SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Collyre Bleu Laiter, bottle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Methylthioninium hydroxide 0.020g

Naphazoline nitrate 0.050g

Excipients ..... q.s 100.000m1

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Non-infectious conjunctival irritation

4.2 Posology and method of administration

1 drop in the lower conjunctival pouch, 2 to 6 times a day for an average of 7 days.

4.3 Contraindications

- Risk of glaucoma (angle-closure),
- Previous history of allergy to one of the constituents,
- Infants and children under 3 years old.

4.4 Special warnings and precautions for use

Warnings

The attention of athletes is drawn to the fact that this product contains an active substance which might react positively to anti-doping tests.

Special precautions for use

Avoid contact with soft hydrophilic contact lenses. There is a risk of staining due to light-induced changes in naphazoline and the presence of methylene blue.

In the event of concomitant treatment with eye-drops containing a different active substance, instil drops 15-minutes apart.

Avoid repeated instillation of drops in patients with hypertension or arteriosclerosis.

Check for absence of narrow irido-corneal angle before drops are first administered.
Stop the treatment if hypersensitivity occurs.

4.5 Interaction with other medicinal products and other forms of interaction

Associations not recommended:

- Non-selective MAO inhibitors: high blood pressure (inhibition of the catabolism of pressure amines). Because of the long action of the MAO inhibitors, this interaction may still occur 15 days after the MAO is stopped. As a precautionary measure, this association is not recommended.

- Guanethidine and related substances: increased hypertensive effect of the phenylephrine, greater and prolonged mydriasis (hyperreactivity due to inhibition of sympathetic tone by guanethidine).

4.6 Pregnancy and lactation

Because of a lack of clinical and experimental data, and vasoconstricting properties of naphazoline, avoid use during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

Mydriasis may develop following repeated instillations and make driving dangerous.

4.8 Undesirable effects

Risk of acute glaucoma due to closure of the iridocorneal angle.

Possibility of transient irritation. Risk of hypersensitivity reaction.

Repeated administration may cause troublesome mydriasis, alteration of the corneal epithelium, and very occasionally an increase in blood pressure, tremor, pallor, headache and cardiac rhythm disorders due to a systemic effect of naphazoline.

4.9 Overdose

Repeated administration may cause troublesome mydriasis, alteration of the corneal epithelium, and very occasionally an increase in blood pressure, tremor, pallor, headache and cardiac rhythm disorders due to a systemic effect of naphazoline.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamie properties

Naphazoline is a synthetic alpha sympathomimetic with ocular vasoconstricting and decongestant properties.

Methylene blue (or methylthioninium) is an antiseptic.

5.2 Pharmacokinetic properties

When administered locally, small amounts of naphazoline may pass into systemic circulation.

5.3 Preclinical safety data

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3 years.

Once opened, the bottle may only be kept for 15 days.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and content of container

10 ml polyethylene dropper bottle.

6.6 Special precautions for disposal and other handling

No special requirements.

7. OPERATOR

OPERATOR:
FRILAB SA
17, rue des Pierres du Niton
CH-1207 Geneva

8. DOSIMETRY

Not applicable.

9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

List II