SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Siccapos® Gel, 2.0 mg/g, eye gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 g of gel contains
Polyacrylic acid (Carbomer 980) 2.0 mg

For the full list of excipients, see

section 6.1.

3. PHARMACEUTICAL FORM

Eye gel

Osmolality: 225 - 275 mOsm/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Substitution of tears in case of a lack in tear production and dry eye syndrome.

4.2 Posology and method of administration

Posology
The treatment of dry eye requires an individual dosage. Depending on the severity and intensity of the symptoms, 1 drop should be instilled into the conjunctival sac 3 to 5 times daily and more often, and before night.

The same dosage applies to adults and children.

Children and adolescents under 18 years of age
Clinical experience has shown the safety and efficacy of the application of Siccapos® Gel in children and adolescents in the dosage recommended for adults. Data from clinical trials are not available.

Method of administration
For ocular use.

A contact of the tube tip with the eye or the skin should be avoided.

For the treatment of the dry eye syndrome, which normally is a long-term or permanent treatment, an ophthalmologist should be consulted.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Siccapos® Gel should not be used while wearing contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Note:
In case of concomitant treatment with other eye drops/ointments, a period of 15 minutes should elapse between the application of the different medicines. In any case, Siccapos® Gel should be applied at last.

4.6 Fertility, pregnancy and lactation

There are no clinical studies available dealing with the use of Siccapos® Gel in pregnancy and lactation.

Because of the mode of action of Siccapos® Gel, a harmful effect on the fetus or the infant is not to be expected.

4.7 Effects on ability to drive and use machines

This medicinal product transiently impairs vision and thus the reaction capability in traffic or when operating machines.

4.8 Undesirable effects

For the assessment of side effects the following frequencies of occurrence are defined:

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

Hypersensitivity reactions against one of the ingredients may occur very rarely.

Siccapos® Gel contains the preservative cetrimide, which may cause eye irritation (burning, redness, foreign-body sensation) and damage of the corneal epithelium,

particularly in frequent and long-term application,. Therefore, preservative-free medicinal products should be preferred for long-term treatment of keratoconjunctivitis sicca.

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.

4.9 Overdose

No cases of overdose have been reported until now. A special treatment is not known and not required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Artificial tears, ATC code: S01XA20

A pharmacological effect is not claimed for Siccapos® Gel. The gel structure of polyacrylic acid, which keeps hold of moisture, is destroyed by the salts in the lacrimal fluid and thus releases the moisture to the eye. For this reason, patients with severe dry eye syndrome usually do not need to use Siccapos® Gel more frequently than patients with less severe dry eye.

5.2 Pharmacokinetic properties

There are no pharmacokinetic data for the application of Siccapos® Gel to the human eye. Because of its physicochemical properties, Siccapos® Gel remains on the surface of the eye as long as possible and does not penetrate into the eye. Because of its high molecular weight, absorption and deposition of the polymer in the ocular tissues are not to be expected.

5.3 Preclinical safety data

Harmful effects after local application are not to be expected. Possible systemically available quantities of the medicinal product represent no toxicological risk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1 g of gel contains:
Sorbitol 40.0 mg, cetrimid (preservative) 0.1 mg, water for injections 957.03 mg, sodium hydroxide, sodium edetate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Siccapos® Gel can be used up to 4 weeks after first opening of the tube.

Siccapos® Gel should not be used beyond the expiry date (imprinted on the tube/folding carton).

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Aluminium tube with screw cap of polyethylen.
The following package sizes are available: Folding carton with 1 tube or 3 tubes of 10 g gel.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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H2005/342

9. DATE OF FIRST AUTHORIZATION/RENEWAL

June 2026

10. DATE OF REVISION OF THE TEXT

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