

## APPROVED PACKAGE INSERT

### SCHEDULING STATUS:

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### PROPRIETARY NAME (AND DOSAGE FORM):

UNIVERSAL EYE DROPS (Solution)

### COMPOSITION:

Each 1ml solution contains:

Phenylephrine hydrochloride	1,25 mg
Boric acid	20,0 mg
Benzalkonium chloride (preservative)	0,1 mg

### PHARMACOLOGICAL CLASSIFICATION:

15.4 Ophthalmic preparations: Other

### PHARMACOLOGICAL ACTION:

Local vasoconstrictor and antiseptic.

### INDICATIONS:

For the relief of eye strain, mild inflammation and allergic conjunctivitis.

### CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

If any allergic reaction should occur, discontinue use and consult your doctor.

**WARNINGS:**

1. Do not use for more than 30 days after first opening.
2. 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.
3. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

**DIRECTIONS FOR USE:**

Instill one or two drops into each eye, three or four times daily.

**IDENTIFICATION:**

Colourless solution.

**PRESENTATION:**

15 ml dropper bottle. Sterile when packed.

**STORAGE INSTRUCTIONS:**

Store below 25 °C and away from light.

Keep out of reach of children

**REFERENCE NUMBER:**

H1348 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF APPLICANT:**

Acino Pharma (Pty) Ltd

No. 106 16<sup>th</sup> Road

Midrand

1686

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