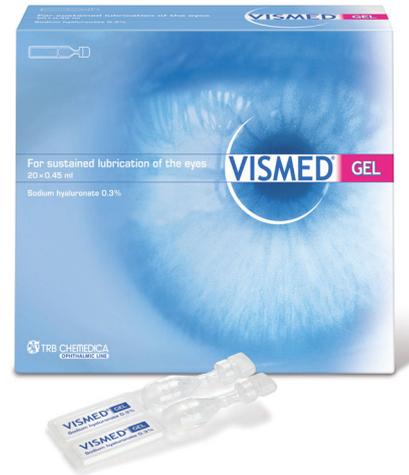




For sustained lubrication of the eyes



NAME OF PRODUCT:

VISMED® GEL

Hydrogel for sustained lubrication of the eyes

INDICATIONS:

Symptoms and signs of dry eye and/or ocular surface damage, due to diseases such as superficial keratitis, Sjögren syndrome or primary dry eye syndrome. For sustained lubrication of the eyes in case of sensation of dryness, burning and ocular fatigue and other minor complaints of no pathological significance, induced, for example, by dust, smoke, dry heat, air conditioning, wind, cold, extended computer screen use, contact lens wear (rigid or soft) or by ophthalmological screening methods.

COMPOSITION:

Active ingredient:

Sodium hyaluronate from fermentation 0.3%

Excipients:

Sodium chloride, potassium chloride, disodium phosphate, sodium citrate, magnesium chloride, calcium chloride and water for injections. The solution is hypotonic (150 mOsm/l) and adjusted to pH 7.3.

PRESENTATION:

Sterile monodose units of 0.45 ml containing 0.3% sodium hyaluronate for topical ophthalmic use. VISMED® GEL is preservative-free.

DOSAGE AND ADMINISTRATION:

Twist off the tab and position the tip of the monodose unit above the eye to be treated: upon slight pressure, VISMED® GEL will easily flow out of the monodose unit. If not otherwise recommended, place one or two drops of VISMED® GEL into the conjunctival sac of the eye as often as needed. A sensation of blurred vision may be experienced immediately after application. After blinking, the solution will disperse and form a transparent and long-lasting coating on the surface of the eye. VISMED® GEL may also be used while wearing contact lenses (rigid or soft). Reclose the container after use. As VISMED® GEL does not contain preservatives, the solution should be used within 12 hours after opening.

CHARACTERISTICS AND MODE OF ACTION:

VISMED® GEL contains a highly purified specific fraction of sodium salt of hyaluronic acid produced by bacterial fermentation and is therefore free from animal proteins. Hyaluronic acid is a natural polymer, which is present throughout the human body and also in the structures of human eyes. Its main physical characteristic is viscoelasticity. This means that VISMED® GEL has a high viscosity between blinks and a low viscosity during blinking, ensuring efficient coating of the surface of the eye.^{1,2} Hyaluronic acid also possesses mucoadhesive properties³ and the ability to entrap water,⁴ thus resembling tear mucus glycoprotein.²



With its carefully balanced concentration and molecular weight of hyaluronic acid, VISMED® GEL is highly effective in coating the cornea. This protective coating of the eye surface has a beneficial effect in the healing of superficial keratitis by promoting rapid cell migration.⁵

The core mechanisms of dry eye are driven by tear hyperosmolarity and tear film instability.⁶ Therefore VISMED® GEL is hypotonic (150 mOsm/l) to counteract the hyperosmolarity of tears associated with sensations of ocular dryness.⁷

VISMED® GEL has a uniquely patented formulation that contains the essential ions calcium, magnesium and potassium found in natural tears and important to maintain healthy structure and function of the cornea.^{8,9}

VISMED® GEL offers an unmatched combination of long-lasting protection, symptomatic relief and comfort by increasing the tear film break-up time,¹⁰ due to its increased residence time,¹¹ and coating ability, as well as providing all of the elements required to restore the normal properties of the tear film.

BIOCOMPATIBILITY:

Results of acute, sub-acute and chronic toxicity studies together with the results of the foetal toxicity, fertility, peri- and post-natal toxicity studies show that hyaluronic acid is very well tolerated.^{12, 13} In addition, animal studies show that repeated topical ocular administration of hyaluronic acid is also well tolerated.¹⁴

INTERACTIONS:

Do not use VISMED® GEL at the same time as any other drug or product applied to the eye since it may modify their effects.

STORAGE:

Store between 2°C and 25°C.

SHELF-LIFE:

3 years if stored in original packaging.

PACKAGING:

VISMED® GEL is presented in boxes of 20 (or 60) monodose units. Each box contains 1 (or 3) heat-sealed polyethylene-aluminium sachet(s), each containing 4 strips of 5 monodose units.

REFERENCES:

1. Bron AJ. *Trans Ophthalmol Soc UK* 1985; 104: 801–26.
2. Tiffany JM. *Adv Exp Med Biol* 1994; 350: 231–8.
3. Saettone MF et al. *Int J Pharm* 1989; 51: 203–12.
4. Balazs EA. *Band P Cosmetics Toiletries* 1984; 99: 65–72.
5. Gomes JAP et al. *Br j Ophthalmol* 2004; 88: 821–25.
6. *The Ocular Surface DEWS Definition and Classification* 2007; 5(2): 75–92.
7. Gilbard JP, Kenyon KR. *Ophthalmology* 1985; 92: 646–50.
8. Reddy IK et al. In: Reddy K (ed) *Ocular therapeutics and drug delivery. A multidisciplinary approach* Basel: Technomic Publications, 1996: 171–211.
9. Green K et al. *Ophthalmic Res* 1992; 24: 99–102.
10. Johnson ME et al. *Graefe's Arch Clin Exp Ophthalmol* 2006; 244: 109–12.
11. Gurny R et al. *Graefe's Arch Clin Exp Ophthalmol* 1990; 228: 510–2.
12. Nozaki Y et al. *Jpn Pharmacol Ther* 1993; 21: 87–102.
13. Sawa M et al. *J Jpn Ophthalmol* 1993; 97: 448–54.
14. TRB Chemedica: Data on file.