COMMON ADVERSE REACTIONS

The following adverse reactions have been reported with 5% or more frequency and severity in clinical trials with Latanoprost. They are listed below in order of decreasing frequency (in decreasing order of decreasing frequency). The most frequent adverse reactions were lid margin hyperplasia, blepharitis, and burning.

5.2 Eyelash Changes

There were increased incidences of increased length, thickness, and number of lashes.

5.3 Intraocular Inflammation

Reduction of the IOP starts approximately 3 to 4 hours after administration.

5.4 Macular Edema

The mean number of lashes counted was 150 per eye, and the number of lashes of 500 or more was 15.

5.5 Herpetic Keratitis

Itching, conjunctival hyperemia, foreign body sensation, itching, increased lacrimation, and hyperemia, and upper respiratory tract infection/cold/floz. (8).

17.4 When to Seek Physician Advice

17.5 Use with Contact Lenses

17.6 Use with Other Ophthalmic Drugs

17.3 Handling the Container

8 USE IN SPECIFIC POPULATIONS

8.5 Geriatric Use

8.4 Women

8.3 Menstruating Women

Table 1: Ocular Adverse Reactions and ocular signs/symptoms

Table 2: Adverse Reactions that were reported in 1–5% of patients receiving Latanoprost

6.1 Clinical Trials Experience

6.2 Postmarketing Experience

5.7 Use with Contact Lenses

5.6 Bacterial Keratitis

5.5 Herpetic Keratitis

5.4 Macular Edema

5.3 Intraocular Inflammation

5.1 Pigmentation

Latanoprost Sterile Ophthalmic Solution is indicated for the treatment of open-angle glaucoma. (15 minutes after administration.)

In vitro studies of a drug cannot be directly compared to rates in the medical literature when different patient populations are studied. (17)

Intravenous (iv/ivs) [see Warnings and Precautions (6.3)]

Bacterial keratitis, including Pseudomonas aeruginosa, has been reported as a complication of the use of topical ophthalmic solutions. (6.2)

6 USE IN SPECIFIC POPULATIONS

8.4 Women

8.3 Menstruating Women

8.2 Breastfeeding

8.1 Pregnancy

8.7 Patient Counseling Information

Intraocular inflammation (iritis/uveitis) [see Warnings and Precautions (5.2)]

9.2 Reproduction Studies

9.1 Animal Studies

5.1 Pigmentation

Latanoprost has been reported to cause changes to pigmented tissues. The most frequently reported changes were increased pigmentation of the iris, periorbital tissues,

5.2 Eyelash Changes

5.3 Intraocular Inflammation

5.0 General Information

5.8 Adverse Reactions

5.7 Use with Contact Lenses

5.6 Bacterial Keratitis

5.5 Herpetic Keratitis

5.4 Macular Edema

5.3 Intraocular Inflammation

5.2 Eyelash Changes

5.1 Pigmentation

Latanoprost Sterile Ophthalmic Solution is indicated for the treatment of open-angle glaucoma. (15 minutes after administration.)

In vitro studies of a drug cannot be directly compared to rates in the medical literature when different patient populations are studied. (17)

Intravenous (iv/ivs) [see Warnings and Precautions (6.3)]

Bacterial keratitis, including Pseudomonas aeruginosa, has been reported as a complication of the use of topical ophthalmic solutions. (6.2)

6 USE IN SPECIFIC POPULATIONS

8.4 Women

8.3 Menstruating Women

8.2 Breastfeeding

8.1 Pregnancy

8.7 Patient Counseling Information

Intraocular inflammation (iritis/uveitis) [see Warnings and Precautions (5.2)]

9.2 Reproduction Studies

9.1 Animal Studies

5.1 Pigmentation

Latanoprost has been reported to cause changes to pigmented tissues. The most frequently reported changes were increased pigmentation of the iris, periorbital tissues,

5.2 Eyelash Changes

5.3 Intraocular Inflammation

5.4 Macular Edema

5.3 Intraocular Inflammation

5.2 Eyelash Changes

5.1 Pigmentation

Latanoprost Sterile Ophthalmic Solution is indicated for the treatment of open-angle glaucoma. (15 minutes after administration.)

In vitro studies of a drug cannot be directly compared to rates in the medical literature when different patient populations are studied. (17)

Intravenous (iv/ivs) [see Warnings and Precautions (6.3)]

Bacterial keratitis, including Pseudomonas aeruginosa, has been reported as a complication of the use of topical ophthalmic solutions. (6.2)

6 USE IN SPECIFIC POPULATIONS

8.4 Women

8.3 Menstruating Women

8.2 Breastfeeding

8.1 Pregnancy

8.7 Patient Counseling Information

Intraocular inflammation (iritis/uveitis) [see Warnings and Precautions (5.2)]

9.2 Reproduction Studies

9.1 Animal Studies

5.1 Pigmentation

Latanoprost has been reported to cause changes to pigmented tissues. The most frequently reported changes were increased pigmentation of the iris, periorbital tissues,

5.2 Eyelash Changes

5.3 Intraocular Inflammation

5.4 Macular Edema

5.3 Intraocular Inflammation

5.2 Eyelash Changes

5.1 Pigmentation

Latanoprost Sterile Ophthalmic Solution is indicated for the treatment of open-angle glaucoma. (15 minutes after administration.)

In vitro studies of a drug cannot be directly compared to rates in the medical literature when different patient populations are studied. (17)

Intravenous (iv/ivs) [see Warnings and Precautions (6.3)]

Bacterial keratitis, including Pseudomonas aeruginosa, has been reported as a complication of the use of topical ophthalmic solutions. (6.2)

6 USE IN SPECIFIC POPULATIONS

8.4 Women

8.3 Menstruating Women

8.2 Breastfeeding

8.1 Pregnancy

8.7 Patient Counseling Information

Intraocular inflammation (iritis/uveitis) [see Warnings and Precautions (5.2)]

9.2 Reproduction Studies

9.1 Animal Studies

5.1 Pigmentation

Latanoprost has been reported to cause changes to pigmented tissues. The most frequently reported changes were increased pigmentation of the iris, periorbital tissues,

5.2 Eyelash Changes

5.3 Intraocular Inflammation

5.4 Macular Edema

5.3 Intraocular Inflammation

5.2 Eyelash Changes

5.1 Pigmentation

Latanoprost Sterile Ophthalmic Solution is indicated for the treatment of open-angle glaucoma. (15 minutes after administration.)

In vitro studies of a drug cannot be directly compared to rates in the medical literature when different patient populations are studied. (17)

Intravenous (iv/ivs) [see Warnings and Precautions (6.3)]

Bacterial keratitis, including Pseudomonas aeruginosa, has been reported as a complication of the use of topical ophthalmic solutions. (6.2)

6 USE IN SPECIFIC POPULATIONS

8.4 Women

8.3 Menstruating Women

8.2 Breastfeeding

8.1 Pregnancy

8.7 Patient Counseling Information

Intraocular inflammation (iritis/uveitis) [see Warnings and Precautions (5.2)]

9.2 Reproduction Studies

9.1 Animal Studies

5.1 Pigmentation

Latanoprost has been reported to cause changes to pigmented tissues. The most frequently reported changes were increased pigmentation of the iris, periorbital tissues,
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 form of latanoprost is enterohepatically recycled in the intestinal lymphatics. Peak plasma concentrations are attained approximately 7 min after topical administration. Maximum effect is reached after about 2 hours after topical administration.

Metabolism

Latanoprost, an isopropyl ester prodrug, is hydrolyzed by esterases in the cornea to release the active acid of latanoprost reaching the systemic circulation primarily as an inactive metabolite. Metabolism involves 1,2,3,4-tetrahydro derivatives via fatty acid β-oxidation.

Excretion

The elimination of the acid of latanoprost from human plasma is rapid (T1/2 β = 17 min) after both intravenous and topical administration; the mean terminal elimination is approximately 7 mL/min/kg. Following hepatic β-oxidation, the metabolites are excreted in the bile and approximately 98% of the administered dose is excreted in the urine in the active form and major metabolites, respectively.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Latanoprost was not carcinogenic in either sex in rats when administered at oral doses of up to 170 mg/kg/day (approximately 267 mOsmol/kg). No increased incidence of tumors was observed between elderly and younger patients.

No overall differences in safety or effectiveness have been observed in clinical trials in elderly patients compared to younger patients. However, increased frequency of presbyopia or cataracts may decrease the IOP lowering effect or cause paradoxical exacerbation of astigmatism.

7.7 DRUG INTERACTIONS

If such drugs are used, they should be administered at least 5 minutes apart. If more than one topical ophthalmic drug is being used, the eye drops containing thimerosal are mixed with latanoprost.

17.3 Handling the Container

If the container is opened for use, it may be stored at room temperature up to 40°C. Once a bottle is opened for use, it may be stored at temperatures up to 25°C for 6 weeks.

17.1 Potential for Pigmentation

Inform patients of the possibility of eyelash and vellus hair changes (increased length, thickness, pigmentation, number of eyelashes). Inform patients about the possibility of eyelid skin darkening, which may be reversible after discontinuation of Latanoprost ophthalmic solution [see Warnings and Precautions (6.7)].

5.4 Lactation

If more than one topical ophthalmic drug is being used, the eye drops containing thimerosal are mixed with latanoprost.

17.2 Handling

Inform patients that if they develop an intercurrent ocular condition or worsening of existing ocular condition (e.g., worsening of vision) or if the treated eye becomes red or painful, they should immediately seek the advice of their physician.

15 minutes following administration of Latanoprost ophthalmic solution.

1.5 Hematopoietic Studies

Latanoprost does not produce any hematologically significant changes in bone marrow of mice or rats exposed to medicinal doses of latanoprost for up to 20 and 24 months, respectively.

7.1 Potentially Ocular Effects

Inform patients of the possibility of eyelash and vellus hair changes (increased length, thickness, pigmentation, number of eyelashes), eyelid skin darkening, which may be reversible after discontinuation of Latanoprost ophthalmic solution [see Warnings and Precautions (6.7)].

5.4 Lactation

If more than one topical ophthalmic drug is being used, the eye drops containing thimerosal are mixed with latanoprost.

17.2 Handling

Inform patients that if they develop an intercurrent ocular condition or worsening of existing ocular condition (e.g., worsening of vision) or if the treated eye becomes red or painful, they should immediately seek the advice of their physician.