

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206185Orig1s000**

**LABELING**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use XELPROS 0.005% safely and effectively. See full prescribing information for XELPROS.

**XELPROS™ (latanoprost ophthalmic emulsion) 0.005%, for topical ophthalmic use**  
**Initial U.S. Approval: 1996**

-----**INDICATIONS AND USAGE**-----

XELPROS is a prostaglandin F<sub>2α</sub> analog indicated for 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 emulsion containing latanoprost 50 mcg/mL (0.005%). (3)

-----**CONTRAINDICATIONS**-----

Known hypersensitivity to latanoprost 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 ocular adverse reactions (incidence ≥5%) for XELPROS are: eye pain/stinging, ocular hyperemia, conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening. (6.1)

**To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

-----**DRUG INTERACTIONS**-----

Thimerosal: Precipitation may occur if drugs containing thimerosal are used concomitantly with XELPROS. If such drugs are used, they should be administered at least five (5) minutes apart. (7)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 09/2018

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

## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

XELPROS® (latanoprost ophthalmic emulsion) 0.005% 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 XELPROS should not exceed once daily; the combined use of two or more prostaglandins, or prostaglandin analogs including XELPROS is not recommended. It has been shown that administration of these prostaglandin drug products more than once daily may decrease the intraocular pressure (IOP) lowering effect or cause paradoxical elevations in IOP.

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

XELPROS may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. 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 XELPROS, and may be reinserted 15 minutes after administration.

### **3 DOSAGE FORMS AND STRENGTHS**

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

### **4 CONTRAINDICATIONS**

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

### **5 WARNINGS AND PRECAUTIONS**

#### **5.1 Pigmentation**

Topical latanoprost ophthalmic products, including XELPROS, have 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. The long-term effects of increased pigmentation are not known.

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 XELPROS can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly. [see *Patient Counseling Information (17)*].

## **5.2 Eyelash Changes**

Latanoprost ophthalmic products, including XELPROS, 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. [see *Patient Counseling Information (17)*].

## **5.3 Intraocular Inflammation**

XELPROS 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 products, including XELPROS. XELPROS 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. XELPROS should be used with caution in patients with a history of herpetic keratitis. XELPROS 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 [see *Patient Counseling Information (17)*].

## **5.7 Use with Contact Lens**

Contact lenses should be removed prior to the administration of XELPROS and may be reinserted 15 minutes after administration [see *Patient Counseling Information (17)*].

## **6 ADVERSE REACTIONS**

The following adverse reactions were reported in postmarketing 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, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in clinical practice.

Across multiple clinical trials conducted with XELPROS (latanoprost ophthalmic emulsion) 0.005%, the most frequently reported ocular adverse reactions were eye pain/stinging upon instillation and ocular hyperemia, reported in 55% and 41% of XELPROS treated patients, respectively (Table 1). Less than 1% of patients discontinued therapy because of intolerance to the eye pain/stinging or to the ocular hyperemia.

**Table 1. Ocular Adverse Reactions Reported by  $\geq 1\%$  of Subjects Receiving XELPROS**

System Organ Class/ Preferred Term	XELPROS (N = 448)
<b>Eye disorders</b>	325 (73%)
Eye pain / stinging	246 (55%)
Ocular hyperemia	185 (41%)
Conjunctival hyperemia	65 (15%)
Eye discharge	53 (12%)
Growth of eyelashes	47 (11%)
Eyelash thickening	35 (8%)
Ocular Itching	20 (5%)
Visual acuity reduced	16 (4%)
Dry eye	13 (3%)
Erythema of eyelid	14 (3%)
Foreign body sensation in eyes	9 (2%)
Punctate keratitis	6 (1%)
Eyelash discoloration	5 (1%)
Eyelid edema	7 (2%)
Conjunctival edema	5 (1%)

## 6.2 Postmarketing Experience

The following reactions have been identified during postmarketing use of topical latanoprost products in clinical practice. Because they are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate 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 emulsion or a combination of these factors, include:

- Nervous System Disorders: Dizziness, headache, toxic epidermal necrolysis
- Eye Disorders: 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
- Skin and Subcutaneous Tissue Disorders: Pruritus
- Infections and Infestations: Herpes keratitis
- Cardiac Disorders: Angina; palpitations; angina unstable
- General Disorders and Administration Site Conditions: Chest pain

## 7 DRUG INTERACTIONS

In vitro studies have shown that precipitation occurs when eye drops containing thimerosal are mixed with XELPROS. If such drugs are used, they should be administered at least five (5) minutes apart.

The combined use of two or more prostaglandins, or prostaglandin analogs including XELPROS 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.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Pregnancy Category C

Reproduction studies have been performed in rats and rabbits. In rabbits, an incidence of 4 of 16 dams had no viable fetuses at a dose that was approximately 80 times the maximum human dose, and the highest nonembryocidal dose in rabbits was approximately 15 times the maximum human dose. There are no adequate and well-controlled studies in pregnant women. XELPROS should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### 8.3 Nursing Mothers

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

### 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.

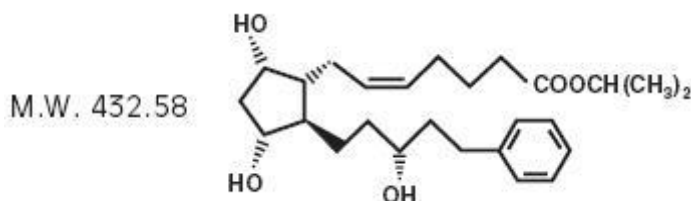
## 10 OVERDOSAGE

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

If overdosage with XELPROS 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 pale yellow to yellow viscous 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.

XELPROS (latanoprost ophthalmic emulsion) 0.005% is a sterile, isotonic, buffered aqueous emulsion of latanoprost with a pH approximately 7.0 and an osmolality of approximately 375mOsmol/kg. Each mL of XELPROS contains 50 micrograms of latanoprost. Potassium sorbate 0.47% is added as a preservative. The inactive ingredients are: castor oil, sodium borate, boric acid, propylene glycol, edetate disodium, polyoxyl 15 hydroxystearate, sodium hydroxide, hydrochloric acid, 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<sub>2α</sub> analogue that is believed to reduce the intraocular pressure (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  $0.16 \pm 0.02$  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 2 hours after topical administration.

**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  $\beta$ -oxidation.

**Excretion:** The elimination of the acid of latanoprost from human plasma is rapid ( $t_{1/2} = 17$  min) after both intravenous and topical administration. Systemic clearance is approximately 7 mL/min/kg. Following hepatic  $\beta$ -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 intravenous dosing, respectively.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Latanoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 170 mcg/kg/day (approximately 2,800 times the recommended maximum human dose) for up to 20 and 24 months, respectively.

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.

Latanoprost has not been found to have any effect on male or female fertility in animal studies.



## 14 CLINICAL STUDIES

### 14.1 Elevated Baseline IOP

In randomized, controlled clinical trials of patients with open angle glaucoma or ocular hypertension with mean baseline IOP of 23 - 26 mmHg, the mean IOP-lowering effect of XELPROS administered once daily in the evening was up to 6 - 8 mmHg.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

XELPROS (latanoprost ophthalmic emulsion) is supplied as an off-white to pale yellow, translucent, isotonic, sterile, buffered emulsion of latanoprost 0.005% (50 mcg/mL). It is supplied as a 2.5 mL emulsion filled in a 5-mL clear low density polyethylene bottle with a clear low density polyethylene dropper tip, and a turquoise high density polyethylene pilfer-proof cap. Each mL contains 50 mcg of latanoprost.

### 2.5 mL fill, 0.005% (50 mcg/mL)

Package of 1 bottle	NDC 47335-317-90
Multi-Pack of 3 bottles	NDC 47335-317-92

Storage: Protect from light. Store at 2°C to 25°C (36°F to 77°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. After opening, XELPROS can be used until the expiration date stamped on bottle and then discarded.

## 17 PATIENT COUNSELING INFORMATION

### Potential for Pigmentation

Advise patients about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuation of XELPROS [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 emulsion. 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 [see *Warnings and Precautions* (5.2)].

### 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 emulsions [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 contact lenses should be removed prior to administration of the emulsion. Lenses may be reinserted 15 minutes following administration of XELPROS [see *Warnings and Precautions (5.7)*].

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 [see *Dosage and Administration (2)*].

Manufactured for: Sun Pharma Global FZE  
By: Sun Pharmaceutical Industries, Ltd.  
Halol-Baroda Highway  
Halol-389, Gujarat, India

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### Trade Multi-Pack of 3 bottles (2.5 mL in 5 mL bottle)



### Professional Sample Multi-Pack of 3 bottles (2.5 mL in 5 mL bottle)

 <p>Professional Sample-Not for Sale</p> <p><b>Xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% 125 mcg/2.5 mL*</p> <p>NDC 47335-317-99 STERILE</p>	<p>SS: 08/2018</p>	<p><b>Xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% 125 mcg/2.5 mL*</p> <p>STERILE For Topical Use in the Eye</p> <p>Professional Sample-Not for Sale</p> <p>Rx Only Multi-pack: Three 2.5 mL bottles. Not to be sold separately.</p>  <p><b>STN</b> Pharma</p>	<p>P861019</p>
<p><b>*Each mL contains:</b> Active: Latanoprost, 50 mcg Preservative: Potassium sorbate, 4.7 mg</p> <p><b>Inactives:</b> Castor oil, sodium borate, boric acid, propylene glycol, edetate disodium, polyvinyl 13 hydroxyesterate, sodium hydroxide, hydrochloric acid, and water for injection.</p> <p><b>Usual Dosage:</b> 1 drop in the affected eye(s) in the evening. Refer to package insert.</p> <p><b>Note:</b> Bottle filled to 1/2 capacity. Store at 2°C to 25°C (36°F to 77°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. After opening, XELPROS can be used until the expiration date stamped on bottle and then discarded.</p> <p>PROTECT FROM LIGHT</p> <p>Distributed by <b>Sun Pharmaceutical Industries, Inc.</b> Cranbury, NJ 08512</p> <p>Manufactured by <b>Sun Pharma Global PZE</b> by Sun Pharmaceutical Ind Ltd. Haldi-Bandi Highway Hald-393, Gujarat, India</p> <p>GUINUS228296      P861019</p>	<p>NDC 47335-317-99 <b>Xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% 125 mcg/2.5 mL*</p> <p>STERILE For Topical Use in the Eye</p>	<p>NDC 47335-317-99 <b>Xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% 125 mcg/2.5 mL*</p> <p>STERILE For Topical Use in the Eye</p> <p>Professional Sample-Not for Sale</p> <p>Rx Only Multi-pack: Three 2.5 mL bottles. Not to be sold separately.</p>  <p><b>STN</b> Pharma</p>	<p>NDC 47335-317-99 <b>Xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% 125 mcg/2.5 mL*</p> <p>STERILE For Topical Use in the Eye</p>  <p>3 47335 51799 2</p>


### Trade (2.5 mL in 5 mL bottle) Carton




### Professional Sample (2.5 mL in 5 mL bottle) Carton



### Trade (2.5 mL in 5 mL bottle) Label

<p>Each mL contains: <b>Active:</b> Latanoprost, 50 mcg <b>Preservative:</b> Potassium sorbate, 4.7 mg <b>Usual Dosage:</b> 1 drop in the affected eye(s) in the evening. <b>Rx Only</b> <b>STERILE</b></p>	<p><b>xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% <b>125 mcg/2.5 mL</b></p>	<p>NDC 47335-317-90</p>  <p>4 7 3 3 5 3 1 7 9 0</p>	<p>Manufactured by: <b>Sun Pharmaceutical Ind. Ltd., India.</b> GUJ/DRUGS/28/396 PJB2181A</p> <div style="border: 1px solid red; padding: 5px;"><p>Batch No.: Exp.:</p></div>	<p>16 mm</p>
<p>62 mm</p>				

### Professional Sample (2.5 mL in 5 mL bottle) Label

<p>Each mL contains: <b>Active:</b> Latanoprost, 50 mcg <b>Preservative:</b> Potassium sorbate, 4.7 mg <b>Usual Dosage:</b> 1 drop in the affected eye(s) in the evening. <b>Rx Only</b>      <b>STERILE</b> <b>Professional Sample—Not for Sale</b></p>	<p><b>xelpros™</b> (latanoprost ophthalmic emulsion) 0.005% <b>125 mcg/2.5 mL</b></p>	<p>NDC 47335-317-98</p>  <p>4 7 3 3 5 3 1 7 9 8</p>	<p>Manufactured by: <b>Sun Pharmaceutical Ind. Ltd., India.</b> GUJ/DRUGS/28/396 PJB2691A</p> <div style="border: 1px solid red; padding: 5px;"><p>Batch No.: Exp.:</p></div>	<p>16 mm</p>
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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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WILEY A CHAMBERS  
09/12/2018