1. NAME OF THE MEDICINAL PRODUCT

Oculac 50 mg/ml, eye drops solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains 50 mg povidone K25

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution

Slightly yellowish, clear aqueous solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of dry eyes.

4.2 Posology and method of administration

For ocular use only.

One drop into the conjunctival sac of the eye 4 times daily, or as required, depending upon the severity of the condition.

Oculac eye drops contain a sterile solution until the original closure is broken. After cap is removed, if tamper evident snap collar is loose, remove before using product. The tip of the container should not come into contact with any surface including the eye, as this may cause injury to the eye and contaminate the solution.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If patients experience headache, eye pain, vision changes, irritation of the eyes, persistent redness or if the condition persists or worsens, treatment should be discontinued and the patient should consult the physician/ ophthalmologist.

Oculac eye drops contain benzalkonium chloride as a preservative. Benzalkonium chloride may cause eye irritation and is known to discolour soft contact lenses. Therefore avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions have been described.

If the patient instils other medication(s) into the eyes (e.g. for the treatment of glaucoma), there must be an interval of at least 5 minutes between medications. Oculac should always be instilled last.

4.6 Fertility, Pregnancy and lactation

Pregnancy:
There are no data from the use of povidone in pregnant women. Systemic exposure via ocular administration is likely to be negligible.

Animal studies are insufficient with respect to reproductive toxicity. The use of Oculac eye drops may be considered during pregnancy, if necessary.

Breast-feeding:
It is unknown whether povidone is excreted in human milk. However, no effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman is negligible. Ocular eye drops can be used during breast-feeding

Fertility:
Studies have not been performed to evaluate the effect of topical ocular administration of Oculac eye drops on human fertility. It is unlikely that povidone from Oculac eye drops affects male or female fertility.

4.7 Effects on ability to drive and use machines

Oculac 50 mg/ml, eye drops solution has no or negligible influence on the ability to drive and use machines.

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. In the event of temporary blurring of vision, patients must refrain from driving vehicles or operating machinery until the vision clears.

4.8 Undesirable effects

Adverse reactions are ranked under heading of frequency, using the following convention: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

The following adverse events have been reported:

- Immune system disorders
  Very rare: Irritation or hypersensitivity reactions

- Eye disorders
  Common: –Eye irritation, abnormal sensation in eye.
  Not known: Blurred vision, eye pain, eye pruritus, ocular hyperaemia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Due to the characteristics of this preparation, a topical overdose with Oculac eye drops is not likely to occur or to be associated with toxicity. Also, no toxic effects are to be expected with an accidental ingestion of the contents of one bottle. No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophtalmologicals, artificial tears and other products, ATC code: S01XA20.

The product does not contain any active pharmacological compounds. Due to their physical properties, non-irritant water soluble polymers can be used for moistening and lubrication of the ocular surface.

5.2 Pharmacokinetic properties

Orally administered povidone with a molecular weight of 12,600 is rapidly excreted in the urine, with the major part being excreted within 11 hours.

Following intravenous administration, long-term accumulation of povidone can be avoided by reducing the proportion of povidone of molecular weight higher than 25,000. On account of the relatively large size of the povidone molecule, penetration through the cornea is unlikely.

5.3 Preclinical safety data

No toxic effects were observed during or after two years' administration of 5 and 10% PVP K25 (povidone) in the feed of rats. No data on mutagenicity or teratogenicity are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Boric acid
Calcium chloride
Potassium chloride
Magnesium chloride
Sodium chloride
Sodium lactate
Sodium hydroxide for pH adjustment
Water for injections

6.2 Incompatibilities

High salt concentrations, e.g. of sodium sulphate in cold and of sodium chloride in warm conditions, can result in precipitation of povidone. Depending on the ionic strength of the solution, methyl- and propylhydroxybenzoates easily form complexes with povidone.

6.3 Shelf life

Unopened container: 2 years
After opening: 4 weeks

6.4 Special precautions for storage

Do not store above 25°C.
Keep container in the outer carton in order to protect from light.

6.5 Nature and contents of container

The container is a transparent PP -bottle with a transparent PP -dropper and a white HDPE screw cap with an integrated safety ring. One bottle contains 10 ml of the solution.

6.6 Special precautions for disposal

The content of the package will remain sterile until the original closure is broken. Any contents remaining 4 weeks after opening should be discarded.

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

1 December 2025