

IXIUM HCS

VISCO DISPERSIVE



DESCRIPTION :

IXIUM HCS is a visco-elastic high molecular weight solution of a non-inflammatory, highly purified grade of Sodium Hyaluronate and Chondroitin Sulfate, clear, isotonic, sterile and non-pyrogenic for intraocular injection during surgery of the anterior segment of the eye. IXIUM HCS is a sterile preparation supplied in a 1,0 mL pre-filled glass syringe with disposable cannula, Luer lock.

CHARACTERISTICS :

The sodium hyaluronate used for the manufacturing of IXIUM HCS is a pharmaceutical quality polysaccharide with a high molecular weight composed of sodium glucuronate and N-acetylglucosamine and is obtained by fermentation of a bacterial origin. Sodium hyaluronate is a physiological substance present in large quantities in numerous conjunctive tissues in man and animals, in particular, in the vitreous, the synovial liquid and the umbilical cord.

IXIUM HCS is a medical device to assist in surgery of the anterior segment of the eye, the rheological and lubricating characteristics of which are completely adapted to the different operating phases of cataract surgery.

IXIUM HCS :

- maintains the endoocular space of the anterior segment and preserves the integrity of the tissues of the eye,
- has outstanding rheological properties, that ease capsulorhexis and lens insertion,
- allows excellent visibility of the operating space
- is simple to remove from the anterior chamber,
- does not interfere with the process of cicatrisation
- is not antigenic and is well tolerated by the human eye.

COMPOSITION :

name		function
Sodium hyaluronate	2000 mg	viscosity
Chondroitin Sulfate	2000 mg	viscosity
Sodium chlorid	700 mg	isotonicity
Water for injection	to 100 ml	dissolution

PROPERTIES :

- IXIUM HCS is a clear, isotonic, sterile, non-pyrogenic, visco-elastic solution, iso-osmotic with aqueous humour, which contains 2 percent by weight of a highly purified grade of sodium hyaluronate of high molecular weight (around 2 400 000 dalton) and 2 percent of Chondroitin Sulfate.
- IXIUM HCS is a visco-elastic gel, whose properties of elasticity, cohesion and coatability provide ideal conditions for intraocular surgery. On account of its visco-elastic properties, IXIUM HCS ensures protection of intraocular tissues, especially the endothelium of the cornea, during surgery.
- IXIUM HCS is used to maintain the depth and integrity of the anterior chamber of the eye, thus facilitating surgery.
- IXIUM HCS is apyrogenic and nonantigenic and is well tolerated by the human eye.

INDICATIONS :

IXIUM HCS is indicated as a surgical aid (medical device) during surgical procedures involving the anterior chamber of the eye, including extraction of the lens and insertion of intraocular lenses. IXIUM HCS maintains the depth of the anterior chamber during the whole surgical procedure and permits greater operative precision without the risk of damaging the endothelium of the cornea or other intraocular tissues.

USAGE PRECAUTIONS :

- The following usage precautions are recommended during surgery of the anterior segment :
- Check the integrity of the packaging before use to ensure the product has remained sterile.
 - The cannula and the syringe are for single intraocular use only.
 - The normal precautions associated with ocular microsurgery should be observed.

- The quantity injected into the anterior chamber of the eye must be adjusted according to the volume of the aqueous humour and the anatomical structure to be protected.
- Remove all the product by irrigation and/or aspiration at the end of the procedure; mechanical blockage of drainage at the trabecular level may cause a transient increase in intraocular pressure after surgery.
- The product must be administered with care and under close monitoring, particularly in patients with pre-existing glaucoma and in cases of glaucoma surgery and where surgery is combined with extraction of the lens. If intraocular pressure rises above normal after surgery, appropriate treatment should be prescribed.
- All post-operative inflammatory reactions (iritis, hypopyon, uveitis) and œdematous corneal decompensation are inherent in surgical procedures involving the anterior chamber of the eye, and no relationship with the product has been established.

INCOMPATIBILITIES :

Do not use quaternary ammonium (benzalkonium chloride) with IXIUM HCS, since sodium hyaluronate precipitates in the presence of quaternary ammonium.

CONTRA-INDICATIONS :

There is no contra-indication to the use of IXIUM HCS, if used as instructed in the product information.

CLINICAL APPLICATIONS :

In surgery involving the anterior segment, IXIUM HCS should be carefully and slowly injected into the anterior chamber using a single-use Luer lock cannula (in no case should a reusable cannula be used, even if it is well cleaned, rinsed and resterilized since it could release particles during injection.) IXIUM HCS is injected before the crystalline lens is removed to perform the capsulorhexis procedure, so that its protective effect will be optimized. At this stage of the operation, IXIUM HCS protects the endothelium of the cornea from potential damage by surgical instruments. IXIUM HCS may be injected into the anterior chamber several times during surgery to replace the product lost during the surgical procedure. At the end of the operation, IXIUM HCS should be aspirated completely using an automatic irrigator/aspirator or an irrigation syringe. Never use the original IXIUM HCS syringe.

MODE OF ADMINISTRATION AND ASSEMBLY OF THE SYRINGE

Use a sterile opening technique when removing from the individual sterility protective pack. Open the pack and place the contents on the sterile operating field. Connect the Luer lock cannula to the hub of the syringe by twisting down to the base and confirm correct assembly. Press down on the plunger gently to expel a few drops of the product to prevent the introduction of air bubbles into the anterior chamber of the eye. The syringe is ready to use.

STORAGE :

Do not expose to excessive temperatures. Protect from light.

IXIUM HCS is a medical device CE 0120

Produced in France by LCA SA.
9 Allée Prométhée, F-28000 Chartres, France
For professional use only.

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High-Performing Viscoelastic

NEW

CHONDROITIN (CS 2%)
HYALURONATE (HA 2%)

IXIUM HCS

VISCO DISPERSIVE



CS

+

HA

► CHONDROITIN SULFATE 20 mg/mL

► SODIUM HYALURONATE 20 mg/mL

EXCELLENT ANTERIOR
CHAMBER STABILITY,
LUBRICATING PROPERTIES
& EFFICIENT REMOVAL

HIGH QUALITY
MADE IN FRANCE

NON ANIMAL ORIGIN

LCA PHARMACEUTICAL
EUROPEAN MAKER

LCA PHARMACEUTICAL
9 allée Prométhée, F-28000 Chartres
Phone : +33 (0)2 37 33 39 30
Fax : +33 (0)2 37 33 39 39
E-mail : lca@lca-pharma.com
Web : www.lca-pharma.com

Designed and manufactured by :



CE
0120

IXIUM HCS M0033 070665

At each stage of the surgical procedure

IXIUM HCS

VISCO DISPERSIVE

IXIUM HCS

Ophthalmic viscoelastic device
Sterile, perfectly clear.
Sodium Hyaluronate 20 mg/mL
Chondroitin Sulfate 20 mg/mL.

IXIUM HCS is perfectly clear and allows excellent visibility of the operating space.

IXIUM HCS

Dynamic viscosity
40 000 mPa.s \pm 15 000 (at 1 sec⁻¹ 25°C)
- Sodium Hyaluronate (EP)
Molecular weight : 2 400 000 Daltons
- Chondroitin Sulfate (EP)
Molecular weight : 50 000 Daltons.

IXIUM HCS

Osmolarity : 370 mOsM \pm 30 mOsM
pH : 7.4 \pm 0.2



IXIUM HCS maintains the endocular space of the anterior segment of the eye and easing capsulorhexis.

IXIUM HCS fills completely the capsular bag.

IXIUM HCS facilitate the intraocular lens insertion and implantation.

IXIUM HCS allows perfect lubrication of all injector devices.

IXIUM HCS provides excellent protection of tissues during phacoemulsification with coaxial microincision and bi-manual

