

Precautions

Auroprost RT is hydrolyzed in the cornea. Bacterial keratitis, macular edema, cystoid macular edema, associated with the use of multiple-dose containers reported. These containers had been inadvertently contaminated by patients had a concurrent corneal disease or a disruption of the ocular epithelial surface. Caution to be need for patients with active Intraocular Inflammation, renal and hepatic Impairment, severe or brittle asthma. These reports have mainly occurred in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema. There is limited experience with angle closure, neovascular glaucoma.

Pregnancy & Lactation

Auroprost RT should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when administered to a nursing woman. Safety and effectiveness in pediatric patients have not been established.

Adverse reactions

Eyelash changes, eyelid skin darkening; Intraocular Inflammation (iritis/uveitis); Iris pigmentation changes; macular edema, cystoid macular edema, Blurred vision, burning, stinging, conjunctival hyperemia, foreign body sensation, itching, punctate epithelial keratopathy, dry eye, excessive tearing, eye pain, lid crusting, lid discomfort/pain, lid edema, lid erythema, photophobia, conjunctivitis, diplopia, and discharge from the eye. Renal artery embolus, retinal detachment and vitreous haemorrhage from diabetic retinopathy can also occur rarely. The systemic adverse effects are upper respiratory tract infection, chest pain, angina, muscle/joint/back pain and rash/allergy.

Drug Interactions

In-vitro studies have shown that precipitation occurs when eye drops containing thiomersal are mixed with Auroprost RT. If such drugs are used they should be administered with an interval of at least five minutes between applications.

Over dosage

Ocular irritation and conjunctival/episcleral hyperemia may occur.

Dosage

One drop in the conjunctival sac of the affected eye(s) once daily in the evening.


Storage

Store below 30°C. Protect from light.

Presentation

Auroprost RT available in pre pierced 3 piece plastic bottles.

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Instructions for use leaflet

AUROPROST RT

Description

Auroprost-RT is a sterile, isotonic, buffered aqueous solution of Latanoprost with a pH of approximately 7.0. The inactive ingredients are non-ionic surface stabilizer, buffers, Benzalkonium chloride as preservative and purified water.

Indications

Auroprost-RT Indicated for the reduction of elevated Intraocular pressure in patients with open angle glaucoma and ocular hypertension.

Clinical Pharmacology

AUROPROST RT is a prostanoid selective FP receptor agonist which is believed to reduce the intraocular pressure by increasing the outflow of aqueous humor. Studies in animals and human suggest that the main mechanism of action is increased uveoscleral outflow.

Pharmacokinetics / Pharmacodynamics

AUROPROST RT is absorbed through the cornea where the isopropyl ester prodrug is hydrolyzed to the acid form to become biologically active. The peak concentration in the aqueous humor is reached about two hours after topical administration. The distribution volume in humans is 0.16±0.02 L/kg. The active acid of latanoprost reaching the systemic circulation is primarily metabolized by the liver to the 1, 2-diol and 1, 2, 3, 4-tetraol metabolites via fatty acid β-oxidation. The elimination of the acid of latanoprost from human plasma was rapid (t 1/2 =17 min) after both intravenous 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 is recovered in the urine after topical and intravenous dosing respectively.

Contraindications

Auroprost-RT has known hypersensitivity to Latanoprost, Benzalkonium chloride or any other ingredients in this product.

Warnings

(Auroprost-RT is for external use only. Not for Injection)

It has been reported to cause changes to pigmented tissues, increased pigmentation of the iris and periorbital tissue and increased pigmentation and growth of eyelashes. These changes may be permanent. Gradually change eye color, increasing the amount of brown pigment in the iris by increasing the number of melanosomes in melanocytes. The long-term effects on the melanocytes and the consequences of potential injury to the melanocytes and deposition of pigment granules to other areas of the eye are currently unknown.