SCHEDULING STATUS
Schedule 0

PROPRIETARY NAME AND DOSAGE FORM
REFRESH Ophthalmic Solution

COMPOSITION
REFRESH Ophthalmic Solution contains:

Polyvinyl alcohol 14 mg/ml
Povidone 6 mg/ml
with sodium chloride and purified water

PHARMACOLOGICAL CLASSIFICATION
A 15.4. Ophthalmic preparations. Other.

PHARMACOLOGICAL ACTION
REFRESH is a non-preserved unbuffered slightly hypotonic solution of polyvinyl alcohol and povidone. When used in the eye it can extend the tear contact time.

PHARMACOLOGICAL ACTION
REFRESH is a non-preserved unbuffered slightly hypotonic solution of polyvinyl alcohol and povidone. When used in the eye it can extend the tear contact time.

INDICATIONS
REFRESH is indicated for the symptomatic relief of irritated dry eyes and symptoms of dry eyes. May also be used as a comfort drop while wearing hard or soft contact lenses.

CONTRAINDICATIONS
REFRESH is contraindicated in patients with hypersensitivity to polyvinyl alcohol, povidone, or any of the excipients.

WARNINGS AND SPECIAL PRECAUTIONS
If eye irritation, eye pain, continued redness and change in vision occurs or worsen, increases or persists for more than 24 hours, discontinue use and consult a medical practitioner.

To avoid contamination or possible eye injury, do not touch tip of the vial to any surface and avoid contact with the eye.

Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling REFRESH to insert soft contact lenses.

Do not use if solution changes colour or becomes cloudy.

Paediatric use
Safety and effectiveness have not been demonstrated with REFRESH in paediatric patients.

Geriatric use
Safety and effectiveness have not been demonstrated with REFRESH in geriatric patients.

Effects on the ability to drive and use machines
REFRESH may cause 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 known medicine interactions.

Concomitant ocular medications should be administered at least 15 minutes apart from the instillation of REFRESH to avoid washout effects.

PREGNANCY AND LACTATION
Safety and/or efficacy in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
Ensure that the container is intact before use. To open, twist off the tab. Apply one or two drops in each eye as needed, or as directed. There is no special dosage schedule for the elderly or for children.

In order to avoid contamination, the dropper should not be allowed to touch the eye or any other surface. Use immediately after opening. Do not store opened container. Discard after use.

SIDE EFFECTS
Post-marketing experience
The following additional adverse reactions have been identified during post-marketing use of REFRESH in clinical practice. Because post-marketing reporting of these reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions.

Eye Disorders
Eye irritation, corneal trauma, eye trauma, eye pain, eye discharge, eye pruritus, ocular hyperaemia, conjunctival hyperaemia, foreign body sensation, increased lacrimation and blurred vision.

Immune system Disorders
Allergic reaction.

An additional adverse reaction reported with the polyvinyl alcohol component alone is hypersensitivity.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Accidental overdose will not present any hazard.

IDENTIFICATION
Low-density polyethylene single-dose containers with a clear, colourless to slightly yellow solution.

PRESENTATION
Cardboard cartons containing 30 single-use containers per carton.

STORAGE INSTRUCTIONS
Store unopened container below 25 ºC.
Do not store opened container. Discard after use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
Z/15.4/348

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 THIS PROFESSIONAL INFORMATION

Date of registration: 28 October 1992

Date of revision of the most recently revised Professional Information as approved by the Authority: 5 Augustus 2009