LONG GROVE
PHARMACEUTICALS

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May 20, 2024

IMPORTANT PRESCRIBING INFORMATION

Subject: Temporary Distribution of AK-FLUOR (fluorescein injection, USP) 10% and 25% with Akorn Label

Dear Healthcare Professional:

This letter is an update to the Dear Health Care Provider Letter dated October 11, 2023, stating that Long Grove Pharmaceuticals, LLC ("Long Grove Pharmaceuticals") is coordinating with the U.S. Food and Drug Administration (FDA) to address potential shortage concerns and to help ensure patients have access to an adequate supply of AK-FLUOR fluorescein injection, USP10% and 25% in the U.S. market.[1]

Long Grove Pharmaceuticals acquired FDA-approved AK-FLUOR from Akorn Operating Company LLC ("Akorn"). Before Long Grove Pharmaceuticals' acquisition, Akorn discontinued production of AK-FLUOR and closed its manufacturing site. Batches of AK-FLUOR manufactured before the facility closure were produced at an FDA-inspected Akorn facility. The information contained in this letter pertains only to the products listed below.

Effective immediately, Long Grove Pharmaceuticals will distribute the following, existing inventory manufactured by Akorn prior to closing to ensure continued access to fluorescein injection and mitigate any potential drug shortages:

[1] Fluorescein Sodium Injection was listed on FDA's Drug Shortage List from April 21, 2023 to December 5, 2023. Please see FDA's Drug Shortages Database for more information.

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Description	Strength	Package Description	NDC No	Lot No	Exp Date
AK-Fluor 25% Injection	EQ 500MG BASE/2ML (EQ 250MG BASE/ML)	12 sterile, single dose vials (2 mL each)	17478-0250-20	091202A	09/30/2024
AK-Fluor 25% Injection	EQ 500MG BASE/2ML (EQ 250MG BASE/ML)	12 sterile, single dose vials (2 mL each)	17478-0250-20	011023A	01/31/2025
AK-Fluor 10% Injection	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	12 sterile, single dose vials (5 mL each)	17478-0253-10	091072A	09/30/2024
AK-Fluor 10% Injection	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	12 sterile, single dose vials (5 mL each)	17478-0253-10	101052A	10/31/2024
AK-Fluor 10% Injection	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	12 sterile, single dose vials (5 mL each)	17478-0253-10	121122A	12/31/2024
AK-Fluor 10% Injection	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	12 sterile, single dose vials (5 mL each)	17478-0253-10	121362A	12/31/2024
AK-Fluor 10% Injection	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	12 sterile, single dose vials (5 mL each)	17478-0253-10	121212A*	12/31/2024

*** Lot 121212A, AK-Fluor 10% Injection was added based on Quality release and approval.**

Packaging Information:

The vial and carton labels will display the Akorn NDC number and Akorn name under the "Distributed By" section. It is important to note that the above batches will be distributed by Long Grove Pharmaceuticals under the Akorn NDC number.

The barcode may not register accurately on the U.S. scanning systems. Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

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AK-FLUOR Injection is available only by prescription in the U.S. Please refer to the package insert of the FDA-approved Akorn's AK-FLUOR Injection for full prescribing information.

Please ensure that your staff and others in your institution who may be involved in the administration of AK-FLUOR Injection receive a copy of this letter, review the information, and maintain a copy of this letter.

Adverse Event Reporting:

The prescribing information includes Akorn's toll-free adverse event number. It offers an option to route AK-FLUOR-related calls to Long Grove Pharmaceuticals.

For medical information inquiries or reporting adverse events linked to AK-FLUOR Injection, healthcare providers should reach out to Long Grove Pharmaceuticals at 1-855-642-2594 or via email at lgrove.pvg@lambda-cro.com. You can also access this information at www.longgrovepharma.com/customer-service.

To report adverse events or quality issues related to this product, you can contact the FDA's MedWatch Adverse Event Reporting Program through the following methods:

- **Online**: Complete and submit the report at www.fda.gov/medwatch/report.htm.
- **Regular Mail or Fax**: Download the reporting form at www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting and send it via regular mail to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178 (1800-332-0178).
- **Phone**: Alternatively, you can call 1-800-332-1088 to request a reporting form, complete it, and return it to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178 (1-800-332-0178).

To place an order or inquire about our products, please reach out to Long Grove Pharmaceuticals Customer Service at longgrovecs@cordlogisitics.com or call 1-833-268-5559. You can also find this information at www.longgrovepharma.com/customer-service.

For any questions about this letter, please don't hesitate to contact Long Grove Pharmaceuticals Customer Service at 1-833-268-5559 or via email at longgrovecs@cordlogistics.com. We're here to assist and provide any necessary information about our product.

Sincerely,

DocuSigned by:
Peter Karas
085CF50C919341E...

Peter Karas
Chief Commercial Officer
Long Grove Pharmaceuticals, LLC