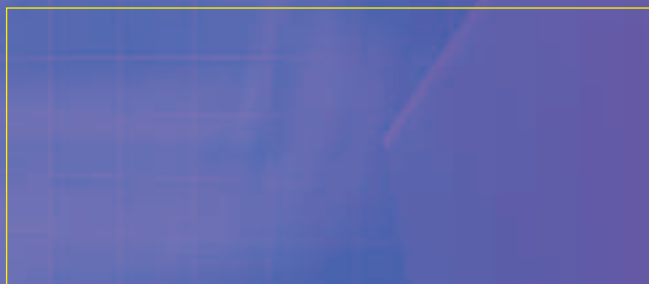




# IXIUM TWIN

VISCO DISPERSIVE/COHESIVE

SODIUM HYALURONATE



#### 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 cicatrization 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

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Designed and manufactured by :



CE  
0120

IXIUM TWIN M0033 07001

High-Performing Viscoelastic

NEW

DUAL PURPOSE TECHNOLOGY  
FOR YOUR CATARACT PROCEDURE

# IXIUM TWIN

VISCO DISPERSIVE/COHESIVE

SODIUM HYALURONATE



2 ml

NaHA 2%  
1 ml

NaHA 1.4%  
1 ml

▶ PHASE 1 : PHACOEMULSIFICATION

▶ PHASE 2 : IOL IMPLANTATION

AT EACH STAGE  
OF THE SURGICAL  
PROCEDURE

HIGH QUALITY  
MADE IN FRANCE

NON ANIMAL ORIGIN

LCA PHARMACEUTICAL  
EUROPEAN MAKER



# At each stage of the surgical procedure

**IXIUM TWIN**  
 VISCO DISPERSIVE/COHESIVE SODIUM HYALURONATE

R H E O L O G Y		
Shear rate	PHASE 1	PHASE 2
<b>Dynamic viscosity at 25 °C</b>		
0.01 s <sup>-1</sup> (at rest)	110 000 mPa.s	25 000 mPa.s
1 s <sup>-1</sup>	55 000 mPa.s (1)	15 000 mPa.s (3)
1 000 s <sup>-1</sup>	380 mPa.s (2)	156 mPa.s (4)
<b>Pseudoplasticity index</b>		
	290	160

## EXCELLENT RHEOLOGICAL PERFORMANCES

The rheological performances are due to two essential parameters :

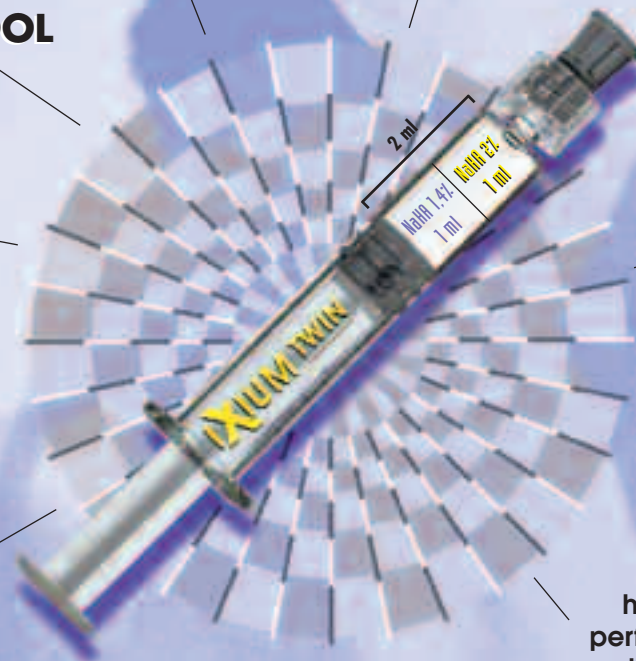
- • Dual dynamic viscosity
- • High molecular weight

## 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.

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



### 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.

