For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Dorvista™

Preservative Free Eye Drops 5 mL

(Dorzolamide Hydrochloride Ophthalmic Solution IP)

COMPOSITION:

Dorzolamide Hydrochloride IP equivalent to Dorzolamide ..... 2% w/v
Aqueous Vehicle ..... q.s.

Description

Dorvista preservative free eye drops contain dorzolamide hydrochloride, a carbonic anhydrase inhibitor formulated for topical ophthalmic use. Carbonic anhydrase (CA) is an enzyme found in many tissues of the body including the eye. It catalyzes the reversible reaction involving the hydration of carbon dioxide and the dehydration of carbonic acid. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion resulting in the reduction of intraocular pressure (IOP). Following topical ocular administration, Dorzolamide reduces elevated intraocular pressure.

Indications

Dorzolamide ophthalmic solution is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Dosage and Administration

The dose is one drop of **Dorvista** preservative free eye drops in the affected eye(s) three times daily.

Dorvista preservative free eye drops may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure.

When used as an adjunctive therapy with an ophthalmic beta-blocker, the dose is one drop of **Dorvista** preservative free eye drops in the affected eye(s) two times daily.

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

Contraindications

Dorzolamide is contraindicated in patients who are hypersensitive to any component of this product.

Warnings and Precautions

DrugInteractions

Although acid-base and electrolyte disturbances were not reported in the clinical trials with dorzolamide ophthalmic solution, these disturbances have been reported with oral carbonic anhydrase inhibitors and have, in some instances, resulted in drug interactions (e.g., toxicity associated with high-dose salicylate therapy). Therefore, the potential for such drug interactions should be considered in patients receiving **Dorvista** preservative free eye drops.

Others

Dorzolamide is a sulfonamide and although administered topically is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration with dorzolamide. Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

Dorzolamide has not been studied in patients with severe renal impairment (CrCl < 30 mL/min). Because dorzolamide and its metabolite are excreted predominantly by the kidney, **Dorvista** preservative free eye drops is not recommended in such patients.

Dorvista preservative free eye drops has not been studied in patients with hepatic impairment and should therefore be used with caution in such patients.

The concomitant administration of **Dorvista** preservative free eye drops and oral

carbonic anhydrase inhibitors is not recommended.
Patients should be advised that if serious or unusual reactions or signs of hypersensitivity occur, they should discontinue the use of the product.

Pregnancy

Teratogenic Effects. Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women. **Dorvista** preservative free eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from dorzolamide, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Use

Safety and effectiveness in paediatric patients have not been established.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Side Effects

The most frequent adverse events associated with dorzolamide ophthalmic solution were ocular burning, stinging or discomfort immediately following ocular administration (approximately one-third of patients). Approximately one-quarter of patients noted a bitter taste following administration. Superficial punctate keratitis occurred in 10- 15% of patients and signs and symptoms of ocular allergic reaction in approximately 10%. Events occurring in approximately 1-5% of patients were conjunctivitis and lid reactions, blurred vision, eye redness, tearing, dryness and photophobia. Other ocular events and systemic events were reported infrequently, including headache, nausea, asthenia/fatigue and rarely, skin rashes, urolithiasis and iridocyclitis.

Storage and handling instructions:

Store below 30°C. Do Not Freeze. Use the solution within one month after opening the container. Do not touch the tip of the container to any surface. Replace cap after using. Protect from light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Presentation:

Dorvista preservative free eye drops: 5 mL of clear, colourless solution in a white opaque preservative free bottle.

Directions for use :

Turn the cap anti-clockwise to open the bottle.

Tilt your head backwards and gently pull down the lower eyelid to form a pocket.

Hold the bottle above the eye & gently squeeze one drop into the pocket.

Shake the bottle once to get rid of any remaining solution form the tip.

Recap the bottle after every use.

Manufactured in INDIA by :

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