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

XALATAN® (latanoprost ophthalmic solution) 0.005%
Initial U.S. Approval: 1996

----------INDICATIONS AND USAGE----------
XALATAN 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 (≥4%) from clinical trials are blurred vision, burning and stinging, conjunctival hyperemia, foreign body sensation, itching, increased pigmentation of the iris, punctate keratitis, and upper respiratory tract infection/nasopharyngitis/influenza. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer at 1-800-438-1985 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
In vitro studies have shown that precipitation occurs when eye drops containing thimerosal are mixed with XALATAN. If such drugs are used, they should be administered at least 5 minutes apart. (7)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: M/YYYY

FULL PRESCRIBING INFORMATION: CONTENTS*

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

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

XALATAN is indicated for the reduction of elevated intraocular pressure 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 XALATAN should not exceed once daily; the combined use of two or more prostaglandins, or prostaglandin analogs including XALATAN 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 IOP starts approximately 3 to 4 hours after administration and the maximum effect is reached after 8 to 12 hours.

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

3 DOSAGE FORMS AND STRENGTHS

Sterile ophthalmic solution containing 50 mcg/mL latanoprost.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Pigmentation

XALATAN 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 XALATAN can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly [*see Patient Counseling Information (17.1)*].

5.2 Eyelash Changes

XALATAN 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 (17.2)*].

5.3 Intraocular Inflammation

XALATAN 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 XALATAN. XALATAN 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 XALATAN. XALATAN should be used with caution in patients with a history of herpetic keratitis. XALATAN 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 (17.3)*].

5.7 Use with Contact Lenses

Contact lenses should be removed prior to the administration of XALATAN, and may be reinserted 15 minutes after administration.

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, 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.

XALATAN was studied in three multicenter, randomized, controlled clinical trials. Patients received 50 mcg/mL XALATAN 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

	Adverse Reactions (incidence (%))	
Symptom/Finding	**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 XALATAN 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 eyelid	3	2
Photophobia	2	1
Eyelid edema	1	3
Systemic Events		
Upper respiratory tract	2	2

infection/nasopharyngitis/influenza		
Myalgia/arthralgia/back pain	1	0.5
Rash/allergic skin reaction	1	0.3

The ocular event/signs and symptoms of blepharitis have been identified as "commonly observed" through analysis of clinical trial data.

6.2 Postmarketing Experience

The following reactions have been identified during postmarketing use of XALATAN 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 XALATAN, 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; localised 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 XALATAN. 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 XALATAN 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

Teratogenic Effects: Pregnancy Category C.

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