SCHEDULING STATUS: **S2**

PROPRIETARY NAME: **ALLERGEX EYE DROPS**

(AND DOSAGE FORM) **(EYE DROPS)**

COMPOSITION:

Every 1 ml contains:

Oxymetazoline hydrochloride 0,25 mg

Preservative:

Benzalkonium chloride 0,1 mg (0,01 % *m/v*)

LIST OF EXCIPIENTS: Borax, Boric acid, Disodium edetate**,** Sodium chloride, Water for injections.

PHARMACOLOGICAL CLASSIFICATION:

15.4 Ophthalmic preparations – Others

PHARMACOLOGICAL ACTION:

Oxymetazoline is a sympathomimetic with vasoconstrictor properties.

INDICATIONS:

ALLERGEX EYE DROPS is indicated for allergic inflammations of the eyes.

CONTRAINDICATIONS:

Do not administer to children less than 6 years of age.

WARNINGS AND SPECIAL PRECAUTIONS:

As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated use of benzalkonium chloride preserved ophthalmic 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.

As with all eye drops containing sympathomimetics, prolonged usage may cause rebound congestion.

DOSAGE AND DIRECTIONS FOR USE:

One to two drops in the eyes morning and evening and when required.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

It may occasionally cause local burning or stinging.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Discontinue treatment.

IDENTIFICATION:

Clear colourless solution.

PRESENTATION:

10 ml or 15 ml in white LDPE bottles, with clear, LDPE dropper inserts and white, LDPE dropper bottle caps.

STORAGE INSTRUCTIONS:

Store in a cool place, at or below 25 °C, in well-closed containers.

Discard contents of bottle 30 days after opening.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

H1274 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Adcock Ingram Limited

1 New Road

Midrand

Erand Gardens, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

29 May 2000

Namibia: NS1 13/15.4/0030