Dosage and Administration

The dose is one drop of Dorzolamide HCl Ophthalmic Solution in the affected eye(s) three times daily. Dorzolamide HCl Ophthalmic Solution may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart. See 2.2 Post-Marketing Experience.

Contraindications

Dorzolamide HCl Ophthalmic Solution contains dorzolamide, a sulfonamide; therefore, patients with a history of sulfonamide hypersensitivity should not be treated with this preparation. [see Warnings and Precautions (5.1)].

Warnings and Precautions

5.1 Sulfonamide Hypersensitivity

In clinical studies, local ocular adverse effects, primarily conjunctivitis and eyelid reactions, were reported with chronic administration of Dorzolamide HCl Ophthalmic Solution. In a 3-month, double-masked, active-treatment-controlled, multicenter study in pediatric patients, the adverse reaction profile of Dorzolamide HCl Ophthalmic Solution was comparable to that seen in adult patients.

6 Adverse Reactions

6.1 Clinical Studies Experience

In a 3-year, double-masked, active-controlled, multicenter study in pediatric patients, the adverse reaction rates observed in the clinical trials of a drug cannot be reliably estimated. See 6.2 Post-Marketing Experience.

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post approval use of Dorzolamide HCl Ophthalmic Solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

2.3 Bacterial Keratitis

In two studies, 17.0% of participants treated with Dorzolamide HCl Ophthalmic Solution had ocular adverse reactions, including conjunctivitis, lid reactions, transient myopia and subconjunctival hemorrhage.

2.4 Allergic Reactions

In two studies, 17.0% of participants treated with Dorzolamide HCl Ophthalmic Solution had ocular adverse reactions, including conjunctivitis, lid reactions, transient myopia and subconjunctival hemorrhage.

2.5 Sulfonamide Hypersensitivity

In two studies, 17.0% of participants treated with Dorzolamide HCl Ophthalmic Solution had ocular adverse reactions, including conjunctivitis, lid reactions, transient myopia and subconjunctival hemorrhage.

2.6 Post-Marketing Experience

The following adverse reactions have been identified during post approval use of Dorzolamide HCl Ophthalmic Solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

2.7 Acute Angle-Closure Glaucoma

In two studies, 17.0% of participants treated with Dorzolamide HCl Ophthalmic Solution had ocular adverse reactions, including conjunctivitis, lid reactions, transient myopia and subconjunctival hemorrhage.

2.8 Bacterial Keratitis

In two studies, 17.0% of participants treated with Dorzolamide HCl Ophthalmic Solution had ocular adverse reactions, including conjunctivitis, lid reactions, transient myopia and subconjunctival hemorrhage.

2.9 Sulfonamide Hypersensitivity

In two studies, 17.0% of participants treated with Dorzolamide HCl Ophthalmic Solution had ocular adverse reactions, including conjunctivitis, lid reactions, transient myopia and subconjunctival hemorrhage.

6.5 Acute Angle-Closure Glaucoma

In a 3-month, double-masked, active-controlled, multicenter study in pediatric patients, the adverse reaction profile of Dorzolamide HCl Ophthalmic Solution was comparable to that seen in adult patients.

7 Drug Interactions

Potential additive effect of oral carbonic anhydrase inhibitor and Dorzolamide HCl Ophthalmic Solution (7.1).

8.1 Pregnancy

8.2 Lactation

8.5 Geriatric Use

8.6 Pediatric Use

8.7 Patient Instructions

16 How Supplied/Storage and Handling

17 Patient Information

17.1 Dorzolamide Hydrochloride Ophthalmic Solution drops in both eyes, repeat Steps 3

17.2 Intercurrent Ocular Conditions

17.3 Handling Ophthalmic Solutions

17.4 Concomitant Topical Ocular Therapy

17.5 Contact Lens Use

17.6 Patient Instructions

18 Adverse Reactions

18.2 Acute Angle-Closure Glaucoma

18.3 Baseline laboratory tests

18.4 Other ocular reactions

18.5 Ocular effects

18.6 Systemic reactions

18.7 Other reactions
higher than the lower limit of detection in human plasma following oral administration.

The increase of urinary carbonic anhydrase activity is within the normal range.

No significant changes in hematology or clinical chemistry measurements were observed.

3.4 Metabolism

In vivo

The efficacy of Dorzolamide HCl Ophthalmic Solution was demonstrated in a two-year study in which treatment was initiated on day one. An oral dose of 2 mg/kg/day in dogs was given to assess the potential for systemic carbonic anhydrase inhibition following ocular administration, respectively.

The oral dose in dogs was 2 mg/kg/day.

No changes in urine specific gravity or urinary pH were observed.

An estimated plasma Cmax level in mice, 582 times higher than the lower limit of detection in human plasma following oral administration.

To ensure the safety of this drug, treatment should be at least 5 minutes apart.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

If you have any eye or skin reactions, especially conjunctivitis or eyelid reactions to Dorzolamide HCl Ophthalmic Solution, use the medicines respectively and do not use the same topical ophthalmic drug combination, respectively.

Each dispensed container is individually packaged and is not subject to light sensitivity.

An estimated plasma Cmax level in mice, 582 times higher than the lower limit of detection in human plasma following oral administration.

Avoid contact with the eye or surrounding structures.

Avoid excessive exposure to light, especially during the day.

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