IXIUM NaHA 1.5%

DESCRIPTION :
IXIUM NaHA 1.5% is a visco-elastic high molecular weight solution of a non-inflammatory, highly purified grade of Sodium hyaluronate, clear, isotonic, sterile and non-pyrogenic for intraocular injection during surgery of the anterior segment of the eye. IXIUM NaHA 1.5% 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 NaHA 1.5% is a pharmaceutical quality polysaccharide with a high molecular weight composed of sodium glucoronate 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 NaHA 1.5% 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 NaHA 1.5% :
• maintains the endoocular space of the anterior segment of the eye and preserves the integrity of the tissues.
• 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	1500 mg	viscosity
Sodium chlorid	900 mg	isotonicity
Water for injection	to 100 ml	dissolution

PROPERTIES :
1• IXIUM NaHA 1.5% is a clear, isotonic, sterile, non-pyrogenic, visco-elastic solution, iso-osmotic with aqueous humour, which contains 1.5 percent by weight of a highly purified grade of sodium hyaluronate of high molecular weight (around 2 400 000 dalton).
2• IXIUM NaHA 1.5% is a visco-elastic gel, whose properties of elasticity, cohesion and coatibility provide ideal conditions for intraocular surgery. On account of its visco-elastic properties, IXIUM NaHA 1.5% ensures protection of intraocular tissues, especially the endothelium of the cornea, during surgery.
3• IXIUM NaHA 1.5% is used to maintain the depth and integrity of the anterior chamber of the eye, thus facilitating surgery.
4• IXIUM NaHA 1.5% is apyrogenic and nonantigenic and is well tolerated by the human eye.

INDICATIONS : IXIUM NaHA 1.5% 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 NaHA 1.5% 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 NaHA 1.5%, since sodium hyaluronate precipitates in the presence of quaternary ammonium.

CONTRA-INDICATIONS : There is no contra-indication to the use of IXIUM NaHA 1.5%, if used as instructed in the product information.

CLINICAL APPLICATIONS : In surgery involving the anterior segment, IXIUM NaHA 1.5% 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 NaHA 1.5% 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 NaHA 1.5% protects the endothelium of the cornea from potential damage by surgical instruments. IXIUM NaHA 1.5% 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 NaHA 1.5% should be aspirated completely using an automatic irrigator/aspirator or an irrigation syringe. Never use the original IXIUM NaHA 1.5% 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 : At room temperature, do not expose to excessive temperatures. Protect from light.

IXIUM NaHA 1.5% is a medical device, CE 0120
Produced in France by LCA SA.
9 Allée Prométhée, F-28000 Chartres, France

For professional use only.

Date of revision of the product information : 10/2007

Designed and manufactured by :

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CE 0120

IXIUM NaHA 1.5% M033 070901

High-Performing Viscoelastic

SODIUM HYALURONATE

IXIUM NaHA 1.5%

HIGH QUALITY
MADE IN FRANCE

THE ULTIMATE VISCOELASTIC THAT FASTENS YOUR PROCEDURE

NON ANIMAL ORIGIN

LCA PHARMACEUTICAL
EUROPEAN MAKER

At each stage of the surgical procedure

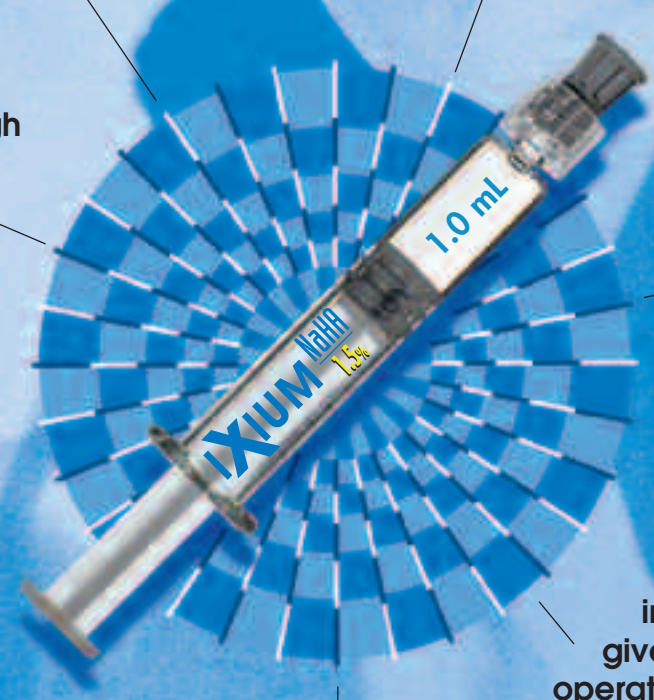
IXIUM NaHA 1.5%

EASY ASPIRATION

IXIUM NaHA 1.5% is a visco-elastic high molecular weight solution of non-inflammatory, highly purified grade of Sodium hyaluronate 1.5%, clear, isotonic, sterile and non-pyrogenic.

OPERATING TIME REDUCTION

The sodium hyaluronate used for the manufacturing of IXIUM NaHA 1.5% is a pharmaceutical quality polysaccharide with a high molecular weight and is obtained by fermentation of a bacterial origin.



SECURITY

IXIUM NaHA 1.5% represents the latest advance in viscoelastics development. Its properties give to the surgeon a great ease of use, reduce operation time by an easy aspiration, and bring the highest level of security due to both (1) an unique process combining aseptic filling and terminal steam sterilisation and (2) use of a hyaluronate sodium from genetic engineering.

LCA Pharmaceutical

IXIUM NaHA 1.5% - Sodium hyaluronate - 15 mg/mL