
626573	3/2016	627046	4/2016	627766	5/2016	628148	6/2016
626576	3/2016	627051	4/2016	627921	5/2016	628151	6/2016
626579	3/2016	627232	4/2016	627924	5/2016	628230	6/2016
626582	3/2016	627235	4/2016	627927	5/2016	628232	6/2016
626684	3/2016	627238	4/2016	627930	5/2016	628365	6/2016
626687	3/2016	627339	5/2016	627933	5/2016	628589	7/2016

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Chlorhexidine Gluconate Oral Rinse, 0.12% - 16 oz Bottle (2 of 3)
Distributed by Hi-Tech Pharmacal Co. LTD
NDC # 50383-720-16

Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
628592	72016	629232	8/2016	629888	9/2016	630732	11/2016
628598	7/2016	629235	8/2016	630058	9/2016	630735	11/2016
628802	7/2016	629307	8/2016	630061	10/2016	630853	11/2016
628805	7/2016	629310	8/2016	630064	10/2016	630856	11/2016
628808	7/2016	629313	8/2016	630221	10/2016	630859	11/2016
628811	7/2016	629316	8/2016	630224	10/2016	631008	11/2016
628814	7/2016	629687	9/2016	630362	10/2016	631026	12/2016
629059	8/2016	629693	9/2016	630365	10/2016	631027	12/2016
629204	8/2016	629696	9/2016	630613	10/2016	631169	12/2016
629207	8/2016	629882	9/2016	630615	11/2016	631172	12/2016

Chlorhexidine Gluconate Oral Rinse, 0.12% - 16 oz Bottle (3 of 3)
Distributed by Hi-Tech Pharmacal Co. LTD
NDC # 50383-720-16

Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
631175	12/2016	632065	1/2017	632472	2/2017	632796	3/2017
631655	12/2016	632068	1/2017	632475	2/2017	632805	3/2017
631658	12/2016	632071	1/2017	632504	2/2017	632808	3/2017
631704	1/2017	632074	1/2017	632507	2/2017	632811	3/2017
631707	1/2017	632211	1/2017	632697	2/2017	632814	3/2017
631861	1/2017	632214	1/2017	632776	3/2017	633072	3/2017
631864	1/2017	632328	2/2017	632781	3/2017	633078	3/2017
631867	1/2017	632331	2/2017	632784	3/2017	633081	3/2017
632059	1/2017	632334	2/2017	632790	3/2017	633084	3/2017
632062	1/2017	632337	2/2017	632793	3/2017	633087	3/2017
633090	3/2017	633093	3/2017	633099	4/2017	633111	4/2017
633681	4/2017	633682	4/2017	633684	4/2017	632221	2/2017
633693	4/2017	633696	4/2017	345618	5/2017	345620	5/2017
346863	7/2017	345607	5/2017	346720	7/2017	346573	7/2017
346571	7/2017	346575	7/2017				

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PerioRx® (Chlorhexidine Gluconate Oral Rinse, 0.12%) – 16 oz bottle **Distributed by Discus Dental LLC**					
Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
627525	5/2016	630467	10/2016	345624	5/2017
628362	6/2016	632218	2/2017	345679	5/2017
628595	7/2016	632500	2/2017	347420	9/2017
629319	8/2016	633075	3/2017	347662	9/2017
629885	9/2016	632799	3/2017		

ORIS® (Chlorhexidine Gluconate Oral Rinse, 0.12%) – 16 oz bottle **Distributed by Dentsply Professional**					
Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
628146	6/2016	629690	9/2016	348295	10/2017

Dear Valued Customer:

We are notifying you of a voluntary recall of all marketed batches (155) of **Chlorhexidine Gluconate Oral Rinse, 0.12% (16 oz bottle), also marketed as ORIS® and PerioRx®**, distributed by Hi-Tech Pharmacal, Discus Dental LLC and Dentsply Professional, respectively. This recall is prompted by an out-of-specification result (for multiple batches) for an unknown impurity of Chlorhexidine gluconate.

On the basis of medical and professional review, adverse patient safety or health hazard concerns are unlikely. However, Hi-Tech is recalling all marketed batches listed in the tables above.

Please examine your inventory and quarantine product subject to recall. The recalled products can be returned to Akorn for credit at the address listed below.

If you further distributed this product, please forward this notification to your customers as it is a **RETAIL LEVEL RECALL**. If the product is returned to you, please do not destroy it and forward it to Akorn, as instructed below using the attached Verification Form:

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- Indicate, by checking the space provided on the form, that you will return all remaining units in your possession within 30 calendar days of this notification. Returned product should be addressed to:

Akorn C/O
Qualanex, LLC
1410 Harris Road
Libertyville, IL 60048
Att: Chlorhexidine Recall

- For proper credit please return the enclosed Verification Form (along with the return of the product, if product return is involved) within 30 days. In order to ensure proper credit, please place your account number on the enclosed form in the space provided.

- Whether or not you have remaining inventory, please complete and return the enclosed Verification Form by mail or by fax (847) 737-3719. If no inventory remains, please check the appropriate box, sign and return to Akorn, Inc. attention.

If you have any question related to the product being recalled, please call Akorn, Inc. Customer Service at 1-800-932-5676 (menu option #1). The hours of operation are Monday to Thursday, 7:00 AM to 6:00 PM CST, and Friday 7:00 AM – 5:00 PM CST. We appreciate your assistance in expediting this effort and apologize for any inconvenience this action may cause you.

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**: **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm** 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

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

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Sincerely,

John Franolic
VP of Regulatory Affairs
Non-Sterile Dosage Forms
Akorn Pharmaceuticals

Attachments: Verification Form

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Product Recall
Akorn Verification Form

Chlorhexidine Gluconate Oral Rinse 0.12% or PerioRx® or ORIS®
Distributed by Hi-Tech Pharmacal Co. LTD, Discus Dental LLC and Dentsply.

Effected Lots by Recall

Chlorhexidine Gluconate Oral Rinse, 0.12% - 16 oz Bottle (1 of 3)
Distributed by Hi-Tech Pharmacal Co. LTD
NDC # 50383-720-16

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Chlorhexidine Gluconate Oral Rinse, 0.12% - 16 oz Bottle (2 of 3)
Distributed by Hi-Tech Pharmacal Co. LTD
NDC # 50383-720-16

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628805	7/2016	629310	8/2016	630064	10/2016	630856	11/2016
628808	7/2016	629313	8/2016	630221	10/2016	630859	11/2016
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628814	7/2016	629687	9/2016	630362	10/2016	631026	12/2016
629059	8/2016	629693	9/2016	630365	10/2016	631027	12/2016
629204	8/2016	629696	9/2016	630613	10/2016	631169	12/2016
629207	8/2016	629882	9/2016	630615	11/2016	631172	12/2016

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NDC # 50383-720-16

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631867	1/2017	632331	2/2017	632784	3/2017	633081	3/2017
632059	1/2017	632334	2/2017	632790	3/2017	633084	3/2017
632062	1/2017	632337	2/2017	632793	3/2017	633087	3/2017
633090	3/2017	633093	3/2017	633099	4/2017	633111	4/2017
633681	4/2017	633682	4/2017	633684	4/2017	632221	2/2017
633693	4/2017	633696	4/2017	345618	5/2017	345620	5/2017
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346571	7/2017	346575	7/2017				

PerioRx® (Chlorhexidine Gluconate Oral Rinse, 0.12%) – 16 oz bottle
Distributed by Discus Dental LLC

Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
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628362	6/2016	632218	2/2017	345679	5/2017
628595	7/2016	632500	2/2017	347420	9/2017
629319	8/2016	633075	3/2017	347662	9/2017
629885	9/2016	632799	3/2017		

ORIS® (Chlorhexidine Gluconate Oral Rinse, 0.12%) – 16 oz bottle
Distributed by Dentsply Professional

Batch #	Expiry Date	Batch #	Expiry Date	Batch #	Expiry Date
628146	6/2016	629690	9/2016	348295	10/2017

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Customer Name: _____

WHOLESALER: _____

We have remaining inventory of **Chlorhexidine Gluconate or PerioRx or Oris** in our possession:

Yes ( ) No ( )

If yes, the following lot and unit quantities remain in our possession:

Lot No: _____Qty. Sealed: _____Qty. Partial: _____

Lot No: _____ Qty. Sealed: _____Qty. Partial: _____

Lot No: _____Qty. Sealed: _____Qty. Partial: _____

Lot No: _____Qty. Sealed: _____Qty. Partial: _____

Lot No: _____Qty. Sealed: _____Qty. Partial: _____

Lot No: _____Qty. Sealed: _____Qty. Partial: _____

Lot No: _____ Qty. Sealed: _____Qty. Partial: _____

We are returning a total of _____Sealed bottles of this product to Akorn C/O Qualanex, LLC.

We are returning a total of _____ partial bottles of this product to Akorn, C/O Qualanex, LLC.

Akorn C/O
Qualanex, LLC
1410 Harris Road
Libertyville, IL 60048
Att: Chlorhexidine Recall

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Customer Contact/Name: _____ **Title:** _____
(Print)

Customer Address: _____ **City:** _____

State:_____ **Zip:** _____ **Phone:**_____**Fax:**_____

DEA: _____

E-Mail address:_____

Signature: _____ **Date:** _____

Wholesaler: _____**Wholesaler Acct. No:** _____

Please fax or email your completed form to one of the following:

Qualanex fax: (847) 737-3719
Qualanex email: recall@qualanex.com