



# 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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### Prednisolone Phosphate

#### Possible Adverse Reaction

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#### 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.

### 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.



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

## Prednisolone Phosphate + Moxifloxacin

### 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.



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

## Moxifloxacin + Bromfenac

### 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 flouoroquinolones or any of the components. Growth of resistant organisms with prolonged use.

### Bromfenac

#### Possible Adverse Reaction

Anterior chamber eye inflammation, Headache, Vitrious 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.



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

## Prednisolone Phosphate + Moxifloxacin HCl + Ketorolac Tromethamine

### 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.

### Ketorolac Tromethamine

#### Possible Adverse Reaction

Stinging and burning on instillation, Allergic reactions, Corneal edema, Iritis, Ocular inflammation, Ocular irritation, superficial keratitis and superficial ocular infections. Eye pain and irritation, Headache, Hypersensitivity reaction, Ocular edema, Corneal infiltrates, Corneal ulcer, Eye dryness, Blurry vision, Bronchospasm or exacerbation of asthma. Corneal erosion, Corneal perforation, Corneal thinning and epithelial breakdown. Bacterial keratitis associated with the use of multiple-dose containers.

#### Potential Contraindications / Warnings and Precautions

Patients less than 3 years of age, Lactation, Pregnancy, Child bearing aged females, 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, or repeat ocular surgeries in a short time, and diabetes mellitus.

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

## Atropine Sulfate

### Atropine Sulfate

#### Possible Adverse Reaction

Eye pain and stinging on administration, Blurred vision, Photophobia, Decreased lacrimation, superficial keratitis. Allergic reactions such as papillary conjunctivitis, contact dermatitis, and lid edema may also occur less commonly. Systemic side effects noted with Atropine 1%: Increased heart rate and blood pressure, dryness of skin, mouth, and throat from decreased secretions from mucus membranes; restlessness, irritability or delirium from stimulation of the central nervous system. Bacterial keratitis possible with multiple use container.

#### Potential Contraindications / Warnings and Precautions

Do not give to children less than 3 months of age. Patients 65 years of age or older, use this preparation with care. Pregnant or breast-feeding, talk to your physician prior to use. Potential for cross-sensitivity to any components. Use precaution if patient using MAOI (potential to precipitate hypertensive crisis).



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

## Timolol + 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, brochospastic 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.

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

## Timolol + Brimonidine Tartrate + Dorzolamide

### 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, brochospastic 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, Bradycarida, 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.

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

## Tropicamide + Phenylephrine HCl

### Tropicamide

#### Possible Adverse Reaction

Transient stinging, blurred vision, photophobia, superficial punctate keratitis, increased intraocular pressure, dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity. Bacterial keratitis associated with the use of multiple-dose containers.

#### Potential Contraindications / Warnings and Precautions

Patients less than 12 years of age (may cause CNS disturbances which may be dangerous in pediatric patients), Lactation, Pregnancy. Known sensitivity to any components. Patients should be warned not to engage in potentially hazardous activities while pupils are dilated.

### Phenylephrine HCl

#### Possible Adverse Reaction

Eye pain and stinging on instillation, temporary blurred vision and photophobia, conjunctival sensitization. Cardiovascular effects are seen primarily in phenylephrine 10% ophthalmic so recommended to use 2.5% (our dose) effects include: increase in blood pressure, syncope, myocardial infarction tachycardia, arrhythmia and subarachnoid hemorrhage. Rebound Miosis. Bacterial keratitis associated with the use of multiple-dose containers.

#### Potential Contraindications / Warnings and Precautions

Neonates and patients less than 1 year of age, Lactation, Pregnancy. Known hypersensitivities to any components. Concomitant use with Atropine may enhance the pressor effects and induce tachycardia. Potent inhalation anesthetic agents may potentiate cardiovascular depressant effects.



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

## Brimonidine Tartrate + Dorzolamide

### 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.



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

## Dexamethasone Phosphate + Moxifloxacin HCl

### Dexamethasone Sodium Phosphate

#### Possible Adverse Reaction

Ocular discomfort, Increased IOP, Conjunctival hemorrhage, Conjunctival hyperemia, Anterior chamber inflammation, Burning and stinging sensation, Eye irritation and infection, Eye pain, Post-injection flare, Wound healing suppression, Corneal perforation, Headache, Vitreous detachment, Subcapsular cataract, Ocular hypertension, Optic nerve damage, Visual field defect. Bacterial keratitis with the use of multiple dose containers.

#### Potential Contraindications / Warnings and Precautions

Infants and patients less than 12 years of age, Lactation, Pregnancy. Known hypersensitivity to any of components. Epithelial herpes simplex keratitis, Acute infectious stages of vaccinia, varicella and many other viral diseases of the corneal and conjunctiva. Mycobacterial infection of the eye, fungal diseases of the eye. Monitor IOP. Prolonged use may result in ocular hypertension and/or glaucoma and increase risk of secondary ocular infections.

### 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.