

Pe-Ha-Blue® PLUS

Sodium hyaluronate 1.7% + trypan blue 0.002%

Description

Pe-Ha-Blue® PLUS comprises one sterile ready-to-use syringe and one sterile single-use luer lock cannula in a blister pack. The syringe contains a clear, viscoelastic hydrogel of 1.7% high molecular weight sodium hyaluronate in an isotonic, physiological phosphate-buffered saline solution (pH 6.8 – 7.4). To enhance contrast during ophthalmic surgery, **Pe-Ha-Blue® PLUS** contains the azo dye trypan blue, which gives the hydrogel a slightly bluish colour.

The product is free from preservatives. It has been subjected to moist heat sterilisation for injectable products and is non-pyrogenic. It is non-toxic to the endothelium. There are no known inflammatory or immunogenic reactions. Chemical composition (w/v) as mg of substance per 1 ml hydrogel: See

Product characteristics and mode of action

The glycosaminoglycane hyaluronic acid is a water-retaining biopolymer and a quantitatively predominant chemical component of the eyeball. The sodium hyaluronate in the **Pe-Ha-Blue® PLUS** hydrogel is a water-soluble salt form of hyaluronic acid, which has a high molecular weight and is obtained via bacterial fermentation and purification. As a biocompatible substance, it possesses favourable physical-rheological properties for ophthalmic surgery. The viscoelastic **Pe-Ha-Blue® PLUS** lubricates, supports and protects the ocular tissue during ophthalmic surgery and maintains the depth of the anterior chamber. The thin protective layer formed by the hydrogel on the ocular cells and tissue facilitates the surgical insertion of the intraocular lens. If the red reflex is compromised during surgery, the trypan blue staining improves the visibility which is needed to perform an optimal capsulorhexis. Due to its water solubility, **Pe-Ha-Blue® PLUS** is easily removed by irrigation and aspiration at the end of surgery.

Indications

Pe-Ha-Blue® PLUS is suitable for use as an adjuvant for anterior chamber surgery with additional contrast enhancement and improved visualisation for the following procedures:

- Cataract surgery with or without intraocular lens implantation
- Glaucoma surgery

Contraindications

Pe-Ha-Blue® PLUS should not be used in patients with known hypersensitivity to sodium hyaluronate, trypan blue or to any other constituent of the hydrogel. Children, pregnant or nursing women should not be treated with hyaluronic acid 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-Blue® PLUS, together with the enclosed single-use cannula sterilised using ethylene oxide, is intended for brief, single intraocular use in one eye only. It must not be resterilised, resealed or reused. Do not resterilise, as this can cause changes to the product characteristics. Do not use **Pe-Ha-Blue® PLUS** 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.

Teratogenic, carcinogenic and/or mutagenic effects have been observed in animal trials using repeated intraperitoneal or intravenous injections of trypan blue, and/or at much higher doses. Consequently, the product must not be used in pregnant or nursing women. In diabetics in particular, trypan blue can cause capsule rigidity and a significant loss in elasticity, which may lead to an elevated risk of capsule rupture.

Potential side effects

After the intraoperative use of **Pe-Ha-Blue® PLUS**, a transient post-operative rise in intraocular pressure may occur. Suitable treatment to reduce the intraocular pressure can counteract this increase. Undesirable staining of the posterior capsule or of the anterior vitreous is possible, but usually disappears without treatment within one week. 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. Sodium hyaluronate and quaternary ammonium compounds such as benzalkonium chloride are chemically incompatible, which may lead to crystalline precipitation. Consequently, this product should never come in contact with surgical instruments or other products that contain these compounds, or which were cleaned using solutions containing quaternary ammonium compounds as biocidal preservatives.

Dosage, mode and duration of treatment

If **Pe-Ha-Blue® PLUS** has been stored in the refrigerator, remove the syringe from the refrigerator at least 20 minutes prior to use.

Evacuate the air from the enclosed sterile ophthalmological single-use cannula (or a comparable sterile cannula) before injecting **Pe-Ha-Blue® PLUS** into the anterior chamber.

The amount used depends on the surgical procedure. To compensate for loss of viscoelasticity caused by leakage or irrigation, several **Pe-Ha-Blue® PLUS** 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-Blue® PLUS** at the end of surgery using a suitable irrigation/aspiration device.

Dosage form

Box with one sterile ready-to-use syringe containing 1.0 ml hydrogel and one sterile single-use luer lock cannula.

Shelf life

Do not use **Pe-Ha-Blue® PLUS** 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 between 2° and 25°C 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. Resterilising or reesterilisation is not a permitted or guaranteed method of restoring the product to a usable condition.

Disposal

The syringe contents are 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.

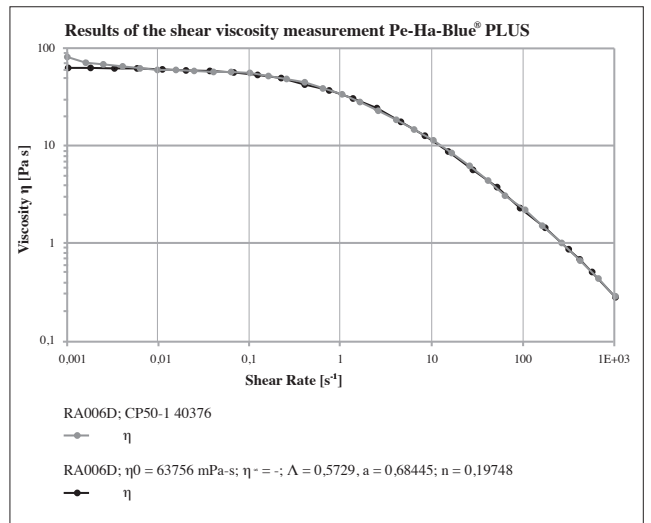
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Formula (w/v)

1 ml contains:	1.7 %
Sodium hyaluronate (a)	17.00 mg
Sodium chloride (b)	8.50 mg
Disodium hydrogen phosphate 2 H ₂ O (c)	0.563 mg
Sodium dihydrogen phosphate 2 H ₂ O (d)	0.045 mg
Trypan Blue (e)	0.02 mg
Water for injection (f)	q. s.

Viscous Behaviour - Example



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