SCHEDULING STATUS: **S2**

PROPRIETARY NAME: **OCULOSAN ®**

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

COMPOSITION:

Each 1 ml contains:

Zinc sulphate 0,2 mg

Naphazoline nitrate 0,05 mg

Preservative:

Benzalkonium chloride 0,01 % *m/v*

List of excipients: Euphrasia tincture, ethanol, hamamelis water, lavender oil, orange flower oil, sodium chloride, water for injection

PHARMACOLOGICAL CLASSIFICATION:

15.4 Ophthalmic preparations - Other

PHARMACOLOGICAL ACTION:

Zinc sulphate displays marked astringent properties. Astringents produce a very fine scurf on the surface of the conjunctiva. Secretion is reduced, slight contraction of the tissue occurs and the capillaries are sealed off, with the result that growth of any bacteria that may be present, is inhibited.

Naphazoline is a vasoconstrictor, and reduces inflammation and swelling of the conjunctiva. The effect of naphazoline is due to direct binding to α-adrenergic receptor sites on unstriated muscle cells in the blood vessels. Naphazoline is systemically absorbed through blood vessels, however the extent of absorption is unknown as no data is available.

INDICATIONS:

Acute and chronic non-infectious conjunctivitis.

Unspecific conjunctival irritations, including allergies.

After successful treatment of bacterial and viral infections.

Irrigation of the tear duct.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

In patients suffering from narrow angle glaucoma, dry eye and keratoconjunctivitis sicca.

Not to be used in infants.

Not to be administered during monoamine oxidase inhibitors or within 14 days of termination of such treatment.

WARNINGS AND SPECIAL PRECAUTIONS:

Uncontrolled use of **OCULOSAN** over extended periods of time should be avoided, due to the rebound effect.

Use with caution in patients with hyperthyroidism, cardiovascular disease, hypertension, diabetes mellitus or hyperglycemia and eye disease, infection or injury.

Contact lens to be removed before instillation and are not to be worn for at least 15 minutes after application of **OCULOSAN**.

Results of ocular tonometry may be affected by previous application of **OCULOSAN**.

Long term use may result in reactive redness of the eye (rebound effect).

If eye pain or change in vision occurs or if redness or irritation of the eye continues, worsens or lasts for more than 72 hours, discontinue treatment and consult with the physician.

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.

Do not use more than 30 days after opening.

INTERACTIONS:

Caution should be exercised with concurrent use of tricyclic antidepressants, as this will potentiate the pressor effect of naphazoline, should systemic absorption of naphazoline take place following ocular administration.

PREGNANCY AND LACTATION:

Safety and/or efficacy has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Use only as directed.

One drop into the lower eyelid four times per day.

SIDE EFFECTS:

A slight and transient burning sensation may occur after instillation.

Less frequent local effects are mydriasis, blurred vision and a slight increase in intra-ocular pressure.

Systemic absorption, especially in children and the elderly has been reported following ocular application of naphazoline containing solutions. Symptoms of naphazoline being absorbed into the body are dizziness, headache, increased sweating, nausea, nervousness and weakness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage or accidental oral ingestion may cause depression of the central nervous system, with marked reduction in body temperature and bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension. Treatment should be symptomatic.

IDENTIFICATION:

A clear, colourless to pale yellowish aqueous solution, with a characteristic odour.

PRESENTATION:

10 ml transparent, plastic dropper bottle.

STORAGE INSTRUCTIONS:

Store at or below 30 ºC, in well-closed, non-metallic containers, protected from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION/REFERENCE NUMBER:

H 1272 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand,1685

Private Bag X 69

Bryanston, 2021, RSA

www.adcock.com

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