

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

PREFRIN-A Topical Ophthalmic Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Phenylephrine hydrochloride	0.12 %w/v
Mepyramine maleate	0.10 %w/v

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Eyedrops, solution
Topical, sterile ophthalmic solution
A clear and colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

PREFRIN-A is used in the symptomatic relief to eyes affected with allergy/inflammation/irritation.

4.2 Posology and method of administration

Adults only: one to two drops may be repeated 3 to 4 hourly.

Method of Administration: topical into the conjunctival sac.

4.3 Contraindications

Use in patients with a known hypersensitivity to any of the active ingredients.

Use in patients with narrow angle glaucoma, or with contact lenses.

Use in the presence of infections, foreign bodies or where irritation is severe.

4.4 Special warnings and special precautions for use

Topical antihistamines are potential sensitizers and use may produce a local sensitivity reaction.

Use with caution on an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

The puncta should be depressed after instillation of drops to reduce drainage through the nasolacrimal duct to the oral and nasal mucosa.

If red eye persists, discontinue use and consult the eye care specialist.

4.5 Interaction with other medicinal products and other forms of interaction

Phenylephrine may increase the activity of:

- Local anaesthetics
- Adrenergic blockers
- Monoamine oxidase inhibitors
- Tricyclic antidepressants

Phenylephrine may decrease the activity of:

- Local anaesthetics
- Adrenergic blockers
- Phenothiazines

Antihistamines may increase the activity of:

- Alcohol
- Anticholinergics
- Sedatives and hypnotics
- Sympathomimetics
- Monoamine oxidase inhibitors
- Phenothiazines

Antihistamines may decrease the activity of:

- Adrenergic blockers
- Barbiturates
- Corticosteroids
- Phenylbutazone

4.6 Pregnancy and lactation

The product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Some reactions experienced in section 4.8 “Undesirable Effects” may have an effect on the ability to drive and use machines.

4.8 Undesirable effects

Prefrin-A may cause pupil dilation.

4.9 Overdose

If accidental ingestion occurs, it is recommended to drink plenty of fluids and observe for a few hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredients of PREFRIN-A Topical Ophthalmic Solution are phenylephrine hydrochloride and mepyramine maleate.

Phenylephrine hydrochloride is a directly acting sympathomimetic with strong alpha-adrenergic and very weak beta-adrenergic stimulant actions. In low concentrations, it “whitens” the eye by producing a response in sympathetic effector cells which results in the constriction of small conjunctival blood vessels. Phenylephrine also has the ability to alleviate the acute symptoms of allergic conjunctivitis. In higher concentrations (up to 10%), the drug decreases the rate of formation of the aqueous humour and hence is of value in the treatment of wide-angle glaucoma.

Phenylephrine relaxes the sphincter muscle of the iris and strongly contracts the radial fibres. If phenylephrine hydrochloride is taken systemically, it does not have central stimulant actions, but it elevates blood pressure through

arteriolar constriction; it also constricts the capacitance vessels and increases the venous return to the heart. However, these systemic effects are kept to a minimum when the drug is topically instilled.

Mepyramine maleate is an antihistaminic drug used prophylactically to prevent allergic reactions. Antihistamine drugs block histamine receptors by occupying “receptive sites” on the effector cell, without themselves initiating a response. These drugs suppress histamine contractions of smooth muscle in various organs, such as the gut and bronchi. When taken systemically, the typical side effects of antihistamines are drowsiness, fatigue and dizziness.

5.2 Pharmacokinetic properties

Refer to 5.1.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenazone (Antipyrine)
Benzalkonium chloride
Boric Acid
Disodium edetate
Sodium metabisulphite
Sodium citrate, dihydrate
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Shelf life: 3 years
In-use shelf life: 28 days from the date of first opening.

6.4 Special precautions for storage

Do not store above 25°C. Discard 28 days after first opening.

6.5 Nature and contents of container

The product will be marketed as a sterile solution in a 15 ml size bottle with dropper tip. Bottles and tips are made from low density polyethylene. The caps are made of polystyrene. A safety seal is placed around the bottle cap to insure integrity of the product.

6.6 Instructions for use and handling

No special requirements

7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
IRELAND

8 MARKETING AUTHORISATION NUMBER

PA 148/34/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st September 1982

Date of last renewal: 1st September 2002

10 DATE OF REVISION OF THE TEXT

March 2004