SYNOVIUM HCS SINGLE INJECTION

# PRODUCT INFORMATION

## DOSAGE :

**SYNOVIUM HCS** is for adults only.
The dosage for **SYNOVIUM HCS** is one intra-articular injection in the knee.
A second injection can be administered between the first and the third month if justified by pain suffered by the patient.

## PRECAUTIONS FOR USE :

The following precautions for use are recommended :

- Check that the individual protective sterile case containing the product has not been opened, before use.
- Respect the asepsis rules.
- Do not inject any other products at the same time as **SYNOVIUM HCS**.
- The precautions for use are those required by the protocol used for joint injections in rheumatology and orthopaedic surgery.
  The specialist remains responsible for his/her own techniques and indications.
- It is recommended to ask the patients, as for any intra-articular injection, to rest for 24 hours and to avoid any athletic and/or professional activity.

Warnings :
Do not inject intravascularly.
Do not inject outside the joint cavity or into the synovial tissue or capsule and/or in the presence of severe effusion.
**SYNOVIUM HCS** has not been studied in pregnant women.

## INCOMPATIBILITIES :

Do not use quaternary ammonium (benzalkonium chloride) to disinfect the skin during intra-articular injection of **SYNOVIUM HCS**.

## CONTRAINDICATIONS :

- All joint inflammations requiring treatment, prior to starting treatment with intra-articular injection of **SYNOVIUM HCS.**
- Do not administer if the patient presents known hypersensitivity to sodium hyaluronate.

## ADVERSE EFFECTS :

**SYNOVIUM HCS** is well tolerated by humans. Some pain may be felt for 48 hours. It is recommended to apply an ice-pack to the injection site for several hours.

## STORAGE :

Keep away from light and frost. Store between +2°C and +25°C.
After opening, the viscoelastic device **SYNOVIUM HCS** should be used immediately and disposed of after use.

Year of authorisation to affix the CE marking : 2009.
Date of review of the product information leaflet : 2017-01.

For professional use only.


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THE TRUE ALTERNATIVE TO NSAIDS

NEW

# SYNOVIUM HCS

SINGLE INJECTION

**SODIUM HYALURONATE**
**CHONDROITIN SULFATE**
**60mg/60mg/3ml**


## SYMPTOMATIC TREATMENT FOR KNEE OSTEOARTHRITIS BY INTRA-ARTICULAR INJECTION

**PAIN RELIEF**
**QUALITY OF LIFE IMPROVEMENT**

Pharmaceutical

Made in France

SYNOVIUM HCS SINGLE INJECTION

PRODUCT INFORMATION

# SYMPTOMATIC TREATMENT FOR KNEE OSTEOARTHRITIS BY INTRA-ARTICULAR INJECTION

## DESCRIPTION :

**SYNOVIUM HCS** is a sterile viscoelastic device containing two active substances :

• A natural derivative of hyaluronic acid, sodium hyaluronate, obtained through biofermentation, non chemically modified, with a high molecular weight ≥ 2 800 000 Daltons and highly concentrated 20mg/ml (i.e. 60 mg per intra-articular injection). Sodium hyaluronate is naturally present in the synovial liquid; it is synthesised by synoviocytes.
Its mechanical properties change according to movement. Thanks to its viscoelasticity, it plays the role of low-frequency lubricant and high frequency shock absorber. It functions as an analgesic by decreasing the sensitivity of the mechano-nociceptor ion channels.

• Chondroitin sulphate is a glycosaminoglycan present in the conjunctive tissue and a component of the cartilage matrix. Its role is to maintain osmotic pressure by absorbing water and to assist in hydrating the cartilage. What is even more important is that it serves as a chondroprotector and protects the cartilage against enzymatic reactions and against damage from free radicals.

## FORM AND PACKAGING :

**SYNOVIUM HCS** is a sterile, transparent, homogeneous, non chemically modified visco-elastic preparation, composed of highly purified sodium hyaluronate and Chondroitin Sulphate, of European Pharmacopoeia injectable grade.

**SYNOVIUM HCS** is a sterile isotonic solution, with physiological pH, packed in a disposable sterile syringe with luer lock, prefilled with 3 ml in a single-syringe box.
A label with the name of the product is placed on the syringe. The syringe is packed in a protective sterile case. The syringe and the information leaflet are included in a case with all the identification markings of the implantable viscoelastic device :
**SYNOVIUM HCS** Box containing 1 syringe.

## COMPOSITION :

Each **SYNOVIUM HCS** syringe contains :

| | |
|---|---|
| Sodium hyaluronate (F.B.) | 60 mg |
| Chondroitin sulphate | 60 mg |
| Sodium chloride | 21 mg |
| Borate Buffer | pH 7.2 ± 0.2 |
| Water for injection | QS 3.0 ml |

Sterilization is carried out in a steam autoclave.
The content of each syringe is sterile and non-pyrogenic.

## PROPERTIES :

Sodium hyaluronate exists naturally in humans and is a major component of inter-cellular spaces. As regards articulation, it is a structural component of the cartilage and the synovial liquid that functions as a lubricant, a shock absorber, a filter and a metabolic medium. Chondroitin sulphate is also a glycosaminoglycan, an essential component of the cartilage matrix that provides excellent resistance to compression.

**SYNOVIUM HCS** is biologically similar to human synovial liquid. It has the following functions :

• Cartilage protection
- The lubricant properties of the sodium hyaluronate and chondroitin sulphate molecules contained in **SYNOVIUM HCS** ensure perfect contact between articular surfaces and protect them from mechanical damage.
- By decreasing the stress load, the elastic properties of sodium hyaluronate and chondroitin sulphate molecules protect the cartilage from compressive forces.
- The strong covering power of chondroitin sulphate improves protection for cartilage (chondro-protection) and other endoarticular tissues.

• Cartilage nutrition
- Small molecules such as water, electrolytes and nutrients can easily become diffused towards the cartilage and the synovial membrane.

• Synovial membrane protection
- Sodium hyaluronate ensures a protective barrier by covering the pain receptors of the synovial membrane.

Sodium hyaluronate is present, in particular, in the synovial liquid of healthy joints, and deteriorates both as regards concentration and molecular weight in arthrotic joints. In the treatment of arthrosis, **SYNOVIUM HCS** therefore improves the impaired rheological characteristics of synovial liquid (viscosity and elasticity).
These characteristics are important for the shock absorption as well as for lubrification and protection of cartilaginous surfaces.

## INDICATIONS :

**SYNOVIUM HCS** viscoelastic devices are indicated for the symptomatic treatment of knee osteoarthritis; in particular, they reduce pain and restore joint mobility by replacing and supplementing the elasto-viscosity of the synovial liquid in arthrotic joints.

The therapeutic indications are all types of painful knee osteoarthritis :

- Primary knee osteoarthritis (Kelgreen radiological stages I, II and III)
- Knee osteoarthritis and associated general factors :
  • Inadequacy of usual treatments.
  • Intolerance and/or contraindication to NSAIDs and or analgesics.
  • Use of anticoagulants, polymedication (AHT, Diabetes, Obesity, cardiovascular and gastrointestinal problems).
  • Contraindications linked to the fitting of prostheses: young subject and various contraindications linked to the patient's state.
- Early knee osteoarthritis in young subjects
- Secondary knee osteoarthritis as a result of injuries and consequences of joint fractures.

## METHOD OF ADMINISTRATION :

**SYNOVIUM HCS** should be administered by a physician performing an intra-articular injection.

• Check the integrity of the protective sterile case and the expiry date.
• Open the protective sterile case aseptically.
• Pick up the syringe aseptically.
• Screw the injection needle onto the luer lock after first removing the tip-cap, without touching the end of the syringe with your finger.
• Perform the intra-articular injection.
The content of the syringe is for single use.
• The syringe and the needle should be disposed of immediately after use.
They should be thrown into a specific waste disposal box.