LATANOPROST - latanoprost solution
Rising Pharma Holdings, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LATANOPROST OPHTHALMIC SOLUTION safely and effectively. See full prescribing information for LATANOPROST OPHTHALMIC SOLUTION .
LATANOPROST Ophthalmic Solution 0.005%, for topical ophthalmic use
Initial U.S. Approval:1996

INDICATIONS AND USAGE

Latanoprost Ophthalmic Solution is a prostaglandin $F_{2\alpha}$ analogue indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. (1)

DOSAGE AND ADMINISTRATION

One drop in the affected eye(s) once daily in the evening. (2)

DOSAGE FORMS AND STRENGTHS

Ophthalmic solution containing 50 mcg/mL latanoprost (0.005%). (3)

CONTRAINDICATIONS

Known hypersensitivity to latanoprost, benzalkonium chloride, or any other ingredients in this product. (4)

WARNINGS AND PRECAUTIONS

- Pigmentation: pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation likely to be permanent. (5.1)
- Eyelash Changes: gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible. (5.2**)**

ADVERSE REACTIONS

Most common adverse reactions (5-15%) from clinical trials are blurred vision, burning and stinging, conjunctival hyperemia, foreign body sensation, itching, increased pigmentation of the iris and punctate keratitis. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Rising Pharma Holdings, Inc at 1-844-874-7464 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.* (6)
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 8/2024

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Latanoprost Ophthalmic Solution is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

2 DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening. If one dose is missed, treatment should continue with the next dose as normal.

The dosage of Latanoprost Ophthalmic Solution should not exceed once daily; the combined use of two or more prostaglandins, or prostaglandin analogs including Latanoprost Ophthalmic Solution is not recommended. It has been shown that administration of these prostaglandin drug products more than once daily may decrease the IOP lowering effect or cause paradoxical elevations in IOP.

Reduction of the IOP starts approximately 3 to 4 hours after administration and the maximum effect is reached after 8 to 12 hours.

Latanoprost Ophthalmic Solution may be used concomitantly with other topical ophthalmic drug products to lower IOP. *In vitro* studies have shown that precipitation occurs when eye drops containing thimerosal are mixed with Latanoprost Ophthalmic Solution. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart. Contact lenses should be removed prior to

the administration of Latanoprost Ophthalmic Solution, and may be reinserted 15 minutes after administration

3 DOSAGE FORMS AND STRENGTHS

Ophthalmic solution containing 50 mcg/mL (0.005 %) latanoprost.

4 CONTRAINDICATIONS

Known hypersensitivity to latanoprost, benzalkonium chloride, or any other ingredients in this product.

5 WARNINGS AND PRECAUTIONS

5.1 Pigmentation

Latanoprost Ophthalmic Solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as latanoprost is administered.

The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of latanoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. Beyond 5 years the effects of increased pigmentation are not known [*see Clinical Studies (14.2)*].

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with Latanoprost Ophthalmic Solution can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

5.2 Eyelash Changes

Latanoprost Ophthalmic Solution may gradually change eyelashes and vellus hair in the treated eye; these changes include increased length, thickness, pigmentation, the number of lashes or hairs, and misdirected growth of eyelashes. Eyelash changes are usually reversible upon discontinuation of treatment.

5.3 Intraocular Inflammation

Latanoprost Ophthalmic Solution should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation because inflammation may be exacerbated.

5.4 Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with Latanoprost Ophthalmic Solution. Latanoprost Ophthalmic Solution should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

5.5 Herpetic Keratitis

Reactivation of Herpes Simplex keratitis has been reported during treatment with Latanoprost Ophthalmic Solution. Latanoprost Ophthalmic Solution should be used with caution in patients with a history of herpetic keratitis. Latanoprost Ophthalmic Solution should be avoided in cases of active herpes simplex keratitis because inflammation may be exacerbated.

5.6 Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

5.7 Contact Lens Use

Latanoprost Ophthalmic Solution contains benzalkonium chloride, which may be absorbed by contact lenses. Contact lenses should be removed prior to the administration of Latanoprost Ophthalmic Solution, and may be reinserted 15 minutes after administration.

6 ADVERSE REACTIONS

The following adverse reactions were reported in post marketing experience and are discussed in greater detail in other sections of the label:

- Iris pigmentation changes [*see Warnings and Precautions (5.1)*]
- Eyelid skin darkening [*see Warnings and Precautions (5.1)*]
- Eyelash changes (increased length, thickness, pigmentation, and number of lashes) [*see Warnings and Precautions (5.2)*]
- Intraocular inflammation (iritis/uveitis) [*see Warnings and Precautions (5.3)*]
- Macular edema, including cystoid macular edema [*see Warnings and Precautions (5.4)*]

6.1 Clinical Trials Experience

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

Latanoprost Ophthalmic Solution was studied in three multicenter, randomized, controlled clinical trials. Patients received 50 mcg/mL Latanoprost Ophthalmic Solution once daily or 5 mg/mL active-comparator (timolol) twice daily. The patient population studied had a mean age of 65±10 years. Seven percent of patients withdrew before the 6-month endpoint.

Table 1: Ocular Adverse Reactions and Ocular Signs/Symptoms Reported by 5–15% of Patients Receiving Latanoprost

Symptom/Finding	Adverse Reactions (incidence (%))	
	Latanoprost (n=460)	Timolol (n=369)
Foreign body sensation	13	8
Punctate keratitis	10	9
Stinging	9	12
Conjunctival hyperemia	8	3
Blurred vision	8	8
Itching	8	8
Burning	7	8
Increased pigmentation of the Iris	7	0

Less than 1% of the patients treated with Latanoprost Ophthalmic Solution required discontinuation of therapy because of intolerance to conjunctival hyperemia.

Table 2: Adverse Reactions That Were Reported in 1–5% of Patients Receiving Latanoprost

	Adverse Reactions (incidence (%))	
	Latanoprost (n=460)	Timolol (n=369)
Ocular Events/Signs and Symptoms		
Excessive tearing	4	6
Eyelid discomfort/pain	4	2
Dry eye	3	3
Eye pain	3	3
Eyelid margin crusting	3	3
Erythema of the eyeli	3	2
Photophobia	2	1
Eyelid edema	1	3
Blepharitis	1	3
Systemic Events		
Upper respiratory tract infection/nasopharyngitis/influenza	3	3
Myalgia / arthralgia/back pain	1	0.5
Rash/allergic skin reaction	1	0.3

6.2 Postmarketing Experience

The following reactions have been identified during post marketing use of Latanoprost

Ophthalmic Solution in clinical practice. Because they are reported voluntarily from a population of unknown size, it is not always possible to reliably estimates their frequency or establish a causal relationship to drug exposure. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to Latanoprost Ophthalmic Solution, or a combination of these factors, include:

Nervous System disorders: Dizziness, headache, toxic epidermal necrolysis

Eye Disorders: Eyelash and vellus hair changes of the eyelid (increased length, thickness, pigmentation, and number of eyelashes); keratitis; corneal edema and erosions; intraocular inflammation (iritis/uveitis); macular edema, including cystoid macular edema; trichiasis; periorbital and lid changes resulting in deepening of the eyelid sulcus; iris cyst; eyelid skin darkening ; localized skin reaction on the eyelids; conjunctivitis; pseudopemphigoid of the ocular conjunctiva.

Respiratory, Thoracic and Mediastinal Disorders: Asthma and exacerbation of asthma; dyspnea

Gastrointestinal Disorders: Nausea; vomiting

Skin and Subcutaneous Tissue Disorders: Pruritus

Infections and Infestations: Herpes keratitis

Cardiac Disorders: Angina; palpitation; angina unstable

General Disorders and Administration Site Conditions: Chest pain

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of Latanoprost Ophthalmic Solution administration in pregnant women to inform drug-associated risks.

In animal reproduction studies, intravenous (IV) administration of latanoprost to pregnant rabbits and rats throughout the period of organogenesis produced malformations, embryofetal lethality and spontaneous abortion at clinically relevant doses *[see Data]*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20% of clinically recognized pregnancies.

Data

Animal Data

Embryofetal studies were conducted in pregnant rabbits administered latanoprost daily by IV injection on gestation days 6 through 18, to target the period of organogenesis. A no observed adverse effect level (NOAEL) was not established for rabbit developmental toxicity. Post-implantation loss due to late resorption was shown as doses ≥0.2 mcg/kg/day (equivalent to 1.3 times the maximum recommended human ophthalmic

dose [RHOD], on a mg/m^2 basis, assuming 100% absorption). Spina bifida and abortion occurred at 5 mcg/kg/day (equivalent to 32 times the maximum RHOD). Total litter loss due to early resorption was observed at doses ≥50 mcg/kg/day (324 times the maximum RHOD). Transient signs of maternal toxicity were observed after IV dosing (increased breathing, muscle tremors, slight motor incoordination) at 300 mcg/kg/day (1946 times the maximum RHOD). No maternal toxicity was observed at doses up to 50 mcg/kg/day.

Embryofetal studies were conducted in pregnant rats administered latanoprost daily by IV injection on gestation days 6 through 15, to target the period of organogenesis. A NOAEL for rat developmental toxicity was not established. Cleft palate was observed at 1 mcg/kg (equivalent to 3.2 times the maximum RHOD, on a mg/m^2 basis, assuming 100% absorption). Brain porencephalic cyst(s) were observed ≥50 mcg/kg (162 times the maximum RHOD). Skeletal anomalies were observed at 250 mcg/kg (811 times the maximum RHOD). No maternal toxicity was detectable at 250 mcg/kg/day.

Prenatal and postnatal development was assessed in rats. Pregnant rats were administered latanoprost daily by IV injection from gestation day 15, through delivery, until weaning (lactation Day 21). No adverse effects on rat offspring were observed at doses up to 10 mcg/kg/day (32 times the maximum RHOD, on a mg/m^2 basis, assuming 100% absorption). At 100 mcg/kg/day (324 times the maximum RHOD), maternal deaths and pup mortality occurred.

8.2 Lactation

Risk Summary

It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Latanoprost Ophthalmic Solution is administered to a nursing woman.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Latanoprost Ophthalmic Solution and any potential adverse effects on the breastfed child from Latanoprost Ophthalmic Solution.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

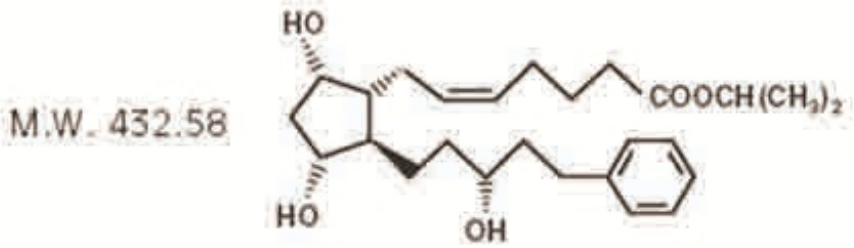
10 OVERDOSAGE

IV infusion of up to 3 mcg/kg of latanoprost in healthy volunteers produced mean plasma concentrations 200 times higher than during clinical treatment with Latanoprost Ophthalmic Solution and no adverse reactions were observed. IV dosages of 5.5 to 10 mcg/kg caused abdominal pain, dizziness, fatigue, hot flushes, nausea, and sweating.

If overdosage with Latanoprost Ophthalmic Solution occurs, treatment should be symptomatic.

11 DESCRIPTION

Latanoprost is a prostaglandin $F_{2\alpha}$ analogue. Its chemical name is isopropyl-(Z)-7[(1R,2R,3R,5S)3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl] cyclopentyl]-5-heptenoate. Its molecular formula is $C_{26}H_{40}O_5$ and its chemical structure is:



Latanoprost is a colorless to slightly yellow oil that is very soluble in acetonitrile and freely soluble in acetone, ethanol, ethyl acetate, isopropanol, methanol, and octanol. It is practically insoluble in water.

Latanoprost Ophthalmic Solution 0.005% is supplied as a sterile, isotonic, buffered aqueous solution of latanoprost with a pH of approximately 6.7 and an osmolality of approximately 267 mOsmol/kg. Each mL of Latanoprost Ophthalmic Solution contains 50 mcg of latanoprost. Benzalkonium chloride, 0.02% is added as a preservative. The inactive ingredients are: sodium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, and water for injection. One drop contains approximately 1.5 mcg of latanoprost.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Latanoprost is a prostaglandin $F_{2\alpha}$ analogue that is believed to reduce the IOP by increasing the outflow of aqueous humor. Studies in animals and man suggest that the main mechanism of action is increased uveoscleral outflow. Elevated IOP represents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss.

12.2 Pharmacodynamics

Reduction of the IOP in man starts about 3–4 hours after administration and maximum effect is reached after 8–12 hours. IOP reduction is present for at least 24 hours.

12.3 Pharmacokinetics

Absorption

Latanoprost is absorbed through the cornea where the isopropyl ester prodrug is hydrolyzed to the acid form to become biologically active.

Distribution

The distribution volume in humans is 0.16 ± 0.02 L/kg. The acid of latanoprost can be measured in aqueous humor during the first 4 hours, and in plasma only during the first hour after local administration. Studies in man indicate that the peak concentration in the aqueous humor is reached about two hours after topical administration.

Elimination

Metabolism

Latanoprost, an isopropyl ester prodrug, is hydrolyzed by esterases in the cornea to the biologically active acid. The active acid of latanoprost reaching the systemic circulation is primarily metabolized by the liver to the 1,2-dinor and 1,2,3,4-tetranor metabolites via fatty acid β-oxidation.

Excretion

The elimination of the acid of latanoprost from human plasma is rapid ($t_{1/2}$ = 17 min) after both IV and topical administration. Systemic clearance is approximately 7 mL/min/kg. Following hepatic β-oxidation, the metabolites are mainly eliminated via the kidneys. Approximately 88% and 98% of the administered dose are recovered in the urine after topical and IV dosing, respectively.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis Mutagenesis Impairment of Fertility

Caricnogenesis

Latanoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 170 mcg/kg/day (approximately 2800 times the recommended maximum human dose) for up to 20 and 24 months, respectively.

Mutagenesis

Latanoprost was not mutagenic in bacteria, in mouse lymphoma, or in mouse micronucleus tests. Chromosome aberrations were observed *in vitro* with human lymphocytes. Additional *in vitro* and *in vivo* studies on unscheduled DNA synthesis in rats were negative.

Impairment of Fertility

Latanoprost has not been found to have any effect on male or female fertility in rat studies at IV doses up to 250 mcg/kg/day (811 times the maximum RHOD, on a mg/m^2 basis, assuming 100% absorption).

14 CLINICAL STUDIES

14.1 Elevated Baseline IOP

Patients with mean baseline IOP of 24 – 25 mmHg who were treated for 6 months in multi-center, randomized, controlled trials demonstrated 6 – 8 mmHg reductions in IOP. This IOP reduction with Latanoprost Ophthalmic Solution 0.005% dosed once daily was equivalent to the effect of timolol 0.5% dosed twice daily.

14.2 Progression of Increased Iris Pigmentation

A 3-year open-label, prospective safety study with a 2-year extension phase was conducted to evaluate the progression of increased iris pigmentation with continuous use of Latanoprost Ophthalmic Solution once-daily as adjunctive therapy in 519 patients with open-angle glaucoma. The analysis was based on observed-cases population of the 380 patients who continued in the extension phase.

Results showed that the onset of noticeable increased iris pigmentation occurred within the first year of treatment for the majority of the patients who developed noticeable increased iris pigmentation. Patients continued to show signs of increasing iris pigmentation throughout the five years of the study. Observation of increased iris pigmentation did not affect the incidence, nature, or severity of adverse events (other than increased iris pigmentation) recorded in the study. IOP reduction was similar regardless of the development of increased iris pigmentation during the study.

16 HOW SUPPLIED/STORAGE AND HANDLING

Latanoprost Sterile Ophthalmic Solution is a clear, isotonic, buffered, preserved colorless solution of latanoprost 0.005% (50 mcg/mL).

It is supplied as a 2.5 mL solution filled in a 5 mL translucent low density polyethylene bottle with insert cap assembly comprising of a turquoise colored, high density polyethylene screw cap over a low density polyethylene nozzle with tamper evident Low density polyethylene dust cover sealing the bottle cap.

2.5 mL fill, 0.005% (50 mcg/mL) : Package of 1 bottle :NDC 64980-516-25

Storage: Protect from light. Store unopened bottle(s) under refrigeration at 2°C to 8°C (36°F to 46°F). During shipment to the patient, the bottle may be maintained at temperatures up to 40°C (104°F) for a period not exceeding 8 days. Once a bottle is opened for use, it may be stored at room temperature up to 25°C (77°F) for 6 weeks.

17 PATIENT COUNSELING INFORMATION

Potential for Pigmentation

Advise patients about the potential for increased brown pigmentation of the iris, which may be permanent. Inform patients about the possibility of eyelid skin darkening, which may be reversible after discontinuation of Latanoprost Ophthalmic Solution [*see Warnings and Precautions (5.1)*].

Potential for Eyelash Changes

Inform patients of the possibility of eyelash and vellus hair changes in the treated eye during treatment with Latanoprost Ophthalmic Solution. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Handling the Container

Instruct patients to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by

common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions [*see Warnings and Precautions (5.6)*].

When to Seek Physician Advice

Advise patients that if they develop an intercurrent ocular condition (e.g., trauma or infection) or have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of the multiple-dose container.

Use with Contact Lenses

Advise patients that Latanoprost Ophthalmic Solution contains benzalkonium chloride, which may be absorbed by contact lenses. Contact lenses should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of Latanoprost Ophthalmic Solution.

Use with Other Ophthalmic Drugs

Advise patients that if more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

If a Dose is Missed

Advise patients that if one dose is missed, treatment should continue with the next dose as normal.

Made in India by:

FDC Limited

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Revised: 07/2024

INSTRUCTIONS FOR USE

Latanoprost Ophthalmic Solution

Before using your latanoprost ophthalmic solution

Before using your latanoprost hydrochloride ophthalmic solution for the first time, be sure the dust cover seal is unbroken (See figure A)

Figure A

Step 1. Wash hands before each use.

Step 2. Snap off the dust cover by turning it clockwise to break the seal. See figure B

Figure B

Step 3. Pull off the dust cover see figure C

Figure C

Step 4.Unscrew the turquoise colored cap by turning in the counterclockwise direction. See figure D

Figure D

THE INSERT TIP IS DESIGNED TO DELIVER PREMEASURED DROP. THEREFORE, DO NOT ENLARGE THE HOLE OF THE INSERT TIP OR TAMPER WITH INSERT TIP.

Giving your Latanoprost Ophthalmic Solution

Step 5. Tilt your head back and pull the lower eyelid down slightly to form pocket between your eyelid and your eye. Dispense drops with gentle pressure. Do not touch your eye or eyelid with the dropper tip. See figure E.

Figure E

Step 6. If your doctor has told you to us Latanoprost Ophthalmic Solution in both eyes, repeat step 4 and step 5.

After using your Latanoprost Ophthalmic Solution

Step 7. Replace the cap after every use, tighten the cap on the nozzle. See figure F

Figure F

This Instruction for Use has been approved by U.S. Food and Drug Administration.

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East Brunswick, NJ 08816

Revised: 07/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Latanoprost Ophthalmic Solution

Sterile

0.005%

Rx Only

2.5 ml

Unvarnished area
Space for
2D barcode
as per DSCSA
requirement

2000015510

*Each mL contains:
latanoprost 50 mcg
Inactive Ingredients
sodium chloride, sodium dihydrogen phosphate, disodium hydrogen phosphate, benzalkonium chloride 0.2 mg added as a preservative.
water for injection

USUAL DOSAGE:
1 drop in the affected eye(s) in the evening.

Keep out of reach of children.
Not child resistant.

Store unopened bottle under refrigeration at 2° to 8°C (36° to 46°F).
Once a bottle is opened for use, it may be stored at room temperature up to 25°C (77°F) for 6 weeks. Protect from light.

MODE OF USE

Snap off the dust cover by turning it clockwise to break the seal

Pull off the dust cover

Unscrew the turquoise coloured cap

Dispense the drops with gentle pressure. Place back the turquoise coloured cap

Important information for Mail-Order Patients: Contact dispensing pharmacy if prescription is not received within 8 days of dispensing date.
SEE DATE ON PRESCRIPTION LABEL

During shipment to the patient, the bottle may be maintained at temperatures up to 40°C (104°F) for a period not exceeding 8 days.

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Manufactured by:
FDC Limited
B-8, MIDC Industrial Area,
Waluj, Aurangabad - 431 136,
Maharashtra, India.
Mfg. Lic. No. 1032

Revised: 07/2024

N 3 64980 51625 9

Rising® IIDC 64980-516-25

Latanoprost Ophthalmic Solution

0.005%

125 mcg/2.5 mL*

FOR USE IN THE EYES ONLY

STERILE

2.5 mL

Rx Only

Unvarnished area
for batch details

Important
information for
Mail-Order Patients:
SEE SIDE PANEL

LATANOPROST

latanoprost solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64980-516
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LATANOPROST (UNII: 6Z5B6HVF6O) (LATANOPROST ACID - UNII:EJ85341990)	LATANOPROST	50 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64980-516-25	1 in 1 CARTON	09/01/2016	
1		2.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202442	09/01/2016	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - FDC Limited (650078413)

Establishment

Name	Address	ID/FEI	Business Operations
FDC Limited		862267994	MANUFACTURE(64980-516) , ANALYSIS(64980-516)

Revised: 8/2024 Rising Pharma Holdings, Inc.