**IXIUM HCS VISCO DISPERSIVE**

*High-Performing Viscoelastic*

**NEW**

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

**IXIUM HCS VISCO DISPERSIVE**

**CS**  
> CHONDROITIN SULFATE 20 mg/mL

**HA**  
> SODIUM HYALURONATE 20 mg/mL

**EXCELLENT ANTERIOR CHAMBER STABILITY, LUBRATING PROPERTIES & EFFICIENT REMOVAL**

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.

**COMPOSITION :**

- Sodium hyaluronate
- Chondroitin Sulfate
- Sodium chloride
- Water for injection

IXIUM HCS is a visco-elastic high molecular weight solution of a non-inflammatory, highly purified grade of sodium hyaluronate and sodium glucuronic acid 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 endocapsular 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 cicatrization
- is not antigenic and is well tolerated by the human eye.

**COMPOSITION :**

- Sodium hyaluronate: 2000 mg function: viscosity
- Chondroitin Sulfate: 2000 mg function: viscosity
- Sodium chloride: 750 mg function: 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.

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.

IXIUM HCS is a sterile preparation supplied in a 1.0 mL dissolution.

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 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 edematous corneal decompensation are inherent in surgical procedures involving the anterior chamber of the eye, and no relationship with the product has been established.

**STORAGE :**

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

**WARNING :**

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

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 syringes.

**USE OF ADMINISTRATION AND ASSEMBLY OF THE SYRINGE**

Use a sterile opening technique when removing from the individual sterile protective pack. Open the pack and place the contents 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 syringes.

**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.

Date of revision of the product information : 10/2007

IXIUM HCS 0120 FEB 2007

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HIGH QUALITY
MADE IN FRANCE

NON ANIMAL ORIGIN

LCA PHARMACEUTICAL
EUROPEAN MAKER
At each stage of the surgical procedure

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

**IXIUM HCS**
Dynamic viscosity
40 000 mPa.s ± 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 ± 30 mOsM
pH : 7.4 ± 0.2

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

**IXIUM HCS** maintains the endoocular 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
Cataract surgery

NEW

IXIUM DUO

Phase 1

IXIUM HCS

CHONDROITIN SULFATE 2.0%
SODIUM HYALURONATE 2.0%

Phase 2

IXIUM NaHA

SODIUM HYALURONATE 1.5%

1

2

Ophthalmic Viscoelastic Devices

LCA PHARMACEUTICAL
PRODUCT INFORMATION

DESCRIPTION: Xium 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. Xium 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 Xium HCS is a pharmaceutical quality polysaccharide with a high molecular weight composed of sodium glucuronate and N-acetylgalcosamine 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.

Xium HCS is a medical device to assist in surgery of the anterior segment of the eye, the ophthalmologic and urologic characteristics of which are completely adapted to the different operating phases of cataract surgery. Xium HCS:

• maintains the endothelial 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 cavity, without leaving any residue,
• does not interfere with the process of cicatrisation,
• is not antigenic and is well tolerated by the human eye.

COMPOSITION:

<table>
<thead>
<tr>
<th>Base</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hyaluronate</td>
<td>2000 mg viscosity</td>
</tr>
<tr>
<td>Chondroitin Sulfate</td>
<td>2000 mg viscosity</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>730 mg isotonicity</td>
</tr>
</tbody>
</table>

Water for injection to 100 ml dissolution

PROPERTIES:

• Xium 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 (2 800 020 daltons) and 2 percent of Chondroitin Sulfate (50 000 daltons).
• Xium HCS is a visco-elastic gel of elasticity, cohesion and cohesivity provide ideal conditions for intraocular surgery. On account of its visco-elastic properties, Xium HCS ensures protection of intracorneal tissues, especially the endothelium of the cornea, during surgery. Xium HCS is used to maintain the depth and integrity of the anterior chamber of the eye, thus facilitating surgery.
• Xium HCS is an apyrogenic and non-antigenic and is well tolerated by the human eye.

INDICATIONS:

Xium 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. Xium HCS maintains the integrity 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. Ensure the product has remained sterile.
• The cannula and the syringe are for single intraocular use only.
• The normal precautions associated with surgical microscopy 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 edematous 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 Xium HCS, since sodium hyaluronate precipitates in the presence of quaternary ammonium.

CONTRA-INDICATIONS:

There is no contra-indication to the use of Xium HCS. It was used as instructed in the product information.

CLINICAL APPLICATIONS:

In surgery involving the anterior segment, Xium 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.) Xium HCS is injected before the crystalline lens is removed to perform the capsulorhexis procedure, so that protective effect will be optimised. At this stage of the operation, Xium HCS protects the endothelium of the cornea from potential damage by surgical instruments. Xium 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, Xium HCS should be aspirated completely using an automatic irrigator/aspirator or an irrigation syringe. Never use the original Xium HCS syringe.

MODE OF ADMINISTRATION AND ASSEMBLY OF THE SYRINGE:

Use a sterile opening technique when removing from the individual sterile 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 plungers 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.

Xium HCS is a medical device CE 0120 Produced in France by LCA SA, 9 Allée Prométhée, F-28000 Chartres, France For professional use only.
**DESCRIPTION:**

IXIUM HPMC is a visco-elastic high molecular weight solution of a non-inflammatory, highly purified grade of Hydroxypropyl Methyl Cellulose 2%, clear, isotonic and sterile for intraocular injection during surgery of the anterior segment of the eye. IXIUM HPMC is a sterile preparation supplied in a 2 mL pre-filled glass syringe Luer lock with disposable cannula.

**CHARACTERISTICS:**

IXIUM HPMC is a medical device for use during surgery involving the anterior chamber of the eye.

- Maintains the depth of the anterior chamber of the eye and protects the peri-ocular tissues.
- Has outstanding rheological properties.
- Is completely transparent.
- Is totally non-antigenic.
- Is simple to remove from the anterior chamber.
- Does not contain any proteins likely to cause inflammatory reactions and/or foreign body reactions.
- Does not require refrigeration or any particular storage condition.
- Does not interfere with the process of cicatrisation.

**COMPOSITION:**

- Name: Hydroxypropyl Methyl Cellulose 2%
- Function: Viscosity
- Sodium chloride 900 mg
- Water for injection 100 mL
- Dissolution

**PROPERTIES:**

1. IXIUM HPMC is a clear, isotonic, sterile, non-pyrogenic, visco-elastic solution, iso-osmotic with aqueous humour, which contains two percent by weight of a highly purified grade of Hydroxypropyl Methyl Cellulose.
2. IXIUM HPMC 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 HPMC ensures protection of intraocular tissues, especially the endothelium of the cornea, during surgery.
3. IXIUM HPMC is used to maintain the depth and integrity of the anterior chamber of the eye, thus facilitating surgery.
4. IXIUM HPMC does not provoke any inflammatory or immunogenic reactions because it does not contain any proteins or biological constituents.
5. IXIUM HPMC is completely soluble in water and can therefore be easily removed by irrigation and aspiration during the intervention.

**INDICATIONS:** IXIUM HPMC 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 HPMC 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.

**PRECAUTIONS:**

- Check the integrity of the packaging before use to ensure the product has remained sterile.
- The cannula and the syringes 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 adematous corneal decompensation are inherent in surgical procedures involving the anterior chamber of the eye, and no relationship with the product has been established.

**CONTRA-INDICATIONS:** There is no contra-indications to the use of IXIUM HPMC if used as instructed in the product information.

**CLINICAL APPLICATIONS:** In surgery involving the anterior chamber of the eye, IXIUM HPMC should be carefully injected into the anterior segment using a Luer lock cannula. IXIUM HPMC may be injected before extracting the lens during capsulorhexis. At this stage of the operation, IXIUM HPMC protects the endothelium of the cornea from potential damage by surgical instruments. IXIUM HPMC 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 HPMC should be aspirated completely using an automatic irrigator/aspirator or an irrigation syringe. Never use the original IXIUM HPMC syringe.

**MODE OF ADMINISTRATION AND ASSEMBLY OF THE SYRINGE:** Open using sterile technique. 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.

**STORAGE:** IXIUM HPMC can be stored at room temperature. It must not be exposed a long time to higher temperatures, and must be protected from light and humidity.

For professional use only IXIUM HPMC is a medical device CE 0120 Produced in France by LCA SA, 9, Allée Prométhée, Z.I. Les Propylées F-28000 Chartres, France

Date of revision of the product information: 10/2007

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**HIGH-QUALITY COST-EFFECTIVE SOLUTION**

**High-Performing Viscoelastic**

IXIUM HPMC HYDROXYPROPYL METHYL CELLULOSE 2%
Hydroxypropyl Methyl Cellulose (HPMC) is of synthetic origin. Therefore IXIMUM HPMC contains no protein resulting of animal extraction. IXIMUM HPMC is a non inflammatory, non pyrogenic product.

IXIMUM HPMC is steam sterilised.

IXIMUM HPMC can be stored at room temperature.

IXIMUM HPMC offers the highest efficiency/cost ratio

IXIMUM HPMC IS A MEDICAL DEVICE FOR USE DURING SURGERY INVOLVING THE ANTERIOR CHAMBER OF THE EYE.

- maintains the depth of the anterior chamber of the eye and protects the peri-ocular tissues,
- has outstanding rheological properties,
- is completely transparent,
- is totally non-antigenic,
- is simple to remove from the anterior chamber,
- does not contain any proteins likely to cause inflammatory reactions and/or foreign body reactions,
- does not require refrigeration or any particular storage condition,
- does not interfere with the process of cicatrisation.

Hydroxypropyl Methyl Cellulose (HPMC) with its high coatibility, provides excellent corneal endothelial cell protection.

IXIMUM HPMC comes in glass syringes filled at 2 ml, offering a comfortable volume for even the most requiring procedures.
The sodium hyaluronate used for the manufacturing of IXIUM 1.5% 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 liquor and the umbilical cord.

IXIUM 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.

### Usage Precautions:
- The cannula and the syringe are for single intraocular use only.
- 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 quantity injected into the anterior chamber of the eye should be observed.
- The cannula and the syringe are for single intraocular use only.
- 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.

### Characteristics:
- Contains 1.5% by weight of a highly purified grade of sodium hyaluronate.
- Iso-osmotic with aqueous humour.
- Visco-elastic properties, easy capsulorhexis, maintains the endoocular space of the anterior segment of the eye, including extraction of the lens and insertion of intraocular lenses.
- IXIUM 1.5% is a sterile preparation supplied in a 1,0 mL pre-filled glass syringe with disposable cannula, Luer lock.

### Composition:
- Sodium hyaluronate 1500 mg
- Sodium chloride 900 mg
- Water for injection 150 mL

### Properties:
- 1. IXIUM 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 1.5% is a visco-elastic gel, whose properties of elasticity, cohesion and cohesivity provide ideal conditions for intraocular surgery. On account of its visco-elastic properties, IXIUM 1.5% ensures protection of intraocular tissues, especially the endothelium of the cornea, during surgery.
- 3. IXIUM 1.5% is used to maintain the depth and integrity of the anterior chamber of the eye, thus facilitating surgery.
- 4. IXIUM 1.5% is non-antigenic and is well tolerated by the human eye.

### Indications:
- IXIUM 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 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.

### Contra-Indications:
- Do not use quaternary ammonium compound solutions (except with IXIUM 1.5%, since sodium hyaluronate precipitates in the presence of quaternary ammonium.

### Clinical Applications:
- In surgery involving the anterior segment, IXIUM 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 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 1.5% protects the endothelium of the cornea from potential damage by surgical instruments. IXIUM 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 1.5% should be aspirated completely using an irrigation/aspiration system, never use the original IXIUM 1.5% syringes.

### Mode of Administration and Assembly of the Syringe:
- Use a sterile opening technique when removing from the individual sterile 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 syringes is ready to use.

### Storage:
- At room temperature, do not expose to excessive temperatures. Protect from light.

### Date of revision of the product information: 10/2007

IXIUM 1.5% is a medical device, CE 0120
Produced in France by LCA SA, 9 Allée Prométhée, 28000 Chartres, France
For professional use only.

E-mail: lca@lca-pharma.com
Web: www.lca-pharma.com
At each stage of the surgical procedure

**IXIUM NaHA 1.5%**

**EASY ASPIRATION**

**OPERATING TIME REDUCTION**

**SECURITY**

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.

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.

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.
INDICATIONS: The normal precautions associated with ocular microsurgery should be observed.

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 canula 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 edematous 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 compounds (e.g. benzalkonium chloride) with IXIUM till 12%, since sodium hyaluronate precipitates in the presence of quaternary ammonium.

CONTRA-INDICATIONS: There is no contra-indication to the use of IXIUM till 12%, if used as instructed in the product information.

CLINICAL APPLICATIONS: In surgery involving the anterior segment, IXIUM till 12% 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 till 12% 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 till 12% protects the endothelium of the cornea from potential damage by surgical instruments. IXIUM till 12% 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 till 12% should be aspirated completely using an automatic irrigator/aspirator or an irrigation syringe. Never use the original IXIUM till 12% syringe.

MODE OF ADMINISTRATION AND ASSEMBLY OF THE SYRINGE: Use a sterile opening technique when removing from the individual sterile 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 till 12% 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
At each stage of the surgical procedure

**IXIUM NaHA**

**2.0%**

**HIGH CONCENTRATION**: 2.0%

**IXIUM NaHA** 2.0% is a visco-elastic high molecular weight solution of non-inflammatory, highly purified grade of Sodium hyaluronate 2%, clear, isotonic, sterile and non-pyrogenic.

**HIGH MOLECULAR WEIGHT**: 2.400.000 Dalton

The sodium hyaluronate used for the manufacturing of **IXIUM NaHA** 2.0% 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.

**HIGH SECURITY LEVEL**:
- Sodium hyaluronate obtained by biofermentation
- Sterilised per steam autoclave

**IXIUM NaHA** 2.0% is a sterile preparation supplied in a 1.0 mL prefilled glass syringe with disposable cannula, Luer lock.
PRODUCT DESCRIPTION:
IXIUM TWIN is a viscoelastic solution of high molecular weight sodium hyaluronate, highly purified, clear, isotonic, sterile and pyrogen-free, for intraocular injection in surgery of the anterior segment of the eye. IXIUM TWIN is supplied in Luer Lock 2.0-ml prefilled glass syringes with a single-use disposable injection cannula.

CHARACTERISTICS:
The sodium hyaluronate used in the manufacture of IXIUM TWIN is a pharmaceutical-grade high molecular weight polysaccharide consisting of sodium glucuronate and N-acetylglucosamine obtained by genetic engineering (Bacterial fermentation). Sodium hyaluronate is a physiological substance present in large quantities in numerous connective tissues in man and animals, and, particularly, in the vitreous humor, synovial fluid and umbilical cord. IXIUM TWIN is a medical device for aid during surgery of the anterior segment of the eye whose rheological characteristics are perfectly suitable for all the various phases in cataract surgery procedures.

IXIUM TWIN:
• maintains the endo-ocular space of the anterior segment of the eye and maintains tissue integrity
• has excellent rheological properties facilitating capsulorhexis and intraocular lens insertion
• enables excellent visibility of the operative space
• is easy to remove from the anterior chamber
• does not interfere with the cicatization process
• is non-antigenic and well tolerated by the human eye.

COMPOSITION:
Ingredients: Percentage formula: Function
Sodium hyaluronate (phase 1) 2000 mg: high viscosity
Sodium hyaluronate (phase 2) 1400 mg: low viscosity
Sodium chloride: 900 mg: isotonicity
Water for injections: qsp 100 mL: dissolution

INDICATIONS:
IXIUM TWIN is indicated as a surgical aid (medical device) in surgical procedures for cataract, including capsulorhexis, phacoemulsification, extraction of the crystalline lens and intraocular lens insertion.
IXIUM TWIN maintains the depth of the anterior chamber throughout the duration of surgery enabling enhanced precision of operative procedures with no risk of trauma to the endothelium or other endo-ocular tissues.

SPECIAL PRECAUTIONS FOR USE:
The following precautions for use are recommended during anterior segment surgery:
• check the integrity of the individual sterility protection of the product prior to use;
• the cannula and syringe are single-use disposable for intraocular injection only;
• the quantity injected into the anterior chamber must be proportional to the volume of the aqueous humor and the anatomical structure to be protected;
• eliminate all the product by irrigation and/or aspiration at the end of the procedure. A mechanical blockage of drainage at trabecular level may occur, giving rise to a transient increase in post-operative intraocular pressure;
• the product is to be administered with caution and under special monitoring in patients presenting with pre-existing glaucoma and in the event of glaucoma surgery and/or surgery combined with crystalline lens extraction.
• In the event of a supra-normal post-operative intraocular pressure, prescribe appropriate treatment;
• all post-operative inflammatory reactions (iritis, hypopyon, uveitis) and corneal decompensations of the edema type are inherent in surgery of the anterior segment of the eye and no causal relationship with the product has been demonstrated.

INCOMPATIBILITIES:
Do not use quaternary ammonium compounds (benzalkonium chloride) with IXIUM TWIN.
Sodium hyaluronate precipitates in the presence of quaternary ammonium compounds.

CONTRA-INDICATIONS:
There is no contra-indication to use of IXIUM TWIN in compliance with the user package leaflet.

CLINICAL APPLICATIONS:
In surgery of the anterior segment of the eye, IXIUM TWIN is injected slowly into the anterior chamber using a single-use disposable Luer Lock cannula (under no circumstances should a reusable cannula be used. A reusable cannula, even if it has been thoroughly cleaned, rinsed and re-sterilized, may release particles during injection. IXIUM TWIN is injected prior to extraction of the crystalline lens to implement the capsulorhexis procedures in order to optimize the product’s protective effect. At this stage in the operation, IXIUM TWIN protects the corneal endothelium from potential lesions due to the surgical instruments. IXIUM TWIN may be injected several times during phacoemulsification to replace the product lost during the surgical procedure. At the end of the procedure, IXIUM TWIN must be entirely aspirated using an automated irrigation/aspiration system or an irrigation syringe.

METHOD OF USE AND ASSEMBLY OF THE SYRINGE:
Open the sachet and place the contents on a sterile operating field. Connect the Luer Lock cannula to the nozzle of the syringe, screw home, and check the assembly. Press the plunger gently to expel a small quantity of product, in order to prevent the introduction of air bubbles into the anterior chamber. The syringe is ready for use.

STORAGE:
At room temperature, do not expose to excessive temperatures. Protect from light.

For professional use only.
IXIUM TWIN is a medical device CE 0120
Produced in France by LCA SA.
9, allée Prométhée, F-28000 Chartres, France

Date of revision of the product information: 10/2007

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IXIUM TWIN VISCO DISPERSIVE/COHESIVE SODIUM HYALURONATE

NEW DUAL PURPOSE TECHNOLOGY FOR YOUR CATARACT PROCEDURE

PHASE 1: PHACOEMULSIFICATION
PHASE 2: IOL IMPLANTATION

HIGH QUALITY MADE IN FRANCE

HIGH-Performing Viscoelastic

AT EACH STAGE OF THE SURGICAL PROCEDURE

IXIUM TWIN VISCO DISPERSIVE/COHESIVE SODIUM HYALURONATE

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NEW HIGH QUALITY MADE IN FRANCE

NON ANIMAL ORIGIN
At each stage of the surgical procedure

**IXIUM TWIN** is the first multipurpose viscoelastic solution for your cataract procedure.

**EXCELLENT RHEOLOGICAL PERFORMANCES**

The rheological performances are due to two essential parameters:

- Dual dynamic viscosity
- High molecular weight

**A SINGLE SURGICAL TOOL**

**IXIUM TWIN** has rheological properties providing space and safety in ocular surgery:

- Protects cells from trauma;
- Creates and maintains tissue spaces;
- Allows indirect manipulation of tissues.

**PHASE 1**

PHASE 1 of **IXIUM TWIN** has a high sodium hyaluronate concentration (2%) imparting a high dynamic viscosity. It provides excellent protection of corneal endothelium cells both because of a remarkable cushioning effect on the anterior chamber during capsulorhexis (1) and its optimal elasticity at the high shear rates generated during phacoemulsification (2).

**PHASE 2**

PHASE 2 has a moderate viscosity due to a sodium hyaluronate concentration of 1.4% which allows perfect lubrication of injector device reforming of the capsular bag, facilitates intraocular lens implantation (3) in the capsular bag. The sufficient cohesivity of phase 2 allows rapid removal of **IXIUM TWIN** (4) at the end of the operation.

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**RHEOLOGY**

<table>
<thead>
<tr>
<th>Shear rate</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01 s⁻¹ (at rest)</td>
<td>110 000 mPa.s</td>
<td>25 000 mPa.s</td>
</tr>
<tr>
<td>1 s⁻¹</td>
<td>55 000 mPa.s (1)</td>
<td>15 000 mPa.s (3)</td>
</tr>
<tr>
<td>1 000 s⁻¹</td>
<td>380 mPa.s (2)</td>
<td>156 mPa.s (4)</td>
</tr>
</tbody>
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**Pseudoplasticity index**

<table>
<thead>
<tr>
<th></th>
<th>PHASE 1</th>
<th>PHASE 2</th>
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</thead>
<tbody>
<tr>
<td>290</td>
<td></td>
<td>160</td>
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