ASD Healthcare
AmerisourceBergen

M-F 7:00AM to 6:00PM CST
asdhealthcare.com
800.746.6273
800.547.9413

July 31, 2018

Urgent: Akorn Inc. issues a voluntary recall for 1 lot of Lidocaine 2.5% and Prilocaine Cream, 2.5%

Dear ASD Healthcare Customer:

Akorn Inc., is issuing a voluntary product recall for Lidocaine 2.5% and Prilocaine Cream, 2.5%®. The affected lots are listed below. This recall is being conducted with the full knowledge of the Food and Drug Administration. Akorn initiated this recall due to observed out of specification results for unknown impurity at the 12 month stability testing. There is limited or no health hazard identified.

Akorn provided the following affected lot information:

Product Description	Package Size	Lot Number	Expiry Dates	NDC	Manufacturer Initial Ship Date
Lidocaine 2.5% and Prilocaine Cream, 2.5%	30 g tubes (1 in 1 carton)	356309	1 March 2019	50383-0667-30	03/16/2017

We ask for your cooperation in taking the following action:

- Immediately quarantine inventory of the affected product.
- Please carry out a physical count and provide the physical count and verify the lot number.
- Return the recalled product with verification form within 30 days to:

  Akorn c/o
  Qualanex, LLC
  1410 Harris Road
  Libertyville, IL 60048

For shipping assistance, product questions or questions about the recall process, please contact Qualanex Customer Service at 800.505.9291 or customerservice@qualanex.com

For medical questions, please contact Akorn Customer Service at 800.932.5676 or customer.service@akorn.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA 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.

For the full recall notice, please view the attached documents in the following pages.

URGENT: Drug Recall Notice

July 30, 2018

Manufacturing Firm:		**Recalling Firm (if applicable):**
Company	Akorn Inc.	**Company** Akorn Inc.
Address	369 Bayview Ave,	**Address** 1925 West Field Court Suite 300
City/State/Zip	Amityville, NY 11701	**City/State/Zip** Lake Forest, IL 60045

PRODUCT:

Product Description	ID Number (NDC/UPC/Catalog)	Package Size	Lot # / Expiration Date (see addendum A if req.)	Manufacturer Initial Ship Date
Lidocaine 2.5% and Prilocaine Cream, 2.5%	NDC 50383-667-30	30 g tubes (1in 1 CARTON)	356309 **Expiry 03-2019**	03/16/2017

REASON: Provide a description of the reason and health hazard for the recall.

This recall is prompted by observed out of specification results for unknown impurity at the 12 month stability testing. There is limited or no health hazard identified.

LEVEL: Specify the level of the recall.

This recall is being carried out to the **RETAIL** level and is only for the specific lot listed above.

CLASS: Indicate if the recall has been classified and provide class (I, II, III).

This recall has yet to be classified. This recall is being conducted with the knowledge of the Food and Drug Administration.

ACTION: Describes actions to be taken by distributors, retailers and/or customers.

By distributor:
1. Stop dispensing and distributing these lots. Quarantine product.
2. Please carry out a physical count and record this data on the verification form and the packing slip included with this letter.
3. Complete and return the attached verification form **even if you do not have the recalled product.**
4. Notifications of this recall are being sent to all direct distributor accounts of Akorn. If you further distributed this product, please forward this notification to your customers as it is a **RETAIL LEVEL RECALL**

5. Return the recalled product and the packing slip using the pre-paid shipping labels within 30 days to:

Akorn c/o
Qualanex, LLC
1410 Harris Road
Libertyville, IL 60048

AKORN SPECIALTY GENERICS

Other Information: Provide necessary contact information for distributor, retailer and consumer for recall, including contact for medical and product questions and cost recovery information.

No other lots, packages or formulations are being recalled.

For shipping assistance, product questions or questions about the recall process, please contact Qualanex Customer Service at (800) 505-9291 or customerservice@qualanex.com.

For medical questions please contact Akorn Customer Service at (800) 932-5676 or customer.service@akorn.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA 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

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.

AUTHORIZED BY:

Name Jesse Kirsh Title Executive Director QA/QC

Signature Jesse Kirsh Date: 7/27/2018

1925 West Field Court, Suite 300 · Lake Forest, IL 60045 · PHONE (800) 932-5676 · FAX (800) 943-3694 · WEB akorn.com