SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Timolol 0.25% w/v Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Timolol 0.25% w/v Eye Drops Solution contains timolol maleate equivalent to 0.25% w/v solution of timolol with preservative.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops solution.

Clear, colourless to light yellow, sterile eye drops solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Timolol Eye Drops Solution is a beta-adrenoreceptor blocking agent used topically in the reduction of elevated intra-ocular pressure in various conditions including the following:

- patients with ocular hypertension

- patients with chronic open-angle glaucoma including aphakic patients

- some patients with secondary glaucoma.

4.2 Posology and method of administration

Posology:

Recommended therapy is one drop 0.25% solution in the affected eye twice a day.

If clinical response is not adequate, dosage may be changed to one drop 0.5% solution in each affected eye twice a day. If needed, Timolol may be used with other agent(s) for lowering intra-ocular pressure. The use of two topical beta-adrenergic blocking agents is not recommended (see section 4.4 'Special warnings and precautions for use').

Intra-ocular pressure should be reassessed approximately four weeks after starting treatment because response to Timolol may take a few weeks to stabilise.

Provided that the intra-ocular pressure is maintained at satisfactory levels, many patients can then be placed on once-a-day therapy.

Transfer from other agents:
When another topical beta-blocking agent is being used, discontinue its use after a full day of therapy and start treatment with Timolol the next day with one drop of 0.25% Timolol in each affected eye twice a day. The dosage may be increased to one drop of 0.5% solution in each affected eye twice a day, if the response is not adequate.

When transferring a patient from a single anti-glaucoma agent other than a topical beta-blocking agent, continue the agent and add one drop of 0.25% Timolol in each affected eye twice a day. On the following day, discontinue the previous agent completely, and continue with Timolol. If a higher dosage of Timolol is required, substitute one drop of 0.5% solution in each affected eye twice a day.

Elderly:
There has been wide experience with the use of timolol maleate in elderly patients. The dosage recommendations given above reflect the clinical data derived from this experience.

Paediatric Population:
Due to limited data, Timolol could only be recommended for use in primary congenital and primary juvenile glaucoma for a transitional period while a decision is made on a surgical approach and in case of failed surgery while awaiting further options.

Posology
Clinicians should strongly evaluate the risks and benefits when considering medical therapy with Timolol in paediatric patients. A detailed paediatric history and examination to determine the presence of systemic abnormalities should precede the use of Timolol.

No specific dosage recommendation can be given as there is only limited clinical data (see also section 5.1).

However, if benefit outweighs the risk, it is recommended to use the lowest active agent concentration available once daily. If IOP could not be sufficiently controlled, a careful up titration to a maximum of two drops daily per affected eye has to be considered. If applied twice daily, an interval of 12 hours should be preferred.

Furthermore the patients, especially neonates, should be closely observed after the first dose for one to two hours in the office and closely monitored for ocular and systemic side effects.

With regard to paediatric use, the 0.1% active agent concentration might already be sufficient.

Method of administration

To limit potential adverse effects only one drop should be instilled per dosing time

Systemic absorption of topically administered beta-blockers can be reduced by nasolacrimal occlusion and by keeping the eyes closed as long as possible (e.g. for 3 - 5 minutes) after instillation of drops. See also sections 4.4 and 5.2.

Duration of treatment:

For a transient treatment in the paediatric population (see also section 4.2 “Paediatric Population”).

Patients should be instructed to avoid allowing the tip of the dispensing container to contact 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.

Usage instructions

1. Wash your hands.
2. Before using the medication for the first time, be sure the safety strip on the front of the container is unbroken. A gap between the bottle and the cap is normal for an unopened container.
3. Tear off the safety strip to break the seal.
4. To open the container, unscrew the cap by turning as indicated by the arrows.
5. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.
6. Invert the container, and press lightly with the thumb or index finger over the "Finger Push Area" until a single drop is dispensed into the eye as directed by your doctor. DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.
7. When using nasolacrimal occlusion or closing the eyelids for 2 minutes, the systemic absorption is reduced. This may result in a decrease in systemic side effects and an increase in local activity.
8. If dispensing is difficult after opening for the first time, replace the cap on the container and tighten (DO NOT OVERTIGHTEN) and then remove by turning the cap in the opposite direction as indicated by the arrows on top of the cap.
9. Repeat steps 4 and 5 with the other eye if instructed to do so by your doctor.
10. Replace the cap by turning until it is firmly touching the container. The arrow on the cap must line up with the arrow on the container for proper closure. Return the container to the original outer carton.
11. The dispenser tip is designed to provide a pre-measured drop; therefore, do NOT enlarge the hole of the dispenser tip.
12. After you have used all doses, there will be some eye drops solution left in the bottle. You should not be concerned since an extra amount of solution has been added and you will get the full amount of Timolol that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

4.3 Contraindications

Hypersensitivity to the active substance, or to any of the excipients listed in section 6.1 or other beta-blocking agents.

- Reactive airway disease including bronchial asthma or a history of bronchial asthma, severe chronic obstructive pulmonary disease.

- Sinus bradycardia, sick sinus syndrome sino-atrial block, second or third degree atrioventricular block not controlled with pace-maker,

- Overt cardiac failure, cardiogenic shock.

4.4 Special warnings and precautions for use

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 and cardiac failure) and hypotension therapy with beta-blockers should be critically assessed and the 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.

Cardiac failure should be adequately controlled before beginning therapy with 'Timolol'. Patients with a history of severe cardiac disease should be watched for signs of cardiac failure and have their pulse rates monitored. Cardiac reactions and, rarely, death associated with cardiac failure have been reported.

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.

Timolol Eye Drops 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.

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.

Beta-blockers may also mask the signs of hyperthyroidism.

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

Other beta-blocking agents
The effect on intra-ocular 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).

There have been reports of skin rashes and/or dry eyes associated with the use of beta-adrenoreceptor blocking drugs. The reported incidence is small and in most cases the symptoms have cleared when treatment was withdrawn. Discontinuation of the drug should

be considered if any such reaction is not otherwise explicable. Cessation of therapy involving beta-blockade should be gradual.

Anaphylactic reactions
While taking beta-blockers, patients with history of atopy or a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge with such allergens and unresponsive to the usual dose of epinephrine (adrenaline) used to treat anaphylactic reactions.

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

Surgical anaesthesia
β-blocking ophthalmological preparations may block systemic β-agonist effects e.g. of epinephrine (adrenaline). The anaesthesiologist should be informed when the patient is receiving timolol.

'Timolol' has been generally well tolerated in glaucoma patients wearing conventional hard contact lenses. 'Timolol' has not been studied in patients wearing lenses made with material other than polymethylmethacrylate (PMMA), which is used to make hard contact lenses.

This formulation of Timolol Eye Drops contains benzalkonium chloride as a preservative which may be deposited in soft contact lenses. Hence, Timolol Eye Drops should not be used while wearing these lenses. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

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.

In patients with angle-closure glaucoma, the immediate objective of treatment is to reopen the angle. This requires constricting the pupil with a miotic. 'Timolol' has little or no effect on the pupil.
When Timolol Eye Drops is used to reduce elevated intraocular pressure in angle-closure glaucoma, it should be used with a miotic and not alone.

A reduction in ocular hypotensive response has been reported in some patients following prolonged therapy with Timolol maleate eye drops.

Muscle weakness: Beta-adrenergic blockade has been reported to potentiate muscle weakness consistent with certain myasthenic symptoms (e.g. diplopia, ptosis, and generalised weakness). Timolol Eye Drops have been reported rarely to increase muscle weakness in some patients with myasthenia gravis or myasthenic symptoms.
Patients should be instructed to avoid allowing the tip of the dispensing container to contact 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 also be advised that if they develop any intercurrent ocular condition (e.g. trauma, ocular surgery or infection), they should immediately seek their physician's advice concerning the continued use of present multi-dose container

There have been reports of bacterial keratitis associated with the use of multiple dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Paediatric Population:
Timolol solutions should generally be used cautiously in young glaucoma patients (see also section 5.2).

It is important to notify the parents of potential side effects so they can immediately discontinue the drug therapy (see section 4.8). Signs to look for are, for example, coughing and wheezing.

Because of the possibility of apnoea and Cheyne-Stokes breathing, the drug should be used with extreme caution in neonates, infants and younger children. A portable apnoea monitor may also be helpful for neonates on Timolol.

4.5 Interaction with other medicinal products and other forms of interaction

No specific drug interaction studies have been performed with timolol.

There is a potential for additive effects resulting in hypotension and/or marked bradycardia when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, beta-adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, rauwolfia alkaloids, parasympathomimetics, guanethidine.

Although 'Timolol' alone has little or no effect on pupil size, mydriasis resulting from concomitant use of ophthalmic beta-blockers and epinephrine (adrenaline) has been reported occasionally.

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.

Oral beta-adrenergic blocking agents may exacerbate the rebound hypertension which can follow the withdrawal of clonidine.

Close observation of the patient is recommended when a beta-blocker is administered to patients receiving catecholamine-depleting drugs such as reserpine, because of possible additive effects and the production of hypotension and/or marked bradycardia, which may produce vertigo, syncope, or postural hypotension.

Oral calcium-channel antagonists may be used in combination with beta-adrenergic blocking agents when heart function is normal, but should be avoided in patients with impaired cardiac function.

The potential exists for hypotension, AV conduction disturbances and left ventricular failure to occur in patients receiving a beta-blocking agent when an oral calcium-channel blocker is added to the treatment regimen. The nature of any cardiovascular adverse effects tends to depend on the type of calcium-channel blocker used. Dihydropyridine derivatives, such as nifedipine, may lead to hypotension, whereas verapamil or diltiazem have a greater propensity to lead to AV conduction disturbances or left ventricular failure when used with a beta-blocker.

Intravenous calcium channel blockers should be used with caution in patients receiving beta-adrenergic blocking agents.

The concomitant use of beta-adrenergic blocking agents and digitalis with either diltiazem or verapamil may have additive effects in prolonging AV conduction time.

Beta-blockers may increase the hypoglycaemic effect of anti-diabetic agents. Beta-blockers can mask the signs and symptoms of hypoglycaemia (see section 4.4 Special warnings and special precautions for use).

4.6 Fertility, pregnancy and lactation

Pregnancy
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 timolol eye drops is administered until delivery, the neonate should be carefully monitored during the first days of life.

Lactation
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.

Fertility
Timolol have not been found to have any effect on male or female fertility in animal studies (refer to section 5.3).

4.7 Effects on ability to drive and use machines

Possible side effects such as dizziness and visual disturbances may affect some patients' ability to drive or operate machinery.

4 CLINICAL PARTICULARS

4.8 Undesirable effects

Like other topically applied ophthalmic drugs, timolol maleate 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 ocular administration of this or other timolol maleate formulations, either in clinical trials or since the drug has been marketed.
Additional side effects have been reported in clinical experiences with systemic timolol maleate, and may be considered potential effects of ophthalmic timolol maleate. Also listed are adverse reactions seen within the class of ophthalmic beta-blockers and may potentially occur with 'Timolol'.

Eye disorders
ocular: signs and symptoms of ocular irritation, (e.g. burning, stinging, itching, tearing, redness), conjunctivitis, blepharitis, keratitis, dry eyes, decreased corneal sensitivity, blurred vision, corneal erosion. Visual disturbances, including refractive changes (due to withdrawal of miotic therapy in some cases), diplopia, ptosis and choroidal detachment following filtration surgery (see 4.4). Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Ear and labyrinth disorders:
ocular: tinnitus

Cardiac disorders
ocular: bradycardia, chest pain, arrhythmia, heart block, congestive heart failure, palpitations, cardiac arrest, cardiac failure, oedema.;

systemic: atrioventricular block (second- or third-degree), sino-atrial block, pulmonary oedema, worsening of arterial insufficiency, worsening of angina pectoris, vasodilation.

Vascular disorders:
ocular: claudication, hypotension, Raynaud's phenomenon, cold hands and feet.

Respiratory, thoracic and mediastinal disorders:
ocular: bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure, dyspnoea, cough;
systemic: rales.

General disorders and administration site conditions:
ocular: asthenia, fatigue;
systemic: extremity pain, decreased exercise tolerance.

Skin and subcutaneous tissue disorders:
ocular: alopecia, psoriasiform rash or exacerbation of psoriasis, skin rash;
systemic: sweating, exfoliative dermatitis.

Immune system disorders:
ocular: systemic lupus erythematosus, pruritus;
systemic: signs and symptoms of allergic reactions including anaphylaxis, angioedema, urticaria, localised and generalised rash, anaphylactic reaction.

Psychiatric disorders:
ocular: depression, insomnia, nightmares, memory loss, hallucination;
systemic: diminished concentration, increased dreaming.

Nervous system disorders
ocular: syncope, cerebrovascular accident, cerebral ischemia, headache, dizziness, increase in signs and symptoms of myasthenia gravis, paraesthesia;
systemic: vertigo, local weakness

Gastrointestinal disorders:
ocular: nausea, diarrhoea, dyspepsia, dry mouth, dysgeusia, abdominal pain, vomiting.

Reproductive system and breast disorders:
ocular: decreased libido, Peyronie's disease, sexual dysfunction such as impotence;
systemic: micturition difficulties.

Metabolism and nutrition disorders:
ocular: hypoglycaemia;
systemic: hyperglycaemia.

Musculoskeletal and connective tissue disorders:
ocular: myalgia;
systemic: arthralgia.

Blood and lymphatic system disorders:
systemic: non-thrombocytopenic purpura.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 Yellow Card Scheme at Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App
Store.

4.9 Overdose

There have been reports of inadvertent overdosage with Timolol resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as dizziness, headache, shortness of breath, bradycardia, hypotension, bronchospasm, acute cardiac insufficiency and cardiac arrest (see 'Side effects').

If overdosage occurs, the following measures should be considered:

1. Gastric lavage, if ingested. Studies have shown that timolol does not dialyse readily.
2. Symptomatic bradycardia: atropine sulphate, 0.25 to 2 mg intravenously, should be used to induce vagal blockade. If bradycardia persists, intravenous isoprenaline hydrochloride should be administered cautiously. In refractory cases, the use of a cardiac pacemaker may be considered.
3. Hypotension: a sympathomimetic pressor agent such as dopamine, dobutamine or noradrenaline should be used. In refractory cases, the use of glucagon has been reported to be useful.
4. Bronchospasm: isoprenaline hydrochloride should be used. Additional therapy with aminophylline may be considered.
5. Acute cardiac failure: conventional therapy with digitalis, diuretics, and oxygen should be instituted immediately. In refractory cases, the use of intravenous aminophylline is suggested. This may be followed, if necessary, by glucagon, which has been reported useful.
6. Heart block (second- or third-degree): isoprenaline hydrochloride or a pacemaker should be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-glaucoma preparations and miotics, beta-blocking agents, selective

ATC Code: S01ED01

Mechanism of action
Timolol maleate is a non-selective beta-adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant, or local anaesthetic activity. Timolol maleate combines reversibly with the beta-adrenergic receptor, and this inhibits the usual biologic response that would occur with stimulation of that receptor. This specific competitive antagonism blocks stimulation of the beta-adrenergic stimulating (agonist) activity, whether these originate from an endogenous or exogenous source. Reversal of this blockade can be accomplished by increasing the concentration of the agonist which will restore the usual biological response.

Clinical efficacy and safety
Unlike miotics, Timolol reduces IOP with little or no effect on accommodation or pupil size. In patients with cataracts, the inability to see around lenticular opacities when the pupil is constricted is avoided. When changing patients from miotics to Timolol a refraction might be necessary when the effects of the miotic have passed.

Diminished response after prolonged therapy with Timolol has been reported in some patients.

Paediatric Population:
There is only very limited data available on the use of Timolol (0.25%, 0.5% twice daily one drop) in the paediatric population. In one small, double masked, randomized, published clinical study conducted for a treatment period up to 12 weeks on 105 children (n=71 on Timolol) aged 12 days – 5 years the data have shown to some extent evidence, that Timolol in the indication *primary congenital and primary juvenile glaucoma* is effective in short term treatment.

5.2 Pharmacokinetic properties

The onset of reduction in intra-ocular pressure can be detected within one-half hour after a single dose. The maximum effect occurs in one or two hours; significant lowering of IOP can be maintained for as long as 24 hours with a single dose.

Paediatric Population:
As already confirmed by adult data, 80% of each eye drop passes through the nasolacrimal system where it may be rapidly absorbed into the systemic circulation via the nasal mucosa, conjunctiva, nasolacrimal duct, oropharynx and gut, or the skin from tear overflow.

Due to the fact that the blood volume in children is smaller than that in adults a higher circulation concentration has to be taken into account. In addition, neonates have immature metabolic enzyme pathways and it may result in an increase in elimination half-life and potentiating adverse events.

Limited data show that plasma timolol levels in children after 0.25% greatly exceed those in adults after 0.5%, especially in infants and are presumed to increase the risk of side effects such as bronchospasm and bradycardia.

5.3 Preclinical safety data

No adverse ocular effects were observed in rabbits and dogs administered Timolol topically in studies lasting one and two years, respectively. The oral LD_{50} of the drug is 1,190 and 900 mg/kg in female mice and female rats, respectively.

Carcinogenesis, mutagenesis, impairment of fertility

In a two-year oral study of timolol maleate in rats there was a statistically significant ($p \leq 0.05$) increase in the incidence of adrenal phaeochromocytomas in male rats administered 300 mg/kg/day (300 times the maximum recommended human oral dose). Similar differences were not observed in rats administered oral doses equivalent to 25 or 100 times the maximum recommended human oral dose.

In a lifetime oral study in mice, there were statistically significant ($p \leq 0.05$) increases in the incidence of benign and malignant pulmonary tumours, benign uterine polyps and mammary adenocarcinoma in female mice at 500 mg/kg/day (500 times the maximum recommended human dose), but not at 5 or 50 mg/kg/day. In a subsequent study in female mice, in which post-mortem examinations were limited to uterus and lungs, a statistically significant increase in the incidence of pulmonary tumours was again observed at 500 mg/kg/day.

The increased occurrence of mammary adenocarcinoma was associated with elevations in serum prolactin which occurred in female mice administered timolol at 500 mg/kg/day, but not at doses of 5 or 50 mg/kg/day. An increased incidence of mammary adenocarcinomas in rodents has been associated with administration of several other therapeutic agents which elevate serum prolactin, but no correlation between serum prolactin levels and mammary tumours has been established in man. Furthermore, in adult human female subjects who received oral dosages of up to 60 mg of timolol maleate, the maximum recommended human oral dosage, there were no clinically meaningful changes in serum prolactin.

Timolol maleate was devoid of mutagenic potential when evaluated in vivo (mouse) in the micronucleus test and cytogenetic assay (doses up to 800 mg/kg) and in vitro in a neoplastic cell transformation assay (up to 100 mcg/ml). In Ames tests the highest concentrations of timolol employed, 5,000 or 10,000 mcg/plate, were associated with statistically significant ($p \leq 0.05$) elevations of revertants observed with tester strain TA100 (in seven replicate assays) but not in the remaining three strains. In the assays with tester strain TA100, no consistent dose-response relationship was observed, nor did the ratio of test to control revertants reach 2. A ratio of 2 is usually considered the criterion for a positive Ames test.

Reproduction and fertility studies in rats showed no adverse effect on male or female fertility at doses up to 150 times the maximum recommended human oral dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate

Sodium dihydrogen phosphate dihydrate

Sodium hydroxide (for pH adjustment)

Benzalkonium chloride

Water for injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

Discard Timolol Eye Drops Solution after 28 days after first opening

6.4 Special precautions for storage

This medicinal product does not require any special storage condition before first opening.

Do not store above 25°C after first opening. Store bottle in the outer carton.

Discard 28 days after first opening.

6.5 Nature and contents of container

Three piece container - 3020 D sterile Opaque LDPE container with sterile Translucent LDPE 3020D Block Nozzles and Sterile Double safe HDPE white Cap.

Eye drops available in 5ml bottles

Not all pack sizes may be marketed

6.6 Special precautions for disposal

Patients should be instructed to avoid allowing the tip of the dispensing container to contact 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.

Any unused medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0054

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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13/05/2024