Summary of product characteristics

Episopt
Ophthalmic solution

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1. Name of the medicinal product:
Episopt Ophthalmic solution

2. Qualitative and quantitative composition:
Each 1 ml contains:
Dorzolamide (as hydrochloride) ..... 20 mg
Timolol (as maleate) ..... 5 mg
For inactive ingredients see section 6.1

3. Pharmaceutical form:
Eye drops

4. Clinical particulars:
4.1 Therapeutic indications:
Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

4.2 Posology and method of administration:
One drop is instilled into the affected eye (s) two times daily.

4.3 Contraindications:
-Hypersensitivity to any component of the product.
-Chronic angle-closure glaucoma.
-Bronchial asthma or a history of bronchial asthma.
-Chronic obstructive pulmonary disease.
-Sinus bradycardia.
-Overt cardiac failure.
-Second or third degree atrioventricular block.
-Cardiogenic shock.
-Hypotension.
-Severe renal impairment.

4.4 Special warnings and precautions for use
-**Episopt** should be used with caution in patients with hepatic impairment.
-Because of the dorzolamide (sulphonamide) component, signs of hypersensitivity may occur; and in this case patients should discontinue the use of the product.
-Because of the timolol component (a beta-blocker), cardiac failure should be watched for and pulse rates should be checked.
-Patients should be instructed that:
-If they develop any ocular reactions, they should discontinue use.
-If they have ocular surgery or develop an intercurrent ocular condition, they should consult the physician.
-They should avoid allowing the tip of the dispensing container to contact the eye or surrounding structures to avoid bacterial contamination.
-If more than one topical ophthalmic drug is being used, the drugs should be administered at least 10 minutes apart.

-Contact lenses should be removed prior to administration of **Episopt®.** Lenses may be re-inserted 15 minutes following administration of the solution.

4.5 Interaction with other medicinal products:
-The systemic effect of **Episopt** (beta-adrenergic blocking agent) may be additive with those of other oral carbonic anhydrase inhibitors.
-There is potential additive effects of beta-blockade, both systemic and on intraocular pressure, in patients receiving oral beta-adrenergic blocking agents and **Episopt**.
-Co-administration of **Episopt** and calcium antagonists or digitalis may have additive effects in prolonging atrioventricular conduction time.
-Co-administration of **Episopt** and catecholamine-depleting drugs such as reserpine, may result in possible additive effects and the production of hypotension and/or marked bradycardia, which may result in vertigo, syncope, or postural hypotension; so patients should be monitored closely.
-Concomitant administration of **Episopt** with quinidine decreases heart rate.

4.6 Pregnancy and lactation:
Episopt should be used during pregnancy and lactation only if the potential benefit justifies the potential risk to the fetus.

4.7 Effects on ability to drive and use machines:
None.

4.8 Undesirable effects:
The common side effects include: ocular burning or stinging, taste perversion. Other adverse effect may include blurred vision, superficial punctuate keratitis, eye tearing, dryness of the eye, conjunctivitis, ocular irritation, cloudy vision, eye pain, dry mouth, cough, and dizziness, eyelid pain or edema, blepharitis, photophobia, diplopia, headache, nausea, asthenia, pharyngitis, sinusitis, and upper respiratory tract and urinary tract infections.

4.9 Overdose:
None.

5. Pharmacological properties:
5.1 Pharmacodynamic properties:
Episopt is a well-tolerated formulation of dorzolamide, a carbonic anhydrase inhibitor sulphonamide, and timolol, a topical beta-adrenergic receptor blocking agent. Each of these two components lowers elevated intraocular pressure (IOP) by decreasing aqueous humor secretion. The combined effect of the two components results in additional intraocular pressure reduction compared with either component administered alone.

5.2 Pharmacokinetic properties:
As with other topically-applied ophthalmic drugs, **Episopt** may be absorbed systemically. Approximately 33% of dorzolamide bind to plasma proteins where as protein binding of timolol is reported to be low. Timolol crosses the placenta and appears in breast milk.

Dorzolamide and timolol metabolites are primarily excreted in the urine together with unchanged drugs.

6. Pharmaceutical particulars:

6.1 List of inactive ingredients:

Hydroxypropyl methylcellulose (E4=4000CP), sodium citrate anhydrous, benzalkonium chloride 10%, mannitol, sodium hydroxide or hydrochloric cid, water for injection.

6.2 Incompatibilities:

None.

6.3 Shelf life:

3 years

6.4 Special precautions for storage:

Store at a temperature below 30° C. Protect from light.

6.5 Nature and contents of container:

Episopt Eye Drops: 5 ml plastic dropper bottle.

6.6 Special precautions for disposal and other handling:

Any unused medicine or waste material should be disposed of by taking to your local pharmacy.

7. Marketing authorization holder:

EIPICO

8. Date of revision of the text:

March 2021.