



Compound Formulation Active Pharmaceutical Ingredients and the Associated Adverse Effects and Potential Contraindications/Warnings and Precautions

Timolol + Brimonidine Tartrate + Dorzolamide + Bimatoprost

Timolol Maleate

Possible Adverse Reaction

Ocular burning/stinging on instillation, blurred vision, cataract, conjunctival injection, headache, hypertension, infection, itching, and decreased visual acuity, potentiation of respiratory reactions including asthma, asthenia/fatigue and chest pain, bradycardia, arrhythmia, hypotension, syncope heart block, cardiac arrest, pulmonary edema, raynaud's phenomenon, nausea, diarrhea, dyspepsia, anorexia, dry mouth, dizziness, somnolence, insomnia, depression, confusion, alopecia, bronchospasm, anaphylaxis, nasal congestion, potentiation of muscle weakness, masked hypoglycemia, masked thyrotoxicosis, ocular pain, ocular irritation (conjunctivitis, blepharitis, keratitis, ocular pain, discharge, crusting, foreign body sensation, tearing, dry eyes, ptosis), visual disturbances, and decreased libido, choroidal detachment after filtration procedures. Bacterial keratitis associated with the use of multiple-dose containers.

Potential Contraindications / Warnings and Precautions

Patients Less than 12 Years, Lactation, Pregnancy, Bronchial Asthma, Severe COPD, chronic bronchitis, emphysema, bronchospastic disease, History of Sinus Bradycardia, Second or third-degree atrioventricular block, Overt cardiac failure, Cardiogenic shock. Known hypersensitivity to any components. Do not use concomitantly with systemic beta-blockers, calcium antagonists, catecholamine-depleting drugs, digitalis, quinidine. Do not use in angle-closure glaucoma.

Brimonidine Tartrate

Possible Adverse Reaction

Oral dryness, Ocular hyperemia, Burning and stinging on instillation, Headache, Blurred vision, Foreign body sensation, Fatigue/drowsiness, Conjunctival follicles, Ocular allergic reactions, Ocular pruritis, Corneal staining/erosion, Photophobia, Eyelid edema, conjunctival edema, Ocular ache/pain, Ocular dryness, tearing, Upper respiratory symptoms, Dizziness, Blepharitis, Ocular irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision and muscular pain. Lid crusting, Conjunctival hemorrhaging, Abnormal taste, Insomnia, Depression, Hypertension, Anxiety, Palpitations/arrhythmias, Nasal dryness and syncope, Bradycardia, Apnea, Hypotension, Nausea, Skin reactions. Bacterial keratitis associated with the use of multiple dose containers.

Potential Contraindications / Warnings and Precautions

Infants and children less than 2 years of age, Lactation, Pregnancy. Potential for cross-sensitivity to any components. Concomitant MAOI, Tricyclic antidepressants, CNS depressants, antihypertensives or cardiac glycosides. Should be used with caution in patients with vascular insufficiency, severe cardiovascular disease.

Dorzolamide

Possible Adverse Reaction

Ocular burning, stinging, or discomfort, immediately following ocular administration. Bitter taste, Superficial punctate keratitis, Ocular allergic reaction, Conjunctivitis and lid reactions, Blurred vision, Eye redness, Tearing, Dryness, Photophobia, Headache, Nausea, Asthenia/fatigue, and rarely Skin rashes, Urolithiasis, Iridocyclitis. Stevens-Johnson syndrome, dizziness, parasthesia, ocular pain, transient myopia, choroidal detachment following filtration surgery, eyelid crusting; dyspnea, epistaxis, dry mouth and throat irritations. Bacterial keratitis associated with the use of multiple-dose containers.

Potential Contraindications / Warnings and Precautions

Neonates and Patients Less than 12 Years, Lactation, Pregnancy. Sulfonamide allergy or Hypersensitivity to any of the components. Patients with low endothelial cell counts, acute angleclosure glaucoma. Concomitant use with oral carbonic anhydrase inhibitors, high-dose salicylate therapy, severe renal impairment.

Bimatoprost

Possible Adverse Reaction

Conjunctival hyperemia and edema, conjunctival hemorrhage, eye irritation, eye pain, eye pruritus, erythema of eyelid, eyelids pruritus, growth of eyelashes, hypertrichosis, instillation site irritation, punctate keratitis, skin hyperpigmentation, vision blurred, and visual acuity reduced. Iris pigmentation changes (brown), Eyelid skin darkening, Eyelash changes (increased length, thickness, pigmentation and number of lashes). When Bimatoprost is discontinued increased pigmentation of the iris is likely to be permanent, while pigmentation of the periobital tissue and eyelash changes have been reported to be reversible. Intraocular inflammation, Macular edema, Foreign body sensation, Punctate keratitis, Stinging, Blurred vision, Itching, Burning, Excessive tearing, Eyelid discomfort/pain, Dry eye, Eye pain, Eyelid margin crusting, Erythema of the eye lid, Photophobia, Asthma like symptoms, Dyspnea. Bacterial keratitis possible with multiple use container.

Potential Contraindications / Warnings and Precautions

Patients less than 16 years, Lactation, Pregnancy, Child-bearing aged females. Potential for cross-sensitivity to any components. Caution in patients with active intraocular inflammation (trauma or infection), uveitis, aphakic patients, pseudophakic patients with torn posterior lens capsule, known risk factors for macular edema.

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