

## URGENT: Drug Recall Notice

**January 17, 2019**

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

**PRODUCT:**

| Product Description                                | ID Number (NDC/UPC/Catalog) | Package Size | Lot # / Expiration Date     | Manufacturer Initial Ship Date |
|--|-----------------------------|--------------|-----------------------------|--------------------------------|
| <b>Clobetasol Propionate Emollient Cream 0.05%</b> | 50383-270-60                | 60g          | 356892<br>Expiry 04/16/2019 | 06/21/17 to<br>02/13/18        |
|  | 50383-270-60                | 60g          | 356927<br>Expiry 04/15/2019 | 08/18/2017 to<br>11/28/18      |
|  | 50383-270-30                | 30g          | 357052<br>Expiry 04/19/2019 | 05/31/17 to<br>12/19/17        |

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

This recall is prompted by an OOS results observed for a preservative, Imidurea, during routine stability testing at 9 months at room temperature, sideways, storage condition. 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 lots listed above.

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

This recall has yet to be classified. It 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.
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

**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](mailto:customerservice@qualanex.com).

For medical questions please contact Akorn Customer Service at (800) 932-5676 or [customer.service@akorn.com](mailto: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](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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: Kim Wasserkrug

Title: SVP, Quality Operations

Signature: 

Date: 01-16-2019

### Product Recall Verification Form

#### Clobetasol Propionate Emollient Cream 0.05%

| Product Description                         | ID Number<br>(NDC/UPC/Catalog) | Package Size | Lot # / Expiration Date     |
|---|--------------------------------|--------------|-----------------------------|
| Clobetasol Propionate Emollient Cream 0.05% | 50383-270-60                   | 60g          | 356892<br>Expiry 04/16/2019 |
| Clobetasol Propionate Emollient Cream 0.05% | 50383-270-60                   | 60g          | 356927<br>Expiry 04/15/2019 |
| Clobetasol Propionate Emollient Cream 0.05% | 50383-270-30                   | 30g          | 357052<br>Expiry 04/19/2019 |

Please email your completed form to [recall@qualanex.com](mailto:recall@qualanex.com) or fax to (847) 737-3719

Ship product to: Akorn c/o Qualanex, 1410 Harris Road Libertyville, IL 60048

#### CUSTOMER INFORMATION:

Your Company Name: \_\_\_\_\_

Company you purchased the product from: \_\_\_\_\_

Your Company Address: \_\_\_\_\_ City: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Form completed by: \_\_\_\_\_ Title: \_\_\_\_\_  
(Print Name)

E-Mail address: \_\_\_\_\_

Completed by Signature: \_\_\_\_\_ Date: \_\_\_\_\_

#### INVENTORY STATUS:

We have remaining inventory of the recalled product in our possession: Yes ( ) No ( )

#### INVENTORY TOTALS:

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

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