EPIOXA CROSS-LINKING- riboflavin 5-phosphate ophthalmic
Glaukos Corporation

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPIOXA™ HD and EPIOXA™ safely and effectively. See full prescribing information for EPIOXA HD and EPIOXA.

EPIOXA HD (riboflavin 5'-phosphate ophthalmic solution) 0.239%, for topical ophthalmic use
EPIOXA (riboflavin 5'-phosphate ophthalmic solution) 0.177%, for topical ophthalmic use
For use with the O_2n™ System and Boost Goggles®
Initial U.S. Approval: 2016

INDICATIONS AND USAGE

EPIOXA HD and EPIOXA are photoenhancers indicated for use in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O_2n System and the Boost Goggles (1).

DOSAGE AND ADMINISTRATION

- Apply topical anesthetic and insert a lid speculum (2).
- Using a cellulose spear sponge soaked with EPIOXA HD, remove the mucin layer from the corneal surface without debriding the corneal epithelium (epithelium-on) by swiping the sponge 4 to 10 times horizontally and vertically (2).
- Apply two drops of EPIOXA HD topically on the eye every 60 seconds for 4 minutes (STEP 1), followed by two drops of EPIOXA topically on the eye every 30 seconds for 6 minutes (STEP 2) (2).
- Gently rinse the corneal surface with approximately 5 mL of balanced salt solution (BSS) (2).
- Perform ultrasound pachymetry. If corneal thickness is less than 325 microns, irradiation should not be performed (2).
- Apply the Boost Goggles and turn on the oxygen flow. Refer to the *Boost Goggles User Guide* (2).
- Center the optical head of the O_2n System over the cornea and irradiate the eye as per the instructions in the *O_2n System Operator's Manual*. The O_2n System automatically delivers irradiation to the eye for 11 minutes 6 seconds at 30 mW/cm^2 with an on/off cycle of 1 second UV-A on/ 1 second UV-A off at a wavelength of 365 nm (2).
- Instill BSS on the cornea every 2 minutes, or more frequently as needed, to maintain corneal hydration during UV-A irradiation (2).
- When the UV-A irradiation has stopped, shut off the oxygen flow and remove the Boost Goggles and lid speculum (2).
- Apply a bandage contact lens (2).

DOSAGE FORMS AND STRENGTHS

- Ophthalmic solution: EPIOXA HD 0.239% in a single-dose glass syringe (3.1)
- Ophthalmic solution: EPIOXA 0.177% in a single-dose glass syringe (3.2)

CONTRAINDICATIONS

- Hypersensitivity (4.1)
- Aphakic and pseudophakic patients without a UV-blocking intraocular lens (4.2)

WARNINGS AND PRECAUTIONS

Herpetic keratitis: Use with caution in patients with a history of herpetic keratitis due to the potential for reactivation (5).

ADVERSE REACTIONS

The most common adverse reaction was conjunctival hyperaemia (31%). Other adverse reactions, occurring in 5% to 25% of eyes included: corneal opacity (haze), photophobia, punctate keratitis, eye pain, eye irritation, increased lacrimation, corneal epithelium defect, eyelid oedema, corneal striae, visual acuity reduced, dry eye, and anterior chamber flare (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact GLAUKOS CORPORATION at 1-888-404-1644 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

EPIOXA HD and EPIOXA are indicated in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O_2n System and the Boost Goggles.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

EPIOXA HD and EPIOXA are for topical ophthalmic use. **NOT** for injection or intraocular use.

EPIOXA HD and EPIOXA are supplied in single-dose syringes. Discard opened syringes after use.

EPIOXA HD and EPIOXA are for use with the O_2n System and Boost Goggles only.

Refer to the *O_2n System Operator's Manual* and *Boost Goggles User Guide* for device instructions.

2.2 Recommended Dosage and Administration Instructions

Apply topical anesthetic and insert a lid speculum.

Using a cellulose spear sponge soaked with EPIOXA HD, remove the mucin layer from the corneal surface without debriding the corneal epithelium (epithelium-on) by swiping the sponge 4 to 10 times horizontally and vertically.

Apply two drops of EPIOXA HD topically on the eye every 60 seconds for 4 minutes (STEP 1), followed by two drops of EPIOXA topically on the eye every 30 seconds for 6 minutes (STEP 2).

Gently rinse the corneal surface with approximately 5 mL of balanced salt solution (BSS).

Perform ultrasound pachymetry. If corneal thickness is less than 325 microns, irradiation should not be performed.

Apply the Boost Goggles and turn on the oxygen flow as per the instructions in the *Boost Goggles User Guide*.

Center the optical head of the O_2n System over the cornea and irradiate the eye as per the instructions in the *O_2n System Operator's Manual*. The O_2n System automatically delivers irradiation to the eye for 11 minutes 6 seconds at 30 mW/cm^2 with an on/off cycle of 1 second UV-A on/1 second UV-A off at a wavelength of 365 nm.

Instill BSS on the cornea every 2 minutes, or more frequently as needed, to maintain corneal hydration during UV-A irradiation.

When the UV-A irradiation has stopped, shut off the oxygen flow, and remove the Boost Goggles and lid speculum.

Apply a bandage contact lens.

3 DOSAGE FORMS AND STRENGTHS

3.1 EPIOXA HD

Ophthalmic solution: 0.239% (2.39 mg/mL) of riboflavin 5'-phosphate in a clear, yellow, solution in a single-dose glass syringe.

3.2 EPIOXA

Ophthalmic solution: 0.177% (1.77 mg/mL) of riboflavin 5'-phosphate in a clear, yellow, solution in a single-dose glass syringe.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

EPIOXA HD and EPIOXA are contraindicated in patients with known hypersensitivity to benzalkonium chloride or any ingredients in EPIOXA HD and EPIOXA.

4.2 Aphakic and Pseudophakic Patients

Epithelium-on corneal collagen cross-linking is contraindicated in aphakic patients and pseudophakic patients without a UV-blocking intraocular lens.

5 WARNINGS AND PRECAUTIONS

5.1 Herpetic Keratitis

Corneal collagen cross-linking should be used with caution in patients with a history of herpetic keratitis due to the potential for reactivation of herpes keratitis.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

Herpetic keratitis *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of EPIOXA HD and EPIOXA in the epithelium-on corneal collagen cross-linking procedure with UV-A irradiation and supplemental oxygen was evaluated in two randomized, parallel-group, sham procedure/vehicle-controlled trials. Study eyes were randomized in a 2:1 treatment allocation to receive corneal collagen cross-linking (CXL) or sham procedure/vehicle control at the baseline visit. In both trials, CXL-treated eyes were followed for 12 months.

Safety data were obtained from a total of 389 CXL-treated eyes.

The most commonly reported adverse reaction in CXL-treated eyes was conjunctival hyperaemia (31%). Other adverse reactions occurring in 5% to 25% of CXL-treated eyes included: corneal opacity (haze), photophobia, punctate keratitis, eye pain, eye irritation, lacrimation increased, corneal epithelium defect, eyelid oedema, corneal striae, visual acuity reduced, dry eye, and anterior chamber flare.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Animal development and reproduction studies have not been conducted with EPIOXA HD and EPIOXA with the O_2n System and Boost Goggles. Since it is not known whether the epithelium-on corneal collagen cross-linking procedure can cause fetal harm or affect reproduction capacity, it should not be performed on pregnant women.

8.2 Lactation

Risk Summary

There are no data on the presence of EPIOXA HD or EPIOXA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for the EPIOXA HD and EPIOXA epithelium-on corneal collagen cross-linking procedure and any potential adverse effects on the breastfed child from the EPIOXA HD and EPIOXA epithelium-on corneal collagen cross-linking procedure or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of EPIOXA HD and EPIOXA for the treatment of keratoconus have been established in pediatric patients aged 13 years and older.

8.5 Geriatric Use

No patients enrolled in the clinical trials were 65 years of age or older.

11 DESCRIPTION

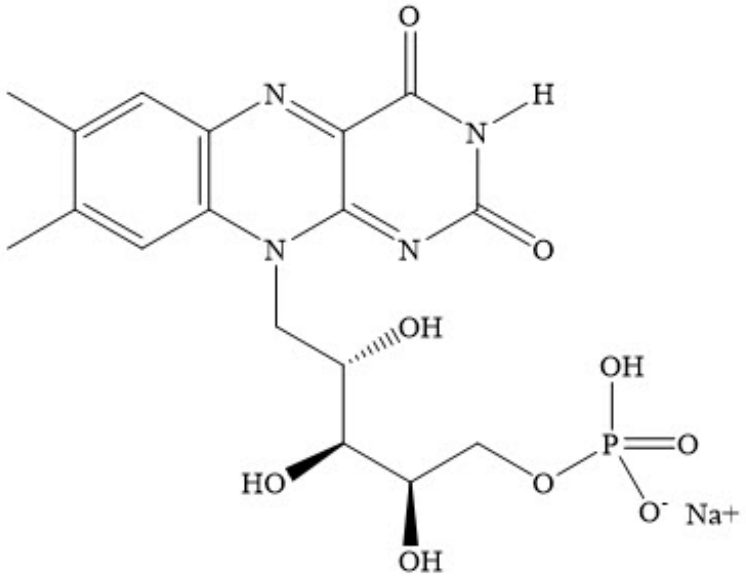
EPIOXA HD (riboflavin 5'-phosphate ophthalmic solution) 0.239% and EPIOXA (riboflavin 5'-phosphate ophthalmic solution) 0.177% contain riboflavin 5'-phosphate, a photoenhancer, for topical ophthalmic use.

EPIOXA HD 0.239% is a clear, yellow, sterile buffered solution containing 2.39 mg/mL riboflavin 5'-phosphate. The pH of the solution is 6.7 to 7.7 and the osmolality is 200 mOsm/kg to 260 mOsm/kg. Each mL of solution contains 2.50 mg of riboflavin 5'-phosphate sodium (equivalent to 1.97 mg/mL riboflavin). Riboflavin 5'-phosphate sodium is a mixture of the sodium salts of riboflavin, riboflavin monophosphates, and riboflavin diphosphates. The inactive ingredients are hydroxypropyl methylcellulose, sodium chloride, dibasic sodium phosphate dihydrate, edetate disodium dihydrate, tromethamine, monobasic sodium phosphate dihydrate, benzalkonium chloride, and water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

EPIOXA 0.177% is a clear, yellow, sterile buffered solution containing 1.77 mg/mL riboflavin 5'-phosphate. The pH of the solution is 6.5 to 7.5 and the osmolality is 330 mOsm/kg to 400 mOsm/kg. Each mL of solution contains 1.85 mg of riboflavin 5'-phosphate sodium (equivalent to 1.46 mg/mL riboflavin). Riboflavin 5'-phosphate sodium is a mixture of the sodium salts of riboflavin, riboflavin monophosphates, and riboflavin

diphosphates. The inactive ingredients are sodium chloride, dibasic sodium phosphate dihydrate, tromethamine, monobasic sodium phosphate dihydrate, and water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

The molecular formula for riboflavin 5'-phosphate sodium (Vitamin B2) is $C_{17}H_{20}N_4NaO_9P$ with a molecular weight of 478.33 g/mol.



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Riboflavin 5'-phosphate sodium (Vitamin B2) is the precursor of two coenzymes, flavin adenine dinucleotide and flavin mononucleotide, which catalyze oxidation/reduction reactions involved in a number of metabolic pathways.

Under the conditions used for corneal collagen cross-linking, riboflavin 5'-phosphate functions as a photoenhancer and generates singlet oxygen which is responsible for the cross-linking.

12.2 Pharmacodynamics

The pharmacodynamics of EPIOXA HD and EPIOXA have not been characterized.

12.3 Pharmacokinetics

The pharmacokinetics of EPIOXA HD and EPIOXA have not been characterized.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity

Animal studies have not been conducted to determine the carcinogenic potential of photoexcited riboflavin.

Mutagenesis

Photoexcited riboflavin has been shown to be genotoxic in the Ames Salmonella reverse mutation assay and in the SOS/umu test system.

The genotoxicity of riboflavin, in the absence of photoexcitation has been examined in vitro in bacterial reverse mutation assays, sister chromatid exchange assay, chromosomal aberration assays and in vivo in a mouse micronucleus study. The overall weight of evidence indicates that riboflavin, in the absence of photoexcitation, is not genotoxic.

Impairment of Fertility

Animal studies to determine the effects of the EPIOXA HD and EPIOXA epithelium-on corneal collagen cross-linking procedure on fertility were not conducted.

14 CLINICAL STUDIES

Two prospective, randomized, parallel-group, sham procedure/vehicle-controlled trials (Study 1 [NCT03442751] and Study 2 [NCT05759559]) were conducted to evaluate the safety and efficacy of epithelium-on corneal collagen cross-linking (CXL) using riboflavin 5'-phosphate ophthalmic solutions with UV-A irradiation and supplemental oxygen in patients with keratoconus.

In both trials, eligible eyes were randomized to receive CXL treatment or sham procedure/vehicle control in a 2:1 treatment allocation at the baseline visit. Aphakic patients and pseudophakic patients without a UV-blocking intraocular lens were excluded. Both eyes of a patient could be enrolled in the trial; however, one eye was treated first, and the second eye was treated between 1 week and 3 months after the first eye. Eyes were evaluated at 1 day, 3 days, 1 week, and 1, 3, 6, and 12 months post-treatment.

In Study 1, eyes randomized to sham procedure/vehicle control were permitted to receive CXL treatment after month 6 and were followed an additional 6 months. The primary efficacy endpoint was at month 6 post-treatment and the secondary efficacy endpoint was at month 12 post-treatment. In Study 2, the primary efficacy endpoint was at month 12 post-treatment and the secondary efficacy endpoint was at month 6 post-treatment.

In Study 1, a total of 280 eyes of 201 patients were randomized into the trial, of which 279 eyes were treated: 189 eyes received CXL treatment and 90 eyes initially received sham procedure/vehicle control. A statistically significant treatment effect was demonstrated at month 6, based on the difference in change from baseline in maximum corneal curvature (K_{max}) between the CXL treatment group and sham procedure/vehicle control group (**Table 1**).

Table 1. Study 1: Mean Baseline K_{max} (D) and Change from Baseline K_{max} (D)

Visit	CXL Treatment (N=189)	Sham Procedure/ Vehicle Control (N=90)	Treatment Difference (95% CI) P-value
Baseline*	59.4 (9.1)	59.3 (9.1)	

Month 6†	-0.3 (-0.6, -0.0)	0.6 (0.2, 1.1)	-1.0 (-1.5, -0.4) $P<0.01$
Month 12‡	-0.4 (-0.7, -0.2)	0.7 (0.3, 1.1)	-1.1 (-1.6, -0.6) $P<0.01$

Randomized eyes that received study treatment

* Mean (standard deviation) K_{max}
† LS Mean change from baseline and corresponding 95% CIs obtained from a RMMM ANCOVA model with treatment as a factor and the baseline K_{max} value and baseline keratoconus severity as covariates. Missing post-baseline K_{max} data were handled by multiple imputation procedure for month 6.
‡ Missing post-baseline K_{max} data were handled by last observation carried forward method for month 12 in Sham Procedure/Vehicle Control eyes that received CXL treatment after month 6.

In a subgroup analysis of patients in this trial at month 6, younger patients (< 29 years) experienced a treatment effect of -2.0 D, as a combination of improvement in the CXL treatment arm (-0.7 D) and deterioration in the sham procedure/vehicle control arm (1.3 D). Older patients (≥ 29 years) did not experience improvement at month 6 in either arm.

In Study 2, a total of 312 eyes of 208 patients were randomized into the trial, of which 312 eyes were treated: 200 eyes received CXL treatment and 112 eyes received sham procedure/vehicle control. A statistically significant treatment effect was demonstrated at month 12, based on the difference in change from baseline in K_{max} between the CXL treatment group and sham procedure/vehicle control group (**Table 2**).

Table 2. Study 2: Mean Baseline K_{max} (D) and Change from Baseline K_{max} (D)

Visit	CXL Treatment (N=200)	Sham Procedure/ Vehicle Control (N=112)	Treatment Difference (95% CI) P-Value
Baseline*	58.0 (8.0)	58.1 (8.6)	
Month 6†	-0.4 (-0.6, -0.2)	0.1 (-0.1, 0.4)	-0.6 (-0.9, -0.2) $P<0.01$
Month 12†	-0.5 (-0.7, -0.3)	0.4 (0.1, 0.8)	-1.0 (-1.3, -0.6) $P<0.01$

Randomized eyes that received study treatment

* Mean (standard deviation) K_{max}
† LS Mean change from baseline and corresponding 95% CIs obtained from a RMMM ANCOVA model with treatment as a factor and the baseline K_{max} value and baseline keratoconus severity and age stratum as covariates. Missing post-baseline K_{max} data were handled by multiple imputation procedure.

In a subgroup analysis of patients in this trial at month 12, younger patients (< 30 years) experienced a treatment effect of -1.1 D, as a combination of improvement in the CXL treatment arm (-0.5 D) and deterioration in the sham procedure/vehicle control arm (0.5 D). Older patients (≥ 30 years) in the CXL treatment arm experienced comparable improvement (-0.6 D) as younger patients (-0.5 D); however, in the sham procedure/vehicle control arm, older patients (-0.0 D) did not deteriorate as much as younger patients (0.5 D).

16 HOW SUPPLIED/STORAGE AND HANDLING

EPIOXA HD (riboflavin 5'-phosphate ophthalmic solution) 0.239%, and EPIOXA (riboflavin

5'-phosphate ophthalmic solution) 0.177%, are clear, yellow, ophthalmic solutions. EPIOXA HD and EPIOXA are co-packaged in an Epithelium-on Cross-linking Kit (NDC 25357-024-01) containing:

- One single-dose glass syringe containing 2 mL of EPIOXA HD 0.239% packaged in a foil pouch.
- One single-dose glass syringe containing 2 mL of EPIOXA 0.177% packaged in a foil pouch.

Store kit **refrigerated** at 2°C to 8°C (36°F to 46°F). Do not freeze. Minimize exposure of the syringes to light once removed from their protective packaging.

For topical ophthalmic use. Single-dose only. Discard syringes after use.

EPIOXA HD and EPIOXA are for use only with the O_2n System, the single-use O_2n System Treatment Activation Card, and Boost Goggles.

17 PATIENT COUNSELING INFORMATION

- Advise patients that there may be discomfort in the treated eye and that sunglasses may help with light sensitivity.
- Instruct patients that they should contact their physician immediately if they experience severe pain in the treated eye or any sudden decrease in their vision.

EPIOXA HD, EPIOXA, the O_2n System, and Boost Goggles are marketed by:

Avedro, a Glaukos company
30 North Avenue
Burlington, MA 01803
USA

Issued 10/2025
ML-000159 Rev 1

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 25357-024-01

Rx Only

Epithelium-on Cross-linking Kit

Epioxa™ HD
(riboflavin 5'- phosphate ophthalmic solution) 0.239%

co-packaged with

Epioxa™
(riboflavin 5'- phosphate ophthalmic solution) 0.177%

For Topical Ophthalmic Use Only

Use only with O_2n™ System, O_2n™ System Single-use Treatment Activation Card, and Boost Goggles®.
Do NOT use if damaged. Single-dose. Discard unused portion.

GLAUKOS®

NDC 25357-024-01

Rx Only

Epithelium-on Cross-linking Kit

Epioxa™ HD

(riboflavin 5'- phosphate ophthalmic solution) **0.239%**

co-packaged with

Epioxa™

(riboflavin 5'- phosphate ophthalmic solution) **0.177%**

For Topical Ophthalmic Use Only

Use only with O2n™ System, O2n™ System Single-use Treatment Activation Card, and Boost Goggles®.
Do NOT use if damaged. Single-dose. Discard unused portion.

GLAUKOS

Manufactured for: Avedro, a Glaukos Company
30 North Avenue, Burlington MA 01803 USA • usaorders@glaukos.com

Storage:
Store at 2°C to 8°C (36°F to 46°F).
Do not freeze. Protect from light.
See Full Prescribing Information.

Epithelium-on Cross-linking Kit Step 2:

1 prefilled Epioxa™ syringe

Each pouch contains 2 mL of Epioxa™ 0.177% ophthalmic solution in a glass syringe.

Active ingredient: 1.77 mg/mL riboflavin 5'-phosphate

Each 1 mL of solution contains 1.85 mg of riboflavin 5'-phosphate sodium (equivalent to 1.46 mg of riboflavin).

Inactive ingredients: sodium chloride, dibasic sodium phosphate dihydrate, tromethamine, monobasic sodium phosphate dihydrate, and water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

Epithelium-on Cross-linking Kit Step 1:

1 prefilled Epioxa™ HD syringe

Each pouch contains 2 mL of Epioxa™ HD 0.239% ophthalmic solution in a glass syringe.

Active ingredient: 2.39 mg/mL riboflavin 5'-phosphate

Each 1 mL of solution contains 2.50 mg of riboflavin 5'-phosphate sodium (equivalent to 1.97 mg of riboflavin).

Inactive ingredients: hydroxypropyl methylcellulose, sodium chloride, dibasic sodium phosphate dihydrate, edetate disodium dihydrate, tromethamine, monobasic sodium phosphate dihydrate, benzalkonium chloride, and water for injection. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

LBL-000934, Rev 2

NDC 25357-024-01

STEP 2

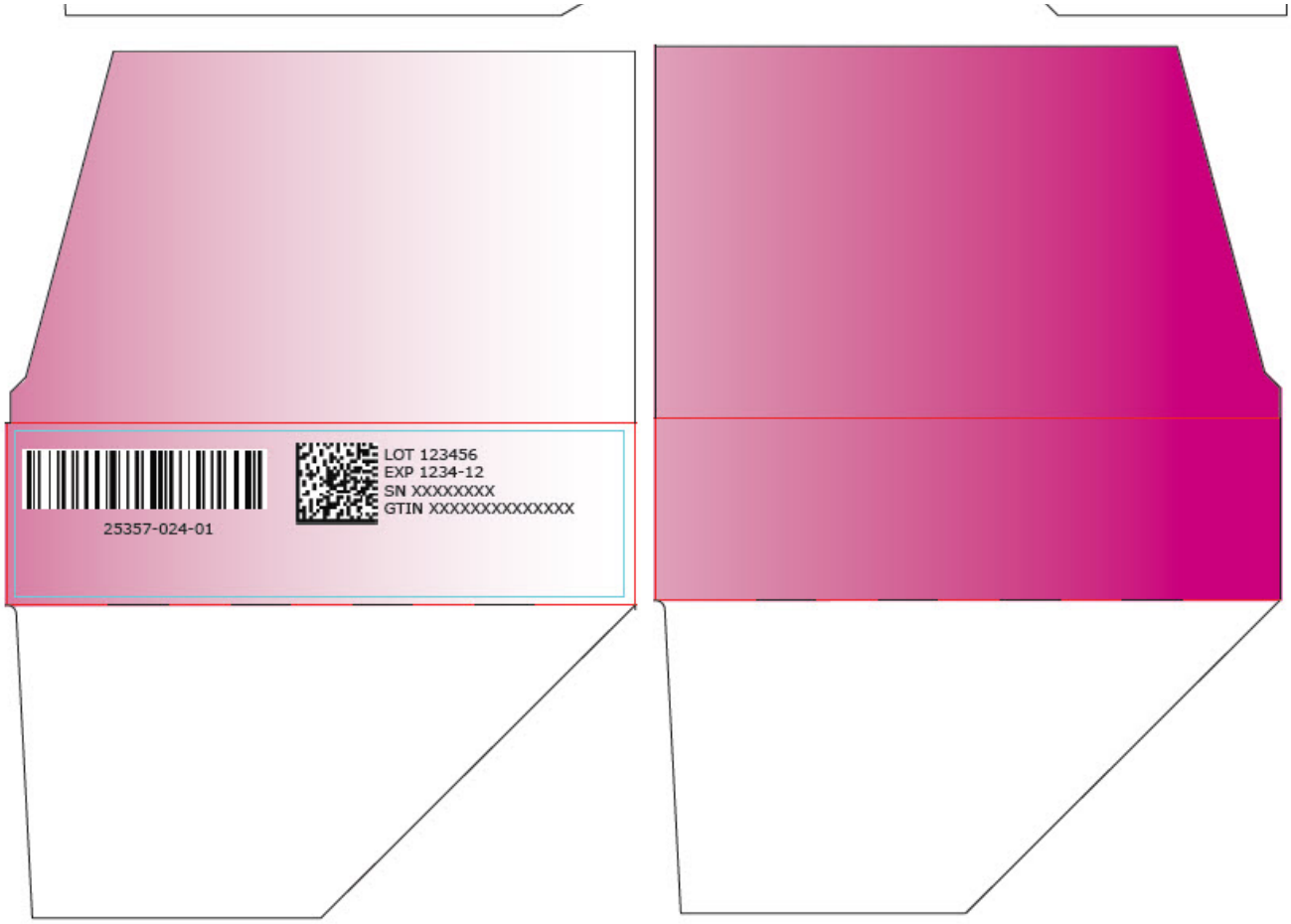
Epioxa™

(riboflavin 5'- phosphate ophthalmic solution) **0.177%**

STEP 1

Epioxa™HD

(riboflavin 5'- phosphate ophthalmic solution) **0.239%**



EPIOXA CROSS-LINKING

riboflavin 5-phosphate ophthalmic kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:25357-024

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:25357-024-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	01/16/2026	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 SYRINGE, GLASS	2 mL
Part 2	1 SYRINGE, GLASS	2 mL

Part 1 of 2

EPIOXA HD

riboflavin 5-phosphate solution/ drops

Product Information	
Item Code (Source)	NDC:25357-026
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RIBOFLAVIN 5'-PHOSPHATE (UNII: 7N464URE7E) (RIBOFLAVIN 5'-PHOSPHATE - UNII:7N464URE7E)	RIBOFLAVIN 5'-PHOSPHATE	2.39 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:25357-026-01	1 in 1 POUCH		
1		2 mL in 1 SYRINGE, GLASS; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA219910	01/16/2026	

Part 2 of 2

EPIOXA

riboflavin 5-phosphate solution/ drops

Product Information	
Item Code (Source)	NDC:25357-027
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RIBOFLAVIN 5'-PHOSPHATE (UNII: 7N464URE7E) (RIBOFLAVIN 5'-PHOSPHATE - UNII:7N464URE7E)	RIBOFLAVIN 5'-PHOSPHATE	1.77 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25357-027-01	1 in 1 POUCH		
1		2 mL in 1 SYRINGE, GLASS; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA219910	01/16/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA219910	01/16/2026	

Labeler - Glaukos Corporation (012835406)

Revised: 11/2025 Glaukos Corporation