

## SUMMARY OF PRODUCT CHARACTERISTICS – VISMED

### 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.<sup>1,2</sup> Hyaluronic acid also possesses mucoadhesive properties<sup>3</sup> and the ability to entrap water,<sup>4</sup> thus resembling tear mucus glycoprotein.<sup>2</sup> This, together with the coating properties of hyaluronic acid results in an increased pre-corneal residence time<sup>5</sup> and tear film break-up time<sup>6,7</sup> 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.<sup>8</sup> The hypotonic solution VISMED® (150 mOsm/l) counteracts the hyperosmolarity of altered tear fluid thus limiting corneal damage.<sup>9</sup>

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.<sup>10,11</sup>

### 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.<sup>12,13</sup> In addition, animal studies show that repeated topical ocular administration of hyaluronic acid is also well tolerated.<sup>14</sup>

### INTERACTIONS:

Do not use VISMED® at the same time as any other drug or product applied to the eye as 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 monodose units. Each box contains 1 heat-sealed polyethylene-aluminium sachet with 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. Jpn Ophthalmol 1993; 97: 448–54.
14. TRB Chemedica: Data on file.

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## SUMMARY OF PRODUCT CHARACTERISTICS – VISMED MULTI

### NAME OF PRODUCT:

VISMED® MULTI  
Lubricant eye drops



### 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 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:

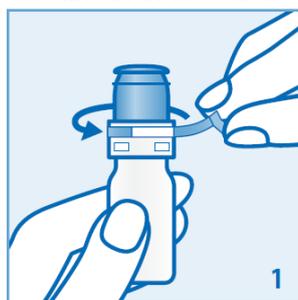
Sterile multidose container of 10 ml containing 0.18% sodium hyaluronate with an innovative squeezable dispenser for topical ophthalmic use. VISMED® MULTI is preservative-free.

### DOSAGE AND ADMINISTRATION:

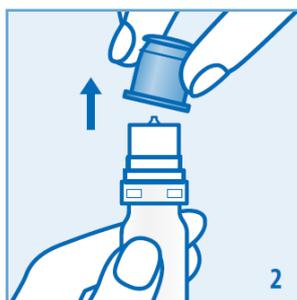
The VISMED® MULTI container is equipped with an innovative dosage system, which facilitates the instillation of the drop into the eye.

Tear off the tamper-evident seal before the first administration (Fig. 1). Remove the protective cap (Fig. 2). Tilt the head backwards and position the tip of the container above the eye to be treated. Do not touch the tip of the opened container and do not touch the surface of the eye with the tip of the container. Move the lower eyelid down with the forefinger of one hand. Press the container and one drop of VISMED® MULTI will easily flow out (Fig. 3). If not otherwise recommended, instill 1 or 2 drops of VISMED® MULTI onto the eye as often as needed. Put the protective cap back on after using VISMED® MULTI (Fig. 4). After blinking, the solution will disperse and form a transparent and long lasting coating on the surface of the eye.

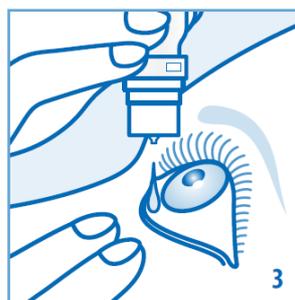
VISMED® MULTI may also be used while wearing contact lenses (rigid or soft). VISMED® MULTI can be used up to 3 months after first use.



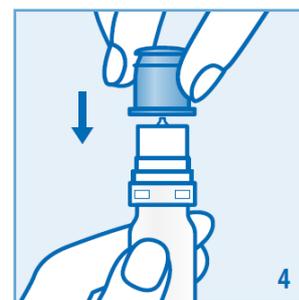
Remove the tamper-evident seal.



Remove the protective cap.



Instill one or two drops onto the eye.



Put the protective cap back on after administration.

### CHARACTERISTICS AND MODE OF ACTION:

VISMED® MULTI contains a highly purified specific fraction of sodium salt of hyaluronic acid produced by bacterial fermentation. 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® MULTI has a high viscosity between blinks and a low viscosity during blinking, ensuring efficient coating of the surface of the eye.<sup>1,2</sup> Hyaluronic acid also possesses mucoadhesive properties<sup>3</sup> and the ability to entrap water,<sup>4</sup> thus resembling tear mucus glycoprotein.<sup>2</sup> This, together with the coating properties of hyaluronic acid results in an increased pre-corneal residence time<sup>5</sup> and tear film break-up time<sup>6,7</sup> and therefore a longer lubrication of the corneal surface. The protective coating of the eye surface offered by VISMED® multi helps prevent dryness and irritation.

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

VISMED® multi 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.<sup>10,11</sup>

### 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.<sup>12,13</sup> In addition, animal studies show that repeated topical ocular administration of hyaluronic acid is also well tolerated.<sup>14</sup>

### INTERACTIONS:

Do not use VISMED<sup>®</sup> MULTI at the same time as any other drug or product applied to the eye as it may modify their effects.

### STORAGE:

Store between 2°C and 25°C.

### SHELF-LIFE:

2 years if stored in original packaging.

### PACKAGING:

VISMED<sup>®</sup> MULTI is presented in a preservative-free, multidose container of 10ml.

### 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. 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(2): 87-102.
13. Sawa M et al. J Jpn Ophthalmol 1993; 97: 448–54.
14. T RB Chemedica: Data on file.



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## SUMMARY OF PRODUCT CHARACTERISTICS – VISMED GEL

### **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.<sup>1,2</sup>

Hyaluronic acid also possesses mucoadhesive properties<sup>3</sup> and the ability to entrap water,<sup>4</sup> thus resembling tear mucus glycoprotein.<sup>2</sup>

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.<sup>5</sup>

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

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.<sup>8,9</sup>

VISMED® GEL offers an unmatched combination of long-lasting protection, symptomatic relief and comfort by increasing the tear film break-up time,<sup>10</sup> due to its increased residence time,<sup>11</sup> 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.<sup>12, 13</sup> In addition, animal studies show that repeated topical ocular administration of hyaluronic acid is also well tolerated.<sup>14</sup>

### **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 monodose units. Each box contains 1 heat-sealed polyethylene-aluminium sachet(s) with 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.



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## SUMMARY OF PRODUCT CHARACTERISTICS – VISMED GEL MULTI

### NAME OF PRODUCT

VISMED® GEL MULTI

Sodium hyaluronate from fermentation 0.3 %.

Hydrogel for sustained lubrication of the eyes.

Sterile, free from preservatives.



### COMPOSITION

1 ml solution contains sodium hyaluronate 3.0 mg, sodium chloride, potassium chloride, disodium phosphate, sodium citrate, magnesium chloride, calcium chloride and water for injections. The solution is hypotonic.

### 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, contact lens wear (rigid or soft) or by ophthalmological screening methods.

### CONTRA-INDICATIONS

Individual hypersensitivity to any constituent of the product.

### INTERACTIONS

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

### UNDESIRABLE EFFECTS

On very rare occasions transient disorders such as irritation of the conjunctiva, foreign body sensation, redness or burning sensation of the eye, short-term blurred vision may occur.

### DOSAGE AND ADMINISTRATION

Tear off the tamper-evident seal before the first administration. Remove the protective cap. Tilt the head backwards and position the tip of the container above the eye to be treated. Move the lower eyelid down with the forefinger of one hand. Press the container and one drop of VISMED® GEL MULTI will easily flow out. If not otherwise recommended, instill 1 or 2 drops of VISMED® GEL MULTI onto 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® GEL MULTI may also be used while wearing contact lenses (rigid or soft).

### PRECAUTIONS

Do not touch the tip of the opened container and do not touch the surface of the eye with the tip of the container. Put the protective cap back on after using VISMED® GEL MULTI. Do not use VISMED® GEL MULTI if the container is damaged. VISMED® GEL MULTI can be used up to 3 months after first use. Any solution not used within 3 months after opening must be discarded. Otherwise the sterility is no longer guaranteed and may be associated with an enhanced risk of infection. Store between 2 °C and 25 °C! Do not use VISMED® GEL MULTI after the expiry date indicated on the container and the folding box. If discomfort persists while using VISMED® GEL MULTI consult a physician. Keep out of reach of children.

### CHARACTERISTICS AND MODE OF ACTION:

VISMED® GEL MULTI contains sodium hyaluronate, a natural polymer, which is also present in the structures of the human eye. The particular physical characteristics of sodium hyaluronate confer to VISMED® GEL MULTI its viscoelastic and water retaining properties. VISMED® GEL MULTI provides a stable coating on the surface of the eye which is only slowly eliminated by blinking. Therefore VISMED® GEL MULTI combines long lasting relief with maximum comfort. VISMED® GEL MULTI is well tolerated due to its unique composition. VISMED® GEL MULTI is free from preservatives.

### PRESENTATION:

10 ml solution in a multidose container.

Last revision date: March 2012

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