SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

COLLYRE BLEU LAITER, eye drops, solution (bottle)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Methylthioninium hydroxide (methylene blue) ..... 0.020 g
Naphazoline nitrate ..... 0.050 g
For 100 ml of eye drops.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Non-infectious conjunctival irritation.

4.2 Posology and method of administration

Posology

Instil **1 drop into the lower conjunctival sac**, **2 to 6 times daily** for an average of 7 days.

4.3 Contraindications

- Risk of angle-closure glaucoma.
- History of hypersensitivity to any component of the product.
- Newborns and children under 3 years of age.

4.4 Special warnings and precautions for use

Special warnings

Athletes should be informed that this medicinal product contains an active substance that may induce a **positive result in anti-doping tests**.

Precautions for use

- Avoid contact with soft hydrophilic contact lenses due to the risk of staining caused by light-induced modification of naphazoline and the presence of methylene blue.
- If used concomitantly with another ophthalmic product containing a different active substance, instil each eye drop **15 minutes apart**.
- Avoid repeated instillations, particularly in patients with **arterial hypertension** or **arteriosclerosis**.
- Ensure the **iridocorneal angle is not narrow** prior to the first instillation.
- Discontinue treatment in case of hypersensitivity.

4.5 Interactions with other medicinal products and other forms of interaction

Not recommended combinations

- **Non-selective MAOIs**
  Risk of hypertensive crises (inhibition of the metabolism of pressor amines) due to the long-lasting effects of MAOIs. This interaction may still occur **up to 15 days after discontinuation** of the MAOI. As a precaution, this combination is not recommended.
- **Guanethidine and related compounds**
  Increased hypertensive effect of naphazoline, greater and prolonged mydriasis (hyperreactivity associated with inhibition of sympathetic tone by guanethidine).

4.6 Fertility, pregnancy and lactation

Avoid use during pregnancy and breastfeeding due to the absence of sufficient clinical and experimental data and because of the **vasoconstrictive properties** of naphazoline.

4.7 Effects on ability to drive and use machines

Repeated instillations may cause **mydriasis**, which may impair the ability to drive or operate machinery.

4.8 Undesirable effects

- Risk of **acute angle-closure glaucoma**.
- Possible transient irritation.
- Risk of hypersensitivity reactions.
- Repeated instillations may cause **troublesome mydriasis**, corneal epithelial alterations, and, rarely, systemic effects of naphazoline such as **increased blood pressure, tremors, pallor, headache, cardiac arrhythmias**.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after marketing authorisation is important as it allows continuous monitoring of the benefit-risk balance. Healthcare professionals should report any suspected adverse reaction via the national reporting system: *Agence nationale de sécurité du médicament et des produits de santé (ANSM)* and the network of Regional Pharmacovigilance Centres – website: **www.signalement-sante.gouv.fr**.

4.9 Overdose

Repeated instillations may lead to troublesome mydriasis, corneal epithelial alterations and, rarely, systemic effects of naphazoline such as increased blood pressure, tremors, pallor, headache and cardiac arrhythmias.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Naphazoline is a synthetic **α-adrenergic sympathomimetic** producing ocular vasoconstriction and decongestion.
Methylene blue (methylthioninium) has **antiseptic properties**.

5.2 Pharmacokinetic properties

Following topical administration, a small amount of naphazoline may pass into the systemic circulation.

5.3 Preclinical safety data
Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium chloride, purified water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

Any opened bottle must be used within **15 days**.

6.4 Special precautions for storage
No special storage conditions.

6.5 Nature and contents of container
10 ml in a polyethylene (PE) dropper bottle.

6.6 Special precautions for disposal and other handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRES FRILAB
104 Boulevard Auguste Blanqui
75013 Paris
France

8. MARKETING AUTHORISATION NUMBER(S)

• 301 328-5: 10 ml in polyethylene (PE) dropper bottle.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed by the MAH]

10. DATE OF REVISION OF THE TEXT

[To be completed by the MAH]

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

PRESCRIPTION AND DISPENSING CONDITIONS

List I (Prescription-only medicine).