1. Name of the medicinal product

Timolol maleate eye drops

2. Qualitative and quantitative composition

Timolol maleate 0.5% w/v

3. Pharmaceutical form

Eye drops, solution.

4.0 Clinical particulars

4.1 Therapeutic indications

ABLOL 5 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 and some patients with secondary glaucoma.

4.2 Posology and method of administration

Recommended therapy is one drop ABLOL 5 Eye Drops solution in the affected eye twice a day. Intra-ocular pressure should be reassessed approximately four weeks after starting treatment because response to ABLOL 5 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.

4.3 Contraindications

Bronchial asthma, history of bronchial asthma or severe chronic obstructive pulmonary disease; sinus bradycardia, second- and third-degree AV block, overt cardiac failure, cardiogenic shock; and hypersensitivity to this product or other beta-blocking agents.

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Pregnancy and lactation

Use in pregnancy: ABLOL 5 Eye Drops has not been studied in human pregnancy. The use of ABLOL 5 Eye Drops requires that the anticipated benefit be weighed against possible hazards. Breast-feeding mothers: Timolol is detectable in human milk. A decision for breast-feeding mothers, either to stop taking ABLOL 5 Eye Drops or stop nursing should be based on the importance of the drug to the mother.

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.

4.8 Undesirable effects

ABLOL 5 eye drops is usually well tolerated.

4.9 Overdose

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.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group – Ophthalmologicals**: Antiglaucoma Preparations & Miotics.**

ATC Code: **S01E D01**

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.

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.

6.0 Pharmaceutical particulars

6.1 List of excipients

- Benzalkonium chloride,
- Disodium hydrogen phosphate dihydrate
- Sodium dihydrogen phosphate dihydrate
- Purified Water For Injection.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dry place below 30°C but do not freeze.

Keep out of the reach and sight of children.

6.5 Nature and contents of container

Container: Low density polyethylene dropper bottles and plug in pack sizes of 10mL.

6.6 Special precautions for disposal and other handling

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

Discard the product in 28 days after first opening

7. Marketing authorization holder

Abacus Parenteral Drugs Limited

Block 191, Plot no.114, Kinga Mukono

P.O.Box 31376, Kampala, Uganda.

8. Marketing authorization number(s)

8577/21/13

9. Date of first authorization/renewal of the authorization

JUL 2014

10. Date of revision of the text

13/02/2016

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