



For optimum efficacy and tolerability



NAME OF PRODUCT:

VISMED®
Lubricant eye drops

INSTRUCTIONS:

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 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 or contact lens wear (rigid or soft).

COMPOSITION:

Active ingredient:

Sodium hyaluronate from fermentation 0.18%

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 0.3 ml containing 0.18% sodium hyaluronate for topical ophthalmic use. VISMED® is preservative-free.

DOSAGE AND ADMINISTRATION:

Twist off tab. If not otherwise recommended, place one or two drops of VISMED® into the conjunctival sac of the eye as often as needed. After blinking, the solution will disperse and form a transparent and long-lasting coating on the surface of the eye. VISMED® may also be used while wearing contact lenses (rigid or soft). As VISMED® does not contain preservatives, any solution not used immediately after opening should be discarded.

CHARACTERISTICS AND MODE OF ACTION:

VISMED® 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® 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 This, together with the coating properties of hyaluronic acid results in an increased pre-corneal residence time⁵ and tear film break-up time^{6,7} and therefore a longer lubrication of the corneal surface. The protective coating of the eye surface offered by VISMED® helps prevent dryness and irritation.

The core mechanisms of dry eye are driven by tear hyperosmolarity and tear film instability.⁸ The hypotonic solution VISMED® (150 mOsm/l) counteracts the hyperosmolarity of altered tear fluid thus limiting corneal damage.⁹

VISMED® 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.^{10,11}

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® 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® 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. Gurny R et al. *Graefes Arch Clin Exp Ophthalmol* 1990; 228: 510–2.
6. Mengher LS et al. *Br J Ophthalmol* 1986; 70: 442–7.
7. Hamano T et al. *Jpn J Ophthalmol* 1996; 40: 62–5.
8. *The Ocular Surface DEWS Definition and Classification* 2007; 5(2): 75–92.
9. Gilbard JP, Kenyon KR. *Ophthalmology* 1985; 92: 646–50.
10. Reddy IK et al. In: Reddy K (ed) *Ocular therapeutics and drug delivery. A multidisciplinary approach* Basel: Technomic Publications, 1996: 171–211.
11. Green K et al. *Ophthalmic Res* 1992; 24: 99–102.
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.