Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Propine 0.1% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dipivefrine hydrochloride 0.1% w/v

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To control intra-ocular pressure in patients with chronic open angle glaucoma or ocular hypertensive patients with anterior chamber open angles.

4.2 Posology and method of adminstration

The usual dosage is one drop in the affected eye(s) every 12 hours.

4.3 Contraindications

a) Patients suffering from closed angle glaucoma

b) Hypersensitivity to any component of the formulation

4.4 Special warnings and special precautions for use

a) Macular oedema is a rare occurrence with adrenaline use in aphakic patients. Prompt reversal generally follows discontinuance of the drug. Macular oedema with dipivefrine does present as a possibility in the aphakic patient.

b) The product contains benzalkonium chloride and should not be used by patients continuing to wear soft (hydrophilic) contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

None Known.

4.6 Pregnancy and lactation

The safety of intensive or protracted use of dipivefrine during pregnancy has not been substantiated. Caution should be exercised when Propine is administered to a nursing mother.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

a) Cardiovascular: tachycardia, arrhythmias and hypertension have been reported with ocular administration of adrenaline, and may occur rarely with Propine therapy.

b) Ocular: the most frequently reported side effects are conjunctival infection and burning and stinging on instillation.

Rebound vasodilation, mydriasis and allergic reactions, including Blepharoconjunctivitis, have been reported occasionally.

Adrenochrome deposits in the conjunctiva and cornea have been associated rarely with use of dipivefrine.

Follicular conjunctivitis has been reported during long term therapy with Propine. The condition is reversible upon discontinuance of the drug.

4.9 Overdose

There are no data available on overdosage with Propine, which is unlikely to occur via the ocular route.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dipivefrine is a prodrug which is converted inside the eye to adrenaline.
Conversion takes place by enzyme hydrolysis.
Adrenaline, an adrenergic agonist, appears to exert its action by decreasing aqueous production and enhancing aqueous outflow facility.

5.2 Pharmacokinetic properties

Onset of action after instillation is about 30 minutes. Time to peak effect is about one hour.

5.3 Preclinical safety data

No information registered.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Sodium chloride
Dilute Hydrochloric acid
Purified water

6.2 Incompatibilities

Propine contains the preservative benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation and may be reinserted 15 minutes following administration.

6.3 Shelf Life

Unopened: 18 months
Once opened, the shelf-life is 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White, low density polyethylene 5ml and 10ml fill dropper bottle and tip: white, medium impact polystyrene (MIPS) screw cap or white, MIPS compliance screw cap (C-cap^{TM}) with external green rotating sleeve. Pack sizes: 5ml, 3 x 5ml, 10ml, 3 x 10ml.

Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
Co Mayo

8 MARKETING AUTHORISATION NUMBER

PA 148/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 November 1979

Date of last renewal: 28 November 2004

10 DATE OF REVISION OF THE TEXT

April 2005