ChondroMAX

INSTRUCTIONS FOR USE

ChondroMAX

Sodium hyaluronate 60 mg/3 ml and chondroitin sodium sulfate 90 mg/3 ml, solution for injection in pre-filled syringe

For intra-articular injection

DESCRIPTION:
ChondroMAX is a sterile, viscoelastic solution containing two highly purified crosslinked biological polymers, sodium hyaluronate and chondroitin sodium sulfate. ChondroMAX consists of sodium hyaluronate derived from bacterial fermentation of a Streptococcus strain and chondroitin sodium sulfate produced from bovine cartilage.

ChondroMAX is a sterile viscoelastic solution processed using an aseptic processing technique and supplied in a disposable glass syringe delivering 3 ml of solution.

COMPOSITION:
Each pre-filled syringe contains sodium hyaluronate 60 mg, chondroitin sodium sulfate 90 mg, sodium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate dodecahydrate, sodium hydroxide and/or hydrochloric acid (for pH adjustment), water for injections.

INDICATIONS:
ChondroMAX is indicated as a viscoelastic supplement or a replacement for synovial fluid in human knee joint.
ChondroMAX is indicated for the symptomatic treatment of mild to severe knee osteoarthritis. The actions of ChondroMAX are lubrication and mechanical support.

CONTRAINDICATIONS:
ChondroMAX is contraindicated in patients with:
- known allergy (hypersensitivity) to sodium hyaluronate, chondroitin sulfate or to any components of ChondroMAX
- pre-existing infections or skin diseases in the area of the intended injection site
- known infection of the index joint
- known systemic bleeding disorders, bleeding or tendency to bleeding

ChondroMAX may contain trace amounts of gram-positive bacterial proteins and is contraindicated for patients with a history of such allergies.

ChondroMAX should not be used in patients with known hypersensitivity to derived bovine material.

UNDESIRABLE EFFECTS:
Joint swelling and transient pain may occur after intra-articular injection. These reactions generally subside over 72 hours.

Reported device-related adverse events
The most common adverse events related to ChondroMAX injection reported in postmarketing surveillance are the following: arthralgia, joint stiffness, joint effusion, joint swelling, joint warmth, gait disturbance. Incidences of fever and malaise have also been reported. These reactions responded within a few days to treatment, applying ice to the site of injection, treatment with Non Steroidal Anti Inflammatory Drugs (NSAIDs) or antipyretics.

DOSAGE AND ADMINISTRATION:

Not for intravenous injection
The product is administered strictly by intra-articular injection. Do not inject the product extra-articularly.

Strict aseptic administration technique must be followed. Injection site must be properly disinfected (70% alcohol or with another disinfectant). Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because hyaluronic acid can precipitate in their presence.

Remove joint effusion, if present, before injecting ChondroMAX. Arthrocentesis prior to injection is recommended. Remove the pre-filled syringe from the package. Before administration, break the visible seal and remove the cap of the pre-filled syringe. Attach to the syringe a sterile hypodermic needle with the appropriate size (gauge) and length (inch) and make sure you have it properly fixed by turning it slightly.
Common needle gauges for injections into the knee are 18 - 21 gauge (1.2 - 0.8 mm). The final needle selection for any intra-articular procedure is determined by the physician. Injection of subcutaneous lidocaine or similar anesthetic may be recommended prior to injection of ChondroMAX.

As with any invasive joint procedure, it is recommended that the patient should avoid any strenuous activities or prolonged (i.e., more than an hour) weight-bearing activities such as jogging or tennis within the 48 hours that follow the intra-articular injection.

PRECAUTIONS FOR USE:
Although sodium hyaluronate and chondroitin sodium sulfate are highly purified biological polymers, the physician should be aware of the potential allergic risks inherent in the use of any biological material.

General precautions should be observed for the intra-articular injection administration. ChondroMAX should be administered in the synovial joint space only by medical professionals trained in intra-articular administration technique.

If pain increases during the injection procedure, the injection should be stopped and the needle withdrawn.
Patients should be carefully examined prior to administration to determine signs of acute inflammation, and the physician should evaluate whether ChondroMAX treatment should be initiated in this case.
Patients experiencing abnormal sequelae after intra-articular administration of ChondroMAX should consult with a physician immediately.

The safety and effectiveness of ChondroMAX have not been established in children and adolescents, pregnant or lactating women. As no clinical evidence is available on the use of sodium hyaluronate and chondroitin sodium sulfate in patients with concomitant inflammatory arthropathy (such as rheumatoid arthritis, gouty arthritis), recent orthopedic surgery or trauma at the index joint, the treatment with ChondroMAX is not recommended in these patients. There were few case reports of increased INR (International Normalised Ratio) in patients receiving concomitant warfarin and glucosamine - chondroitin supplements. Due to limited information, caution is advised regarding the ChondroMAX administration in patients taking anticoagulants or antiplatelet agents.

WARNINGS:
Verify the expiry date and the integrity of the packaging before use. Do not use ChondroMAX after the "Use by date" shown on the packaging.
Do not use the syringe if its seal is opened or damaged.
The product is administered only if the solution is clear.
After opening, the contents of the syringe should be used immediately.
The product ChondroMAX is for single use! Do not re-use. Each pre-filled syringe of ChondroMAX is intended to be used once only for a single patient.
The used needle and syringe must be discarded after injection and should not be kept for other administrations. Re-use of needles or syringes already used can lead to the transmission of infectious agents (including HIV and hepatitis).
Do not resterilize, as this may damage or alter the product.

CHARACTERISTICS AND MODE OF ACTION:
ChondroMAX is a product for viscosupplementation, which is a safe, effective and well established treatment in osteoarthritis consisting in injecting a hyaluronic acid based solution into the affected synovial joint.
ChondroMAX acts as a temporary replacement and supplement for synovial fluid. ChondroMAX relieves joint pain, improves articular mobility and protects cartilage.

Hyaluronic acid is a major component of the synovial fluid and cartilage and, thanks to its viscoelastic and rheological properties is responsible of the lubrication and cushioning in joints. It decreases friction between joint surfaces and protects soft tissue from trauma by acting as a shock absorber.

The quantity and quality of hyaluronic acid in the synovial fluid are reduced in the patients who have osteoarthritis because its synthesis by the synovial and cartilage cells is disturbed. The protection of articular surfaces thus is strongly altered, the cartilage becomes vulnerable and exposed to structural degradations due to the forces of friction and compression.

Chondroitin sulfate, a sulfate glycosaminoglycan, is an important structural component of the extracellular cartilage matrix. The role of chondroitin sulfate is to optimize the rheological behavior of hyaluronic acid, due to specific interactions.
Furthermore, in in vitro studies, chondroitin sulfate inhibits the main enzymes involved in destruction of the cartilaginous matrix: metalloproteinases and aggrecanases. Chondroitin sulfate also inhibits pro-inflammatory factors secretion. These data support the observed clinical activity as a symptomatic slow-acting for osteoarthritis with pain improvement and enhancement function. ChondroMAX, administered as a single injection, restores good lubrication and shock absorption in the joint and will provide significant improvement of symptoms.

Viscosupplementation with hyaluronic acid is an effective and well tolerated treatment for knee osteoarthritis. Viscosupplementation is a well tolerated treatment of other joints osteoarthritis but a consensus position at the world-wide level was not reached until now for the efficacy of viscosupplementation with hyaluronic acid for other joints osteoarthritis than knee osteoarthritis.

HOW SUPPLIED:
Each pre-filled syringe of ChondroMAX contains 3 ml of a sterile viscoelastic solution of sodium hyaluronate 60 mg and chondroitin sodium sulfate 90 mg.
ChondroMAX is available in carton box containing: one blister with a single-use pre-filled syringe and Instructions for use.
ChondroMAX is a medical device. To be used under the direction ofa physician.

SHELF LIFE AND STORAGE:
Store at temperatures below 25°C, in the original package, in order to protect from light.
Do not freeze.
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Number of the decision on the registration of the medical device:/Broj rešenja o registraciji medicinsk og sredstva:
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Explanation of Symbols	
	Consult Instructions for use
LOT	Batch code
	Use by date
	Do not re-use
STERILE A	Sterilised using aseptic processing techniques
	Do not resterilize
25°C	Upper limit of temperature
	Do not use if package is damaged
	Manufacturer
CE	Product conform with requirements in the European Medical Device Directive
0050	Number of Notified Body

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