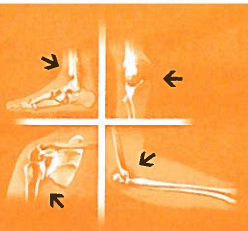
PRODUCT INFORMATION

ARTHRUM HCS

CHONDROITIN SULPHATE (CS 40mg)
SODIUM HYALURONATE (HA 40mg) / 2 ml



ENGLISH

ARTHRUM HCS
Sodium hyaluronate and chondroitin sulphate for intra-articular injection.

COMPOSITION :

A syringe (2ml) contains 40 mg of Sodium hyaluronate and
40 mg of Chondroitin sulphate.

DESCRIPTION :

ARTHRUM HCS is an injectable sterile viscoelastic device containing two components :

- **Sodium hyaluronate** is a glycosaminoglycan, a natural derivative of hyaluronic acid, obtained through bio-fermentation; it has a high molecular weight (2.8 million Daltons) and high concentration (20mg/ml).
  Sodium hyaluronate is naturally present in the extracellular matrix, in soft connective tissues and synovial fluid where it is synthesised by synoviocytes.
  As a viscoelastic fluid, synovial fluid acts as a lubricant at low frequency, and as a shock absorber at high frequency, limiting mechanical stress and pain in the joint.
- **Chondroitin sulphate** is a glycosaminoglycan of marine origin; it is highly purified and has a high concentration of 20mg/ml.
  Chondroitin sulphate is naturally present in connective tissue and is one of the major constituents of the cartilage matrix. Its function is to maintain osmotic pressure by absorbing water and contributing to cartilage hydration.

The components of **ARTHRUM HCS** are not chemically modified, thus eliminating any risk of allergy and cytotoxic potential and ensuring safety and good tolerance.

FORM AND PRESENTATION :

ARTHRUM HCS is a sterile, transparent, smooth viscoelastic prepared from a high grade purified injectable of sodium hyaluronate and chondroitin sulphate, in accordance with the European Pharmacopoeia monographs.

ARTHRUM HCS is a sterile solution at physiological pH, presented in a disposable glass syringe, fitted with a Luer lock and pre-filled to a volume of 2ml.
A label stating the product name is affixed to the syringe. Syringes are sealed in individual sterile packaging.
The syringe, intra-articular injection needle and accessories (information leaflet, traceability labels) are included in protective packaging containing all the identification particulars of the **ARTHRUM HCS** injectable viscoelastic device.

ARTHRUM HCS is available in boxes of 1 and 3 syringes.

The **ARTHRUM HCS** pre-filled syringe is sterilised via pressurised steam autoclave within its individual sterile packaging. The contents and exterior of the syringe are sterile so that **ARTHRUM HCS** can be used safely in the surgical unit.
The contents of each syringe is sterile and non pyrogenic.

PROPERTIES :

Sodium hyaluronate is a glycosaminoglycan found naturally in humans and is a major constituent in intracellular spaces. In the joints, it is a structural component of cartilage and synovial fluid, which acts as a lubricant, shock absorber, filter and metabolic intermediate.
Chondroitin sulphate is also a glycosaminoglycan, an essential constituent of the cartilage matrix, to which it provides excellent resistance to compression.
ARTHRUM HCS is biologically similar to human synovial fluid and contributes to the following functions :

- **Protects the cartilage**
  - The lubricant properties of the sodium hyaluronate and chondroitin sulphate molecules contained in **ARTHRUM HCS** allow articular surfaces to slide over one another easily, and protect them from mechanical damage.
  - The elastic properties of the sodium hyaluronate molecules reduce stress under load, thereby protecting the cartilage against excessive compressive forces.
  - The high adhesion properties and the covering power of chondroitin sulphate improve the protection of cartilage and other endoarticular tissue.
- **Protects the synovial membrane**

The normal synovial membrane lines the joint cavities. It maintains articular cartilage trophicity and synovial fluid secretion. It acts as a filtration and defence barrier.
Sodium hyaluronate and chondroitin sulphate provide a protective barrier by coating the pain receptors that are present in the synovial membrane.

- **Reduces pain and improves mobility**
  - Sodium hyaluronate and chondroitin sulphate restore and improve the viscoelasticity of pathological synovial fluid in osteoarthritic joints.
    Consequently, they help to maintain the intra-articular space, reduce pain and restore joint mobility.

INDICATIONS :

The therapeutic indications are all types of painful osteoarthritis in synovial joints, especially gonarthrosis.

DOSAGE AND DIRECTIONS FOR USE :

- Check the integrity of the individual sterile packaging and expiry date.
- Open the individual sterile packaging in such as way as to ensure sterility.
- Remove the syringe and injection needle [from the packaging] in sterile conditions.
- Carefully unscrew the plug from the tip of the syringe.
- Screw the injection needle onto the Luer lock system without touching the tip of the syringe.
- Perform the intra-articular injection.
- The syringe and needle should be discarded immediately after use, into a disposable sharps container.

Dosage :
Inject **ARTHRUM HCS** into the affected joint once weekly for a period of three weeks.

PRECAUTIONS :

The following precautions are advised :

- Do not use if the product's individual protective packaging has been damaged.
- Comply with asepsis guidelines.
- Do not inject other products at the same time as **ARTHRUM HCS**.
- Aspirate all effusions of synovial fluid prior to injection to ensure the correct intra-articular location.
- The precautions for use are those set out by the protocol for intra-articular injections in rheumatology. The specialist physician shall remain responsible for his or her own techniques and indications.
- As with any intra-articular injection, patients are advised to rest for 24 hours and avoid any form of activity, sports-related or otherwise.

Warnings : The syringe should be used only once, the contents of the syringe should be used immediately following opening of the individual sterile packaging. The syringe must be discarded if not all of the product has been used or if the individual sterile packaging has been opened.
Do not sterilise the product contained in the syringe by heating or any other method. Such action is liable to lead to the loss of physicochemical properties and microbiological contamination of the product constituting a serious risk of infection and inflammation of the joint.
Do not inject via intra-vascular route.
Do not inject outside the joint cavity or into the synovial tissue or capsule or in the presence of a large effusion.
ARTHRUM HCS has not been studied in pregnant women.
It has not been established that **ARTHRUM HCS** can regenerate cartilage.

INCOMPATIBILITIES :

Do not use quaternary ammonium (benzalkonium chloride) for skin disinfection prior to use of **ARTHRUM HCS**.

CONTRAINDICATIONS :

- All inflammatory joint diseases are to be addressed prior to embarking on treatment by intra-articular **ARTHRUM HCS** injection.
- Do not administer if the patient has a known hypersensitivity to sodium hyaluronate and chondroitin sulphate.
- **ARTHRUM HCS** has not been tested on pregnant or nursing women, or in children under 18 years of age.

SIDE EFFECTS :

ARTHRUM HCS is well tolerated in humans. Sometimes, mild pain and/or moderate edema may occur within 48 hours of treatment. Applying an ice pack for several hours is recommended.

STORAGE :

Do not expose to light or freezing temperatures. Store between +2°C and +25°C.

Restricted to medical use only.

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