



URGENT: Drug Recall Notice

December 20, 2018

Manufacturing Firm:		Recalling Firm (if applicable):	
Company	Akorn AG	Company	Akorn Inc.
Address	Riethofstrasse 1	Address	1925 West Field Court Suite 300
City/State/Zip	Hettlingen, Switzerland 8442	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
Cosopt Ophthalmic Solution, 10 mL	NDC 17478-605-10	10 mL bottle	426007, Exp. 04/2020 426008, Exp. 04/2020	06/12/18 – 11/20/18 05/24/18 – 11/20/18

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

This recall is prompted by observed out of specification results for Cosopt Ophthalmic Solution, 10 mL. Out of specification for opalescence has been registered at 7 month stability study. Health hazard has been identified as limited.

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. 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

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 Kim Wasserkrug Title Sr. VP, Quality Operations

Signature  Date: 12-17-2018



Product Recall Verification Form

Cosopt Ophthalmic Solution, 0.3%

Product Description	ID Number (NDC/UPC/Catalog)	Package Size	Lot # / Expiration Date
Cosopt Ophthalmic Solution	NDC 17478-605-10	10 mL bottle	426007, Exp. 04/2020 426008, Exp. 04/2020

Please email your completed form to 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:

Lot #	Quantity of Sealed Cases	Units per full case (12, 24, 40, etc.)	Quantity loose Each's (vials, bottles, etc.)