1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

OCULERGE (eye drop)

COMPOSITION

Each 1 ml of OCULERGE contains:

Antazoline HCl	0,5 mg
Tetrahydrozoline HCl	0,4 mg

Excipients:

Benzalkonium chloride, hydroxypropyl methylcellulose, water for injection

Preservatives:

Benzalkonium chloride 0,005 % *m/v*

CATEGORY AND CLASS

A 15.4 Ophthalmic preparations, Other

PHARMACOLOGICAL ACTION

Antazoline, a synthetic antihistamine, is combined with tetrahydrozoline, a vasoconstrictor.

Tetrahydrozoline causes conjunctival decongestion.

INDICATIONS

- Hay-fever conjunctivitis.
- Allergic conjunctivitis.

CONTRAINDICATIONS

- Patients who experience hypersensitivity to any of the ingredients.
- Patients receiving monoamine oxidase inhibitors, or within 14 days of its termination.
- Closed-angle glaucoma.
- Safety in pregnancy and lactation has not been established.
- Not recommended for children under 6 years of age.

WARNINGS AND SPECIAL PRECAUTIONS

For external use only.

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.

OCULERGE eye drops should be used with caution in the presence of hypertension, cardiac irregularities, hyperglycaemia (diabetes mellitus) or hyperthyroidism.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

1 drop, 3 or 4 times daily, or more, into the lower eyelid.

SIDE EFFECTS

Transient irritation may occur.

Systemic reactions may occur.

Hypersensitivity reactions, nausea and headache have been reported.

Drowsiness may be experienced by some patients.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Accidental ingestion (especially in children) may cause depression of the central nervous system with reduction in body temperature and symptoms of bradycardia, sweating, drowsiness and coma. Hypertension may be followed by rebound hypotension.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

Clear, colourless, odourless liquid.

PRESENTATION

15 ml solution is packed in a white low density polyethylene dropper bottle with a white high density polyethylene round screw cap and a low density polyethylene clear torpedo shaped nozzle with an orifice.

The container is packed into an outer cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C in well-closed containers.

Protect from light.

Do not use more than 30 days after opening.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

31/15.4/0144

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES

FOR HUMAN USE

Date of registration: 08 April 1997

Date of the most recent amendment to the professional information as approved by the Authority: 08 April 1997

Namibia: NS1 10/15.4/0555