ASHFORD LABORATORIES LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name : **ACCULOL Eye Drops**
(Betaxolol Hydrochloride Ophthalmic Solution USP)

1.2 Strength: **0.5%**

1.3 Pharmaceutical Dosage Form: **Ophthalmic Solution (Eye Drops)**

2-Quality and Quantitative Composition:

Each mL contains: Betaxolol ……. 5 mg
(*as Betaxolol HCl*)

3-Pharmaceutical Form: Ophthalmic solution (Eye Drops)

4-Clinical Particulars:

4.1 Therapeutic indications:

Acculol 0.5% Eye Drops is used in lowering intraocular pressure and may be used in patients with open-angle glaucoma and ocular hypertension. It may be used alone or in combination with other intra ocular pressure lowering medications.

4.2 Posology and method of administration:

Instill into the affected eye(s) 1 to 2 drops twice daily.

4.3 Contraindications:

Hypersensitivity to any component of this preparation. Acculol 0.5% Eye Drops is contraindicated in patients with sinus bradycardia, greater than first degree atrioventricular block, cardiogenic shock, or patients with overt cardiac failure.

4.4 Special warning and precautions for use:

Diabetes, thyrotoxicosis, patients with excessive restrictions of pulmonary function, pregnancy. Do not touch dropper tip to any surface, as this may contaminate the contents. Do not use with contact lenses in eyes. Patients who are concurrently receiving a beta-adrenergic blocking agent orally should be observed for a potential additive effect either on intraocular pressure or on the known systemic effects of beta-blockade. Safety and efficacy has not been established in usual pediatric dose.

4.5 Interaction with other medicinal products and other forms of interactions:

Concomitant therapy with betaxolol eye drops and epinephrine might cause mydriasis. Concomitant therapy with betaxolol eye drops and catecholamine-depleting drugs/oral beta-blockers might cause hypertension and/or bradycardia because of the possible additive effect. Caution should be exercised in patients using concomitant adrenergic psychotropic drugs.

4.6 Pregnancy and Lactation:

There are no adequate and well-controlled studies in pregnant women. Acculol 0.5% Eye Drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In breast-feeding, it is not known whether ophthalmic betaxolol is distributed into breast milk and problem in humans have not been documented.

4.7 Effects of the ability to drive and use machines:

None known

4.8 Undesirable Effects:

Rare instances of decreased corneal sensitivity, erythema, itching, corneal punctate staining, keratitis, anisocoria, photophobia, dryness, tearing, discomfort.

4.9 Overdose and special antidotes:

None known

5-Pharmacological Properties:

Betaxolol is a cardioselective beta blocker. It is reported to lack intrinsic sympathomimetic activity. Betaxolol has some membrane-stabilising activity. Betaxolol is used as the hydrochloride in the management of hypertension, angina pectoris and glaucoma.

In hypertension betaxolol hydrochloride is given in initial doses of 10 to 20 mg as a single daily dose by mouth; doses may be increased if necessary after 1 to 2 weeks according to the patient's response, to 40 mg daily. Similar doses are used in angina pectoris.

Eye drops containing the equivalent of 0.25 of 0.5% betaxolol as the hydrochloride are instilled twice daily to reduce raised intra-ocular pressure in ocular hypertension and open-angle glaucoma.

Ref. Martindale. The Extra Pharmacopoeia, 33rd edition, p. 848

6-Pharmaceutical Particulars:

6.1 List of excipients

1. Sodium Chloride USP
2. Disodium Edetate USP
3. Benzalkonium Chloride 50 % Solution NF
4. Purified Water USP

6.2 Incompatibilities: None

6.3 Shelf life :

a.) As packages for sale : **3 years**

b.) After first opening: **Discard 4 weeks from opening**

6.4 Special precautions for storage: Store at temperature 20°C – 25°C.

6.5 Nature and contents of container :

5 mL, Packed in LDPE clear bottle and plug with HDPE blue cap

7-Marketing Authorization Holder : **Linkabs Pharmaceuticals Ltd.**

8-Marketing Authorization Numbers : **04-7442**

9-Date of first authorization/renewal of the authorization : **7 October 2015**

10-Date of revision of the text : --

ASHFORD LABORATORIES LIMITED

PACKAGING SAMPLES

Product Name: **ACCULOL Eye Drops** Description: **Insert**

ACCULOL

0.5% Eye Drops

FORMULATION:
Each mL contains: Betaxolol (as Betaxolol Hydrochloride) ..... 5 mg
with 0.0002 mL of 50% Benzalkonium Chloride solution as preservative.

INDICATIONS: Acculol 0.5% Eye Drops is used in lowering intraocular pressure and may be used in patients with open-angle glaucoma and ocular hypertension. It may be used alone or in combination with other intra ocular pressure lowering medications.

DOSAGE and ADMINISTRATION: Instill into the affected eye(s) 1 to 2 drops twice daily.

CONTRAINDICATIONS: Hypersensitivity to any component of this preparation. Acculol 0.5% Eye Drops is contraindicated in patients with sinus bradycardia, greater than first degree atrioventricular block, cardiogenic shock, or patients with overt cardiac failure.

PRECAUTIONS: Diabetes, thyrotoxicosis, patients with excessive restrictions of pulmonary function, pregnancy. Do not touch dropper tip to any surface, as this may contaminate the contents. Do not use with contact lenses in eyes. Patients who are concurrently receiving a beta-adrenergic blocking agent orally should be observed for a potential additive effect either on intraocular pressure or on the known systemic effects of beta-blockade. Safety and efficacy has not been established in usual pediatric dose.

ADVERSE REACTIONS: Rare instances of decreased corneal sensitivity, erythema, itching, corneal punctate staining, keratitis, anisocoria, photophobia, dryness, tearing, discomfort.

Use in Pregnancy and Lactation: There are no adequate and well-controlled studies in pregnant women. Acculol 0.5% Eye Drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In breast-feeding, it is not known whether ophthalmic betaxolol is distributed into breast milk and problem in humans have not been documented.

DRUG INTERACTIONS: Concomitant therapy with betaxolol eye drops and epinephrine might cause mydriasis. Concomitant therapy with betaxolol eye drops and catecholamine-depleting drugs/oral beta-blockers might cause hypertension and/or bradycardia because of the possible additive effect. Caution should be exercised in patients using concomitant adrenergic psychotropic drugs.

AVAILABILITY: Available in dropper tip bottle of 5 mL.

STORAGE CONDITIONS: Store in a cool dry place. Protect from light. Discard four weeks from opening. Store at temperature 20°C - 25°C.

Manufactured by:
Ashford Laboratories Ltd.
Macau

PIA04000-08

Registration Numbers:
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NAFDAC Reg. No. 04-7442