SCHEDULING STATUS
Schedule 0

PROPRIETARY NAME AND DOSAGE FORM
PREFRIN Liquifilm Sterile Eye Drops

COMPOSITION
PREFRIN Liquifilm Sterile Eye Drops contain:
Phenylephrine hydrochloride 1,2 mg/ml
Liquifilm (polyvinyl alcohol) 14 mg/ml

Preservative:
Benzalkonium chloride 0,005 % m/v.

PHARMACOLOGICAL CLASSIFICATION
A. 15.4 Ophthalmic preparations. Other.

PHARMACOLOGICAL ACTION
PREFRIN Liquifilm is a lubricating decongestant that whitens the eyes and has been found to be beneficial in the relief of minor eye irritation caused by colds, hay fever, dust, smog, hard contact lenses, sun, swimming and wind, in the absence of infection.

INDICATIONS
Relief of minor eye irritations.

CONTRAINDICATIONS
PREFRIN Liquifilm is contraindicated in patients with hypersensitivity to any ingredients in this product.
PREFRIN Liquifilm is contraindicated in narrow angle glaucoma.
Not intended for use with soft contact lenses.

WARNINGS AND SPECIAL PRECAUTIONS
Potential systemic effects
PREFRIN Liquifilm should be used with caution in patients with arteriosclerosis, hypertension, hyperthyroidism, prostatic enlargement or diabetes.

PREFRIN Liquifilm should be used with caution in patients receiving monoamine oxidase (MAO) inhibitor therapy or within 14 days of stopping such treatment as patients may experience hypertensive crisis.

To minimise risk of potential systemic effects, the puncta should be depressed after instillation of drops to reduce drainage through the nasolacrimal duct to the oral and nasal mucosa.

Eye inflammation
Use PREFRIN Liquifilm with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

Use with contact lenses
PREFRIN Liquifilm contains the preservative benzalkonium chloride, which may be absorbed by and cause discolouration of soft contact lenses. Patients wearing soft (hydrophilic) contact lenses should be instructed to remove contact lenses prior to administration of PREFRIN Liquifilm and wait at least 15 minutes following administration before reinserting soft contact lenses.

Potential for eye injury or contamination
To prevent eye injury or contamination, care should be taken to avoid touching the dispensing container to the eye or to any other surface.

Examination of patient
If patient experiences eye pain, changes in vision, ocular irritation or if eye irritation and redness persist over 72 hours, discontinue use and consult a doctor.

Preservative
As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

Paediatric use
Safety and effectiveness have not been demonstrated with PREFRIN Liquifilm in paediatric patients. PREFRIN Liquifilm is not recommended to be used in paediatric patients.

Effects on the ability to drive and use machines
PREFRIN Liquifilm may cause pupillary dilation and transient blurring of vision, which may impair the ability to drive or operate machines. The patient should wait until their vision has cleared before driving or using machinery.

INTERACTIONS
No interaction studies have been performed. Concurrent use of MAOI, tricyclic antidepressants, guanethidine or systemic adrenergic blockers with PREFRIN Liquifilm may alter the effects of PREFRIN Liquifilm.

PREGNANCY AND LACTATION
Safety and efficacy in pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE
One or two drops instilled into each eye. May be repeated at intervals of 3 to 4 hours as required.

SIDE EFFECTS
Post-marketing experience
The following adverse reactions have been identified during post-marketing use of PREFRIN Liquifilm. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made.

Eye disorders
Dry eye, eye discharge, eye irritation, eye pain, eye pruritus, increased lacrimation, mydriasis, ocular hyperaemia, blurred vision

Immune system disorders
Hypersensitivity reaction including symptoms or signs of eye allergy and skin allergy

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Ocular overdosage may rarely cause systemic sympathomimetic effects (e.g. palpitation, tachycardia, premature ventricular contractions, occipital headache, pallor, trembling, increased perspiration and hypertension). These effects may be treated with an alpha-adrenoreceptor blocking agent followed, if necessary, by a beta-adrenoreceptor blocking agent.

In case of ophthalmic overdose, wash the eyes with abundant water or saline solution and seek medical help.

IDENTIFICATION
A clear colourless solution.

PRESENTATION
PREFRIN Liquifilm Sterile Eye Drops are supplied in sterile dropper bottles containing 15 ml solution.

STORAGE INSTRUCTIONS
Store below 25 °C. Keep bottle tightly closed when not in use. Do not use for more than 30 days after opening. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
J/15.4/84

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Allergan Pharmaceuticals (Pty) Ltd
30 New Road (entrance off Bavaria Road)
Randjespark Ext. 11, Midrand, 1682
Johannesburg, Gauteng
South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of registration: 23 December 1976
Date of the most recently revised Professional Information as approved by the Authority: 23 December 1976