1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S2

PROPRIETARY NAME AND DOSAGE FORM

SAFYR BLEU EYE DROPS

COMPOSITION

Each 1 ml of SAFYR BLEU EYE DROPS contains 0,5 mg naphazoline nitrate.

Excipients:

Benzalkonium chloride, disodium edetate, sodium chloride for injection, water for injection.

Preservative:

Benzalkonium chloride 0,01 % *m/v*

CATEGORY AND CLASS

A 15.4 Ophthalmic preparation (others)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Sympathomimetic (conjunctival decongestant).

INDICATIONS

Provides rapid relief from irritations to the eyes due to dust, allergies, sun glare, swimming, smoke, smog, exposure to wind and cinema.

CONTRAINDICATIONS

Not known.

WARNINGS AND SPECIAL PRECAUTIONS

Accidental administration by mouth may cause depression of the central nervous system with marked reduction of body temperature and bradycardia, sweating, drowsiness and coma, particularly in children; it should be used with great caution, if at all, in infants and young children. Hypertension may be followed by rebound hypotension.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Unscrew the cap and gently squeeze 2 to 3 drops into the eye every three to four hours.

SIDE EFFECTS

After local use of naphazoline transient irritation may occur.

Nausea and headache have been reported.

Rebound congestion may occur after frequent or prolonged use.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Overdosage may cause depression of the central nervous system with marked reduction of body temperature and bradycardia, sweating, drowsiness and coma, particularly in children.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

Clear bright liquid.

PRESENTATION

5 ml, 10 ml and 15 ml are packed into a white linear low density polyethylene bottle and sealed with a high density polyethylene tamper evident screw cap, with a linear low density polyethylene puffer controlling dropper. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C and protect from light.

Keep container tightly closed.

Discard 30 days after opening.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H1318 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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