## Instructions for use — English

# Pe-Ha-Visco®

Hydroxypropyl methylcellulose

**Description**

**Pe-Ha-Visco®** is a clear, sterile, isotonic and viscoelastic preparation of hydroxypropyl methylcellulose (HPMC) for intraocular use, dissolved in a buffered physiological solution (pH 6.8 – 7.5).
The hydrogel contains 2.0% or 2.4% HPMC and is filled in a ready-to-use syringe for single use. It is packaged in a sterile blister pack.
The product is free from preservatives. It has been subjected to moist heat sterilisation for injectable products and is non-pyrogenic. There are no known inflammatory or immunogenic reactions.

Chemical composition (w/v) as mg of substance per 1 ml hydrogel: See table.

**Product characteristics and mode of action**

As an aid during surgery of the anterior segment of the eye, **Pe-Ha-Visco®** maintains the depth of the anterior chamber and protects the surrounding intraocular tissue.
**Pe-Ha-Visco®** supports intraocular surgery thanks to its viscoelastic and wetting properties.
Due to its water solubility, **Pe-Ha-Visco®** is easily removed by irrigation and aspiration at the end of surgery.

**Indications**

**Pe-Ha-Visco®** is used as a volume substitute for the aqueous humour during intraocular surgery such as lens extraction and insertion of an intraocular lens.
**Pe-Ha-Visco®** maintains the depth of the anterior chamber throughout surgery and reduces the risk of traumatisation of the corneal endothelium, the iris and the ciliary body as a result of direct contact with surgical instruments.

**Contraindications**

**Pe-Ha-Visco®** should not be used in patients with known hypersensitivity to hydroxypropyl methylcellulose or to any other constituent of the hydrogel.
Children, pregnant or nursing women should not be treated with hydroxypropyl methylcellulose as there is no clinical data available on its use in these patients.

**Precautions**

Observe all routine precautions which are required during ophthalmic surgery.
**Pe-Ha-Visco®**, together with the enclosed single-use cannula, sterilised using ethylene oxide, is intended for single intraocular use in one eye only. It must not be resterilised, resealed or reused. Do not resterilise the solution, as this can cause changes to the product characteristics. Do not use **Pe-Ha-Visco®** if there is any damage to the ready-to-use-syringe or sterile packaging.
The product should be used for one patient only during a single appointment.

**Potential side effects**

After the intraoperative use of **Pe-Ha-Visco®**, a transient post-operative rise in intraocular pressure may occur. Suitable treatment to reduce the intraocular pressure can counteract this increase.

The healthcare professional should advise the patient
- of any potential adverse events related to the product,
- that the patient must report any adverse event or complication to a physician.

**Drug and chemical interactions**

To date, there is no available data on the incompatibility of the product with other products for use on or in the eye.

**Dosage, mode and duration of treatment**

Evacuate the air from the enclosed sterile ophthalmological single-use cannula (or a comparable sterile cannula 20-25G/with luer lock) before injecting **Pe-Ha-Visco®** into the anterior chamber.
For intraocular lens implantation, coat the implant and the instruments with **Pe-Ha-Visco®** immediately before surgery. This also protects the endothelium and surrounding tissue.
The **Pe-Ha-Visco®** volume for injection will vary based on the individual patient and the surgical procedure. To compensate for loss of viscoelasticity caused by leakage or irrigation, several **Pe-Ha-Visco®** injections may be performed. Do not exert any further pressure on the plunger prior to removing the cannula from the eye. This prevents the aspiration of air bubbles into the cannula.
Remove all **Pe-Ha-Visco®** at the end of surgery using a suitable irrigation/aspiration device.

**Dosage form**

a) Box with one sterile ready-to-use syringe containing 2.0 ml hydrogel and one sterile single-use luer lock cannula.
b) Box with 10 sterile ready-to-use syringes containing 2.0 ml hydrogel and 10 sterile single-use luer lock cannulas.

**Shelf life**

Do not use **Pe-Ha-Visco®** after the expiry date. The expiry date (year/month) is printed on the syringe blister pack and box.

**Storage**

Store in the original packaging in a dry place at room temperature and away from light. Avoid freezing or impact. Always observe the information symbols on the packaging.
Store this product in a location inaccessible to children.

**User information/Recommended user type**

For use solely by trained ophthalmologists.

If a product from damaged packaging is used, or a product reused on other patients, or on the same patient at a later time, the intended properties and sterility of the product cannot be guaranteed. Potential material contamination and transfer of pathogens from the general environment, the clinical environment or (other) patients could lead to health complications. Resealing or resterilisation is not a permitted or guaranteed method of restoring the product to a usable condition.

**Disposal**

The syringe contents are non-toxic and non-flammable.
Unused syringes and their contents are not infectious and may be disposed of before or after their expiry date, in accordance with national and local regulations. Used syringes and cannulas must be disposed of as epidemiologically hazardous waste in line with national and local regulations for safe handling and disposal.

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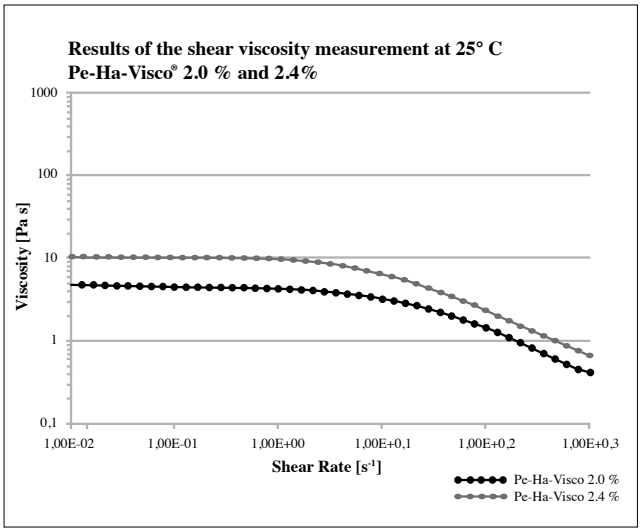
Storage at room temperature

Free from pyrogens

Formula (w/v)

| 1 ml contains: | 2.0 % | 2.4 % |
|---|---|---|
| Hydroxypropyl methylcellulose (HPMC) (a) | 20.00 mg | 24.00 mg |
| Sodium chloride (b) | 6.40 mg | 6.40 mg |
| Potassium chloride (c) | 0.750 mg | 0.750 mg |
| Calcium chloride 2 $H_2O$ (d) | 0.480 mg | 0.480 mg |
| Magnesium chloride 6 $H_2O$ (e) | 0.300 mg | 0.300 mg |
| Sodium acetate 3 $H_2O$ (f) | 3.900 mg | 3.900 mg |
| Sodium citrate 2 $H_2O$ (g) | 1.700 mg | 1.700 mg |
| Water for injection (h) | q.s. | q.s. |

Viscous Behaviour - Example

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