HyalMAX

INSTRUCTIONS FOR USE

HyalMAX
Sodium hyaluronate 30 mg/2 ml, sterile solution for injection in pre-filled syringe

For intra-articular injection.

DESCRIPTION:
HyalMAX is a sterile, viscoelastic solution of sodium hyaluronate. HyalMAX contains 30 mg/2 ml of sodium hyaluronate with a molecular weight of 1.5 - 2.4 million daltons dissolved in physiological saline solution with the average osmolality of 335 milliosmoles, in a single-use syringe. The sodium hyaluronate is purified from the bacterial fermentation of a Streptococcus strain.
Each milliliter of HyalMAX contains 15 mg of sodium hyaluronate, sodium chloride and water for injections.

Sterile by moist heat.

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

CONTRAINDICATIONS:
The following pre-existing conditions may constitute relative or absolute contraindications to the use of HyalMAX:
- allergy (hypersensitivity) to any of the components of HyalMAX
- pre-existing infections of the skin region at the injection site
- known infection of the index joint
- known systemic bleeding disorders.

HyalMAX may contain trace amounts of grampositive bacterial proteins and is contraindicated for patients with a history of such allergies.

POTENTIAL ADVERSE EVENTS:
Sodium hyaluronate is a natural component of the human tissues. Since sodium hyaluronate was found to be non-inflammatory, any inflammatory response is considered to be caused by the injection procedure itself. Mild to moderate episodes of transient swelling and discomfort have occasionally been observed following intra-articular injection of sodium hyaluronate preparations.
There are minimal risks associated with the procedure of injecting substances into joints in general, primarily infections and bleeding.

METHOD OF ADMINISTRATION AND DOSAGE:
HyalMAX is administered only by medical professionals trained for intra-articular administration technique.

HyalMAX must be administered strictly intra-articular.
Do not administer intravenously.

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.
HyalMAX is administered in the affected joint once a week for 3 consecutive weeks. If treatment is bilateral, a separate syringe should be used for each knee. Not to exceed one treatment course for any individual joint in any 6-month period.
Any joint effusion present should be removed by joint aspiration before injecting HyalMAX.
The intra-articular space should not be overfilled.

HyalMAX is available as a ready to use prefilled syringe, and must not be diluted. The content of a pre-filled syringe HyalMAX is sterile and must be used immediately after the packaging has been opened.
HyalMAX should be injected slowly into the joint space, using a standard intra-articular injection technique.
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. Remove the air from the syringe before the injection.
Common needle gauges for injections into the knee are 18 - 21 gauge (1.2 - 0.8 mm). The final needle selection for any procedure is determined by the physician.

PRECAUTIONS:
General precautions should be observed for the intra-articular injection administration.
Sodium hyaluronate 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 HyalMAX treatment should be initiated in this case.
As in any invasive joint procedure, it is recommended caution to avoid overusing the joint immediately after the intra-articular injection.
Patients experiencing abnormal sequelae to the administration of sodium hyaluronate should consult with a physician immediately.

To date, there are insufficient data to recommend the use in children and adolescents, pregnant or lactating women.

HyalMAX should not be intra-articularly administered simultaneously or mixed with other products.

WARNINGS:
The product HyalMAX is for single use! Do not reuse. Each pre-filled syringe of HyalMAX is intended to be used once only for a single patient.
Do not use the syringe if its seal is opened or damaged.
Do not resterilize, as this may damage or alter the product.
The product is administered only if the solution is clear.
The used needles and syringes must be discarded after each injection and should not be kept for other administrations. Reuse of needles or syringes already used can lead to the transmission of infectious agents (including HIV and hepatitis).
HyalMAX should be allowed to reach room temperature, if necessary, approximately 20 - 45 minutes prior to use.
Keep out of the reach and sight of children.
Do not use after the expiration date shown on the label.

CHARACTERISTICS AND MODE OF ACTION:
Sodium hyaluronate from HyalMAX is a polysaccharide composed of sodium glucuronate and N-acetylglucosamine.
Sodium hyaluronate is ubiquitously distributed throughout the human tissues and is present in high concentrations in such tissues as vitreous humor, synovial fluid, umbilical cord and dermis.
In synovial joints, sodium hyaluronate acts as a lubricant and shock absorber, allowing a normal movement, without joint pain. In case of degenerative joint disease (osteoarthritis), the viscoelasticity of the synovial fluid is impaired, causing the mechanical stress on the joint and the breakdown of the articular cartilage to greatly increase leading to limited and painful joint movement.
The lubricating and shock-absorbing properties of sodium hyaluronate administered intra-articularly reduce pain and improve joint mobility. This effect can be maintained for 6 months following a treatment cycle of 1 - 3 intra-articular injections.
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 milliliter of HyalMAX contains 15 mg of sodium hyaluronate, 9 mg of sodium chloride and water for injections. Each syringe contains 2 ml of a sterile viscoelastic solution of sodium hyaluronate 30 mg.
HyalMAX is available in carton box containing:

- one blister with a single-use pre-filled syringe and Instructions for use.
- three blisters with a single-use pre-filled syringe each and Instructions for use.

STORAGE:
Store at temperatures below 25°C, in the original package.
Do not freeze.

Date of revision of the text: February 2019

4791

4791

Manufacturer:/Proizvođač:
S.C. ROMPHARM COMPANY S.R.L. 1A Eroilor Street, Otopeni, 075100 Ilfov, Romania

VEMAX PHARMA

Authorized representative of the manufacturer in the Republic of Serbia:
VEMAX011 PHARMA DOO BEOGRAD-VOŽDOVAC, Mosorska 9, 11042 Beograd, Srbija

Number of the decision on the registration of the medical device:
515-02-01067-23-003 od: 25.04.2023.

CE **0050**

Explanation of Symbols	
	Consult Instructions for use
LOT	Batch code
	Use by date
	Do not re-use
STERILE	Sterilised using steam or dry heat
	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