



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

### Prednisolone Phosphate + Moxifloxacin + Bromfenac

#### Prednisolone Phosphate

##### Possible Adverse Reaction

Burning or stinging, dysgeusia, foreign body sensation, allergic reaction, headache, Increased intraocular pressure with possible development of glaucoma and infrequent optic nerve damage, Keratitis, Mydriasis, Subscapular posterior cataract, Visual field defect, Wound healing impairment, Corneal ulcer, development of secondary infection (bacterial, fungal or viral), and conjunctivitis. Allergic reactions, dysgeusia, foreign body sensation, pruritis, blurry vision, conjunctival hyperemia, loss of accommodation and ptosis, acute anterior uveitis and perforation of the globe. The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. Bacterial keratitis associated with the use of multiple-dose containers.

##### Potential Contraindications / Warnings and Precautions

Infants, Lactation, Pregnancy. Known hypersensitivity to corticosteroids or any of the components. Prolonged use of corticosteroids may result in posterior subcapsular cataract formation and may increase intraocular pressure in susceptible individuals. Patients with glaucoma can have an increase in intraocular pressure-monitor pressure routinely if used for 10 days or longer. Monitor for secondary infections, acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. Various ocular diseases and long-term use have been known to cause corneal and scleral thinning.

#### Moxifloxacin HCl

##### Possible Adverse Reaction

Conjunctivitis, Decreased visual acuity, Dry eye, Keratitis, Ocular discomfort, Ocular hyperemia, Ocular pain, Ocular pruritus, Subconjunctival hemorrhage, and Tearing, Anaphylaxis, Growth of resistant organisms, Fever, Increased cough, Infection, Otitis media, Pharyngitis, Rash and Rhinitis.

##### Potential Contraindications / Warnings and Precautions

Patients less than 1 year, Lactation, Pregnancy. Known hypersensitivity to fluoroquinolones or any of the components. Growth of resistant organisms with prolonged use.

#### Bromfenac

##### Possible Adverse Reaction

Anterior chamber eye inflammation, Headache, Vitreous floaters, Iritis, Eye pain, Ocular hypertension, Burning sensation, Conjunctival hyperemia, Corneal erosion, Corneal perforation, Corneal thinning, Corneal ulcer, Epithelial keratopathy, Eye irritation, Eye pruritus, Eye redness, Hypersensitivity reaction, Keratitis, Prolonged bleeding, Stinging sensation, Abnormal sensation in eyes, Anaphylaxis

##### Potential Contraindications / Warnings and Precautions

Lactation, Pediatric patients, Pregnancy, Slow or Delayed Healing (NSAIDS), Potential for cross-sensitivity (NSAIDS) or any of the components. Increased bleeding time of ocular tissue, Keratitis, Corneal reactions. Corneal adverse events are increased in patients with dry eye syndrome, rheumatoid arthritis, repeat ocular surgeries in a short time, and diabetes mellitus.

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