1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. **NAME OF THE MEDICINAL PRODUCT**
   DUOSOPT EYE DROPS (Dorzolamide & Timolol Maleate Eye Drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration:

Dorzolamide & Timolol Maleate Eye Drops

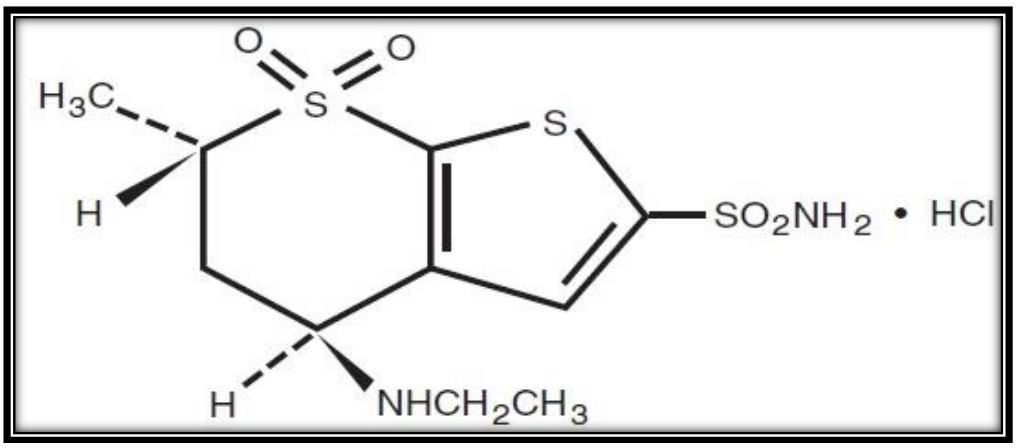
- **Dorzolamide Hydrochloride**

Chemical Name:
(4S, 6S)-4-(ethylamino)-6-methyl-7, 7-dioxo-5, 6-dihydro-4H-thieno [2, 3-b] thiopyran-2-sulfonamide hydrochloride.

Molecular weight: 324.443 g/mol

Molecular formula: $C_{10}H_{16}N_2O_4S_3$

Structural Formula:-



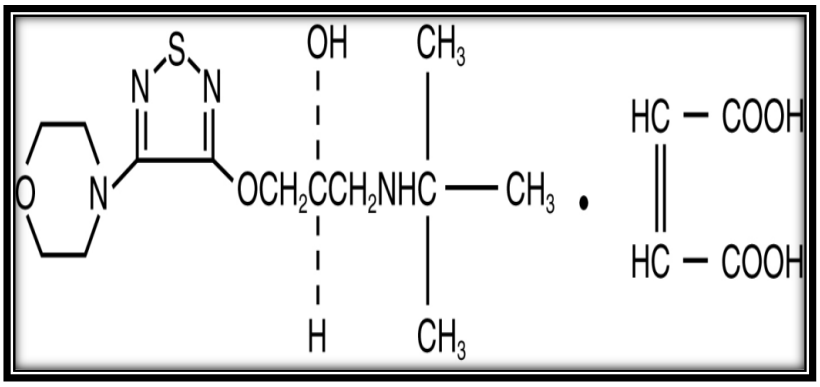
- **Timolol Maleate:**

Chemical Name:
(2S)-1-(tert-butylamino)-3-[(4-morpholin-4-yl-1, 2, 5-thiadiazol-3-yl) oxy] propan-2-ol

Molecular weight: 432.49 g/mol

Molecular formula: $C_{13}H_{28}N_4O_7S$

Structural Formula:-



Pharmaceutical Form Visual description of the appearance of product:
Colourless to slightly yellow colour solution, free from any type of visible particles.

Quantitative Declaration:

Composition:

Dorzolamide Hydrochloride	BP	2.226% w/v
Eq. to Dorzolamide		2.0% w/v
Timolol Maleate	USP	0.68% w/v
Eq. to Timolol		0.5% w/v
Benzalkonium Chloride Solution (As Preservative)	NF	0.015% w/v
Sterile Aqueous Base		Q.s

3. PHARMACEUTICAL FORM

Eye Drops

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

INDICATIONS AND USAGE

Dorzolamide/Timolol eye drops, solution is indicated in the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or pseudo-exfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.

4.2 Posology and method of administration
DOSAGE AND ADMINISTRATION

Posology

The dose is one drop of Dorzolamide/Timolol eye drops, solution in the (conjunctival sac of the) affected eye(s) two times daily.

If another topical ophthalmic medicinal product is being used, the other agent should be administered at least ten minutes apart.

Patients should be instructed to wash their hands before use and avoid allowing the tip of the container to come into contact with the eye or surrounding structures.

Patients should also be instructed that ocular solutions, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Patients should be informed of the correct handling of the ophthalmic Dorzolamide/Timolol bottles.

Paediatric population

Efficacy in paediatric patients has not been established. Safety in paediatric patients below the age of two years has not been established. (For information regarding the safety in paediatric patients ≥ 2 and < 6 years of age, see section 5.1).

Method of administration

1. The tamper-proof seal on the bottle neck must be unbroken before the product is being used for the first time. A gap between the bottle and the cap is normal for an unopened bottle.

2. The cap of the bottle should be taken off.

3. The patient's head must be tilted back and the lower eyelid must be pulled gently down to form a small pocket between the eyelid and the eye.

4. The bottle should be inverted and squeezed until a single drop is dispensed into the eye. THE EYE OR EYELID MUST NOT BE TOUCHED WITH THE DROPPER TIP.

5. After using Dorzolamide/Timolol, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop active substances getting into the rest of the body.

6. If you need to use the drops in both eyes, repeat the steps for your other eye.

7. The cap must be put back on and the bottle must be closed straight after it has been used.

4.3 Contraindications

Dorzolamide/Timolol eye drops, solution is contraindicated in patients with:

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Reactive airway disease, including bronchial asthma or a history of bronchial asthma, or severe chronic obstructive pulmonary disease.
- Sinus bradycardia, sick sinus syndrome, sino-atrial block, second- or third-degree atrioventricular block not controlled with a pacemaker, overt cardiac failure, cardiogenic shock.
- Severe renal impairment (CrCl < 30ml/min) or hyperchloraemic acidosis.
- The above is based on the components and are not unique to the combination.

4.4 Special warnings and precautions for use

Cardiovascular/respiratory reactions

Like other topically applied ophthalmic agents timolol is absorbed systemically. Due to beta-adrenergic component, timolol, the same types of cardiovascular, pulmonary and other adverse reactions seen with systemic beta-adrenergic blocking agents may occur. Incidence of systemic ADRs after topical ophthalmic administration is lower than for systemic administration. To reduce the systemic absorption, see section 4.2.

Cardiac disorders

In patients with cardiovascular diseases (e.g. coronary heart disease, Prinzmetal's angina, cardiac failure) and hypotension, therapy with beta-blockers should be critically assessed and therapy with other active substances should be considered. Patients with cardiovascular diseases should be watched for signs of deterioration of these diseases and of adverse reactions.

Due to its negative effect on conduction time, beta-blockers should only be given with caution to patients with first degree heart block.

Vascular disorders

Patients with severe peripheral circulatory disturbance/disorders (i.e. severe forms of Raynaud's disease or Raynaud's syndrome) should be treated with caution.

Respiratory disorders

Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following administration of some ophthalmic beta-blockers. Dorzolamide/Timolol eye drops, solution should be used with caution, in patients with mild/moderate chronic obstructive pulmonary disease (COPD) and only if the potential benefit outweighs the potential risk.

Hepatic impairment

This medicinal product has not been studied in patients with hepatic impairment and should therefore be used with caution in such patients.

Immunology and hypersensitivity

As with other topically-applied ophthalmic agents, this medicinal product may be absorbed systemically. Dorzolamide contains a sulphonamide group, which also occurs in sulphonamides. Therefore, the same type of adverse reactions found with systemic administration of sulphonamides may occur with topical administrations, including severe reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis. IF signs of serious reactions or hypersensitivity occur, discontinue use of this preparation.

Local ocular adverse effects, similar to those observed with dorzolamide hydrochloride eye drops, have been seen with this medicinal product. If such reactions occur, discontinuation of this medicinal product should be considered.
While taking beta-blockers, patients with a history of atopy or a history of severe anaphylactic reaction to a variety of allergens may be more reactive to accidental, diagnostic or therapeutic repeated challenge with such allergens and may be unresponsive to the usual doses of adrenaline used to treat anaphylactic reactions.

Concomitant therapy

The effect on intraocular pressure or the known effects of systemic beta-blockade may be potentiated when timolol is given to the patients already receiving a systemic beta-blocking agent. The response of these patients should be closely observed. The use of two topical beta-adrenergic blocking agents is not recommended (see section 4.5).

The use of dorzolamide and oral carbonic anhydrase inhibitors is not recommended.

Withdrawal of therapy

As with systemic beta-blockers, if discontinuation of ophthalmic timolol is needed in patients with coronary heart disease, therapy should be withdrawn gradually.

Additional effects of beta-blockade

Hypoglycaemia/diabetes

Beta-blockers should be administered with caution in patients subject to spontaneous hypoglycaemia or to patients with labile diabetes, as beta-blockers may mask the signs and symptoms of acute hypoglycaemia.

Hyperthyroidism

Therapy with beta-blockers may also mask the signs of hyperthyroidism. Abrupt withdrawal of beta-blocker therapy may precipitate a worsening of symptoms.

Corneal diseases

Ophthalmic beta-blockers may induce dryness of eyes. Patients with corneal diseases should be treated with caution.

Surgical anaesthesia

Beta-blocking ophthalmic preparations may block systemic beta-agonist effects e.g., of adrenaline. The anaesthetist should be informed when the patient is receiving timolol.

Therapy with beta-blockers may aggravate symptoms of myasthenia gravis.

Additional effects of carbonic anhydrase inhibition

Therapy with oral carbonic anhydrase inhibitors has been associated with urolithiasis as a result of acid-base disturbances, especially in patients with a prior history of renal calculi. Although no acid-base disturbances have been observed with this medicinal product, urolithiasis has been reported infrequently. Because Dorzolamide/Timolol eye drops, solution contains a topical carbonic anhydrase inhibitor that is absorbed systemically, patients with a prior history of renal calculi may be at increased risk of urolithiasis while using this medicinal product.

Other

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. This medicinal product has not been studied in patients with acute angle-closure glaucoma.

Corneal oedema and irreversible corneal decompensation have been reported in patients with pre-existing chronic corneal defects and/or a history of intraocular surgery while using dorzolamide. There is an increased potential for developing corneal oedema in patients with low endothelial cell counts. Precautions should be used when prescribing Dorzolamide/Timolol eye drops, solution to these groups of patients.

Choroidal detachment has been reported with administration of aqueous suppressant therapy (e.g. timolol, acetazolamide) after filtration procedures.

As with the use of other antiglaucoma medicines, diminished responsiveness to ophthalmic timolol maleate after prolonged therapy has been reported in some patients. However, in clinical studies in which 164 patients have been followed for at least three years, no significant difference in mean intraocular pressure has been observed after initial stabilisation.

Benzalkonium chloride

This medicine contains 0.075 mg benzalkonium chloride in each ml. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

Contact lens use: Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Patients must be instructed to remove contact lenses prior to application of Dorzolamide/Timolol eye drops solution and wait at least 15 minutes after instillation of the dose before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

Specific medicine interaction studies have not been performed with Dorzolamide/Timolol eye drops solution.

In clinical studies, this medicinal product was used concomitantly with the following systemic medications without evidence of adverse interactions: ACE-inhibitors, calcium channel blockers, diuretics, non-steroidal anti-inflammatory medicines including aspirin, and hormones (e.g. oestrogen, insulin, thyroxine).

There is a potential for additive effects resulting in hypotension and/or marked bradycardia when ophthalmic beta-blocker solution is administered concomitantly with oral calcium channel blockers, catecholamine depleting medicines or beta-adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, parasympathomimetics, gaunethidine, narcotics, and monoamine oxidase (MAO) inhibitors.

Potentiated systemic beta-blockade (e.g., decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (e.g. quinidine, fluoxetine, paroxetine) and timolol. Although Dorzolamide/Timolol eye drops, solution alone has little or no effect on pupil size, mydriasis resulting from concomitant use of ophthalmic beta-blockers and adrenaline (epinephrine) has been reported occasionally.

Beta-blockers may increase the hypoglycaemic effect of antidiabetic agents.
Oral beta-adrenergic blocking agents may exacerbate the rebound hypertension which can follow the withdrawal of clonidine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Dorzolamide/Timolol eye drops, solution should not be used during pregnancy.

Dorzolamide

No adequate clinical data in exposed pregnancies are available. In rats, dorzolamide produced teratogenic effects at meternotoxic doses (see section 5.3).

Timolol

There are no adequate data for the use of timolol in pregnant women. Timolol should not be used during pregnancy unless clearly necessary. To reduce the systemic absorption, see section 4.2. Epidemiological studies have not revealed malformative effects but show a risk for intra-uterine growth retardation when beta-blockers are administered by the oral route. In addition, signs and symptoms of beta-blockade (e.g., bradycardia, hypotension, respiratory distress and hypoglycaemia) have been observed in the neonate when beta-blockers have been administered until delivery. If this medicinal product is administered until delivery, the neonate should be carefully monitored during the first days of life.

Breast-feeding

It is not known whether dorzolamide is excreted in human milk. In lactating rats receiving dorzolamide, decreases in the body weight gain of offspring were observed.

Beta-blockers are excreted in breast milk. However, at therapeutic doses of timolol in eye drops it is not likely that sufficient amounts would be present in breast milk to produce clinical symptoms of beta-blockade in the infant. To reduce the systemic absorption, see section 4.2.

If treatment with Dorzolamide/Timolol eye drops, solution is required then breast-feeding is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Possible side effects such as blurred vision may affect some patients' ability to drive, and/or operate machinery.

4.8 Undesirable effects

In clinical studies for Dorzolamide hydrochloride + Timolol maleate combination eye drops solution the observed adverse reactions have been consistent with those that were reported previously with Dorzolamide hydrochloride and/or Timolol maleate.

During clinical studies, 1,035 patients were treated with Dorzolamide hydrochloride + Timolol maleate combination eye drops solution. Approximately 2.4% of all patients discontinued therapy with this medicinal product because of local ocular adverse reactions, approximately 1.2% of all patients discontinued because of local adverse reactions suggestive of allergy or hypersensitivity (such as lid inflammation and conjunctivitis).

Like other topically applied ophthalmic medicines, timolol is absorbed into the systemic circulation. This may cause similar undesirable effects as seen with systemic beta-blocking agents. Incidence of systemic ADRs after topical ophthalmic administration is lower than for systemic administration.

The following adverse reactions have been reported with Dorzolamide hydrochloride + Timolol maleate combination eye drops solution or one of its components either during clinical trials or during post-marketing experience: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data):

*These adverse reactions were also observed with Dorzolamide hydrochloride + Timolol maleate combination eye drops, solution during post-marketing experience.

**Additional adverse reactions have been seen with ophthalmic beta-blockers and may potentially occur with dorzolamide hydrochloride + timolol maleate combination eye drops, solution.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No data are available in humans in regard to overdose by accidental or deliberate ingestion of dorzolamide hydrochloride + timolol maleate combination eye drops, solution.

Symptoms

There have been reports of inadvertent overdoses with timolol maleate ophthalmic solution resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as dizziness, headache, and shortness of breath, bradycardia, bronchospasm, and cardiac arrest. The most common signs and symptoms to be expected with overdoses of dorzolamide are electrolyte imbalance, development of an acidotic state, and possibly central nervous system effects.

Only limited information is available with regard to human overdose by accidental or deliberate ingestion of dorzolamide hydrochloride. With oral ingestion, somnolence has been reported. With topical application the following have been reported: nausea, dizziness, headache, fatigue, abnormal dreams, and dysphagia.

Management

Treatment should be symptomatic and supportive. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored. Studies have shown that timolol does not dialyse readily.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacodynamic properties:

Dorzolamide Hydrochloride Eq. to Dorzolamide:

Pharmacotherapeutic group: Antiglaucoma agent
ATC code: S01EC03

Pharmacodynamic properties
Dorzolamide is topical CA inhibitor that is indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers. Dorzolamide reduces IOP by approximately 17-23% in patients with elevater IOP.

Mechanism of action

Carbonic anhydrase (CA) is an enzyme found in many tissues of the body including the eye. It catalyses the reversible reaction involving the hydration of carbon dioxide and the dehydration of carbonic acid. In humans, carbonic anhydrase exists as a number of isoenzyme, the most active being carbonic anhydrase II (CA-II), found primarily in red blood cells (RBCs), but also in other tissues. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. The result is a reduction in intraocular pressure (IOP).

Dorzolamide HCl Ophthalmic Solution contains Dorzolamide hydrochloride, an inhibitor of human carbonic anhydrase II. Following topical ocular administration, Dorzolamide HCl Ophthalmic Solution reduces elevated intraocular pressure. Elevated intraocular pressure is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss.

Clinical Study

The efficacy of Dorzolamide Hydrochloride Ophthalmic Solution was demonstrated in clinical studies in the treatment of elevated intraocular pressure in patients with glaucoma or ocular hypertension (baseline IOP≥23 mmHg). The IOP lowering effect of Dorzolamide Hydrochloride Ophthalmic Solution was approximately 3 to 5 mmHg throughout the day and this was consistent in clinical studies of up to one year duration. The efficacy of Dorzolamide Hydrochloride Ophthalmic Solution when dosed less frequently than three times a day (alone or in combination with other products) has not been established. In a one year clinical study, the effect of Dorzolamide Hydrochloride Ophthalmic Solution 2% t.i.d. on the corneal endothelium was compared to that of betaxolol ophthalmic solution b.i.d. and Timolol maleate ophthalmic solution 0.5% b.i.d. There were no statistically significant differences between groups in corneal endothelial cell counts or in corneal thickness measurements. There was a mean loss of approximately 4% in the endothelial cell counts for each group over the one year period.

Timolol Maleate EQ to Timolol

Pharmacotherapeutic group: Antiglaucoma agent

ATC code: S01ED51

Pharmacodynamic properties:
Similar to propranolol and nadolol, Timolol is a non-selective, beta-adrenergic receptor antagonist. Timolol does not have significant intrinsic sympathomimetic, direct myocardial depressant, or local anesthetic (membrane-stabilizing) activity, but does possess a relatively high degree of lipid solubility. Timolol, when applied topically to the eye, has the action of reducing elevated, as well as normal, intraocular pressure, whether or not accompanied by glaucoma. Elevated intraocular pressure is a major risk factor in the pathogenesis of glaucomatous visual field loss and optic nerve damage.

Mechanism of action:
Timolol maleate is a beta1 and beta2 (non-selective) adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant, or local anaesthetic (membrane-stabilizing) activity. Beta-adrenergic receptor blockade reduces cardiac output in both healthy subjects and patients with heart disease. In patients with severe impairment of myocardial function, beta-adrenergic receptor blockade may inhibit the stimulatory effect of the sympathetic nervous system necessary to maintain adequate cardiac function. Beta-adrenergic receptor blockade in the bronchi and bronchioles results in increased airway resistance from unopposed parasympathetic activity. Such an effect in patients with asthma or other bronchospastic conditions is potentially dangerous. Timolol Maleate Ophthalmic Solution, when applied topically on the eye, has the action of reducing elevated as well as normal intraocular pressure, whether or not accompanied by glaucoma. Elevated intraocular pressure is a major risk factor in the pathogenesis of glaucomatous visual field loss. The higher the level of intraocular pressure, the greater the likelihood of glaucomatous visual field loss and optic nerve damage. The onset of reduction in intraocular pressure following administration of Timolol Maleate Ophthalmic Solution can usually be detected within one-half hour after a single dose. The maximum effect usually occurs in one to two hours and significant lowering of intraocular pressure can be maintained for periods as long as 24 hours with a single dose. Repeated observations over a period of one year indicate that the intraocular pressure-lowering effect of Timolol Maleate Ophthalmic Solution is well maintained. The precise mechanism of the ocular hypotensive action of Timolol Maleate Ophthalmic Solution is not clearly established at this time. Tonography and fluorophotometry studies in man suggest that its predominant action may be related to reduce aqueous formation. However, in some studies a slight increase in outflow facility was also observed.

Application:
This medication is used to treat high pressure inside the eye due to glaucoma (open angle-type) or other eye diseases (e.g., ocular hypertension). Lowering high pressure inside the eye helps to prevent blindness. This medication works by decreasing the amount of fluid within the eye. Timolol belongs to a class of drugs known as beta-blockers.

5.2 Pharmacokinetics Properties

Dorzolamide hydrochloride

Unlike oral carbonic anhydrase inhibitors, topical administration of dorzolamide hydrochloride allows for the active substance to exert its effects directly in the eye at substantially lower doses and therefore with less systemic exposure. In clinical trials, this resulted in a reduction in IOP without the acid-base disturbances or alterations in electrolytes characteristic of oral carbonic anhydrase inhibitors.

When topically applied, dorzolamide reaches the systemic circulation. To assess the potential for systemic carbonic anhydrase inhibition following topical administration, active substance and metabolite concentrations in red blood cells (RBCs) and plasma and carbonic anhydrase inhibition in RBCs were measured.

Dorzolamide accumulates in RBCs during chronic dosing as a result of selective binding to CA-II while extremely low concentrations of free active substance in plasma are maintained. The parent active substance forms a single N-desethyl metabolite that inhibits CA-II less potently than the parent active substance but also inhibits a less active isoenzyme (CA-I). The metabolite also accumulates in RBCs where it binds primarily to CA-I. Dorzolamide binds moderately to plasma proteins (approximately 33%).

Dorzolamide is primarily excreted unchanged in the urine; the metabolite is also excreted in urine.

After dosing ends, dorzolamide washes out of RBCs non-linearly, resulting in a rapid decline of active substance concentration initially, followed by a slower elimination phase with a half-life of about four months.

When dorzolamide was given orally to simulate the maximum systemic exposure after long term topical ocular administration, steady state was reached within 13 weeks. At steady state, there was virtually no free active substance or metabolite in plasma; CA inhibition in RBCs was less than that anticipated to be necessary for a pharmacological effect on renal function or respiration. Similar pharmacokinetic results were observed after chronic, topical administration of dorzolamide hydrochloride. However, some elderly patients with renal impairment (estimated CrCl 30-60 ml/min) had higher metabolite concentrations in RBCs, but no meaningful differences in carbonic anhydrase inhibition and no clinically significant systemic side effects were directly attributable to this finding.

Timolol maleate

In a study of plasma active substance concentration in six subjects, the systemic exposure to timolol was determined following twice daily topical administration of timolol maleate ophthalmic solution 0.5%. The mean peak plasma concentration following morning dosing was 0.46 ng/ml and following afternoon dosing was 0.35ng/ml.

5.3 Preclinical safety data

The ocular and systemic safety profile of the individual components is well established.

Dorzolamide

In rabbits given maternotoxic doses of dorzolamide associated with metabolic acidosis, malformations of the vertebral bodies were observed.

Timolol

Animal studies have not shown teratogenic effect.

Furthermore, no adverse ocular effects were seen in animals treated topically with dorzolamide hydrochloride and timolol maleate ophthalmic solution or with concomitantly-administered dorzolamide hydrochloride and timolol maleate. In vitro and in vivo studies with each of the components did not reveal a mutagenic potential. Therefore, no significant risk for human safety is expected with therapeutic doses of Dorzolamide/Timolol eye drops solution.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

MATERIAL NAME	SPECS.
BENZALKONIUM CHLORIDE SOLUTION (50%)	NF
MANITOL	USP
CITRIC ACID ANHYDROUS	USP/NF
H.P.M.C E5	USP
SODIUM HYDROXIDE PELLETS	NF
PURIFIED WATER	BP/IH

6.2 Shelf life

24 months

6.3 Special precautions for storage

Store below 30 degrees C.
Do not freeze.
Protect from light.
Keep out of the reach of children.

6.4 Nature and contents of container

The liquid is filled in a multi dose container, and contain Benzalkonium chloride solution, Mannitol, Citric Acid, H.P.M.C E5, Sodium Hydroxide Pellets, and Purified Water.

Solution is filled in 5 ml Opaque sterile plastic bottle (LDPE).

6.5 Special precaution for disposal of a used medicinal product or waste materials derived such medicinal product and other handling of the product

No special requirements

7.0 Name and complete address (es) of the Applicant & manufacturer(s) of the FPP

Applicant

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