

# HA1 MSM®

Hyaluronic acid sodium salt 1,6% (32 mg)  
+ MSM (Methylsulfonylmethane) 5%  
for intra-articular injection  
1 pre-filled syringe of 2 ml

## INDICATIONS

HA1 MSM® acts as a substitute of synovial fluid into joints affected by degenerative or mechanical osteoarthritis that gives pain or reduced mobility.

## DESCRIPTION

HA1 MSM® is a CE-marked medical device conforming to directive MDD 93/42/CEE, containing 16 mg/ml of hyaluronic acid obtained by fermentation and chemically unmodified and MSM. HA1 MSM® is a transparent, sterile, non-pyrogenic and viscoelastic solution supplied in a 2 ml syringe. Hyaluronic acid is a natural polysaccharide present in numerous human tissues, especially synovial fluid, and acts on joints both as a cartilage and ligament lubricant and as a shock absorber. Many studies have shown that the injection of hyaluronic acid into joints affected by osteoarthritis restores synovial fluid viscosity and elasticity, with a consequent reduction in pain and improvement in the joint's mobility. HA1 MSM® acts only in the joint into which it is injected, without exercising any systemic action.

## COMPOSITION

Sodium Hyaluronate, MSM, Sodium Chloride, Sodium dihydrogen phosphate dehydrate, Dibasic Sodium phosphate dodecahydrate, water WFI.

## WARNINGS - PRECAUTIONS FOR USE:

HA1 MSM® is suitable only for intra-articular injections and must only be dispensed by a doctor who has received specific training on the intra-articular injection technique.

Before use, check the integrity of the syringe and the expiration date. Do not use needles other than those listed. The product should not be injected in the presence of a infected or severely inflamed joint. The infiltration must be avoided in the case of infections in place or inflammatory conditions of the skin in proximity of the injection. As no clinical experience is available for the use of Hyaluronan in children, treatment with HA1 MSM® is not recommended in these cases. After the intra-articular injection it is advisable to recommend to the patient to avoid physical activities demanding stress for the articulation and resume normal activities after a few days.

HA1 MSM® is a disposable product, the quality and sterility are guaranteed only if the syringe is sealed. Any residue must be discarded and not reused even after new sterilisation. Do not use the product if the package is already opened or damaged. The assembled syringe must be discarded immediately after use, regardless of whether or not the solution has been completely administered. After use, dispose according to applicable national practice.

## INCOMPATIBILITIES:

There are incompatibilities between sodium hyaluronate and quaternary ammonium compounds, such as solutions of benzalkonium chloride. Contact between HA1 MSM® and these substances should be therefore avoided.

## SIDE EFFECTS:

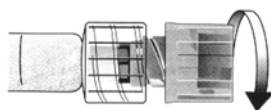
There may be some temporary side reactions following injection of HA1 MSM®, such as pain, stiffness, warmth, redness or swelling. These secondary manifestations may be relieved by applying ice on the treated articulation. Usually these effects disappear after a short time. If symptoms persist, consult a physician. Any other unwanted side effects associated with the injection of HA1 MSM® should be reported to a doctor.

## METHODS OF USE:

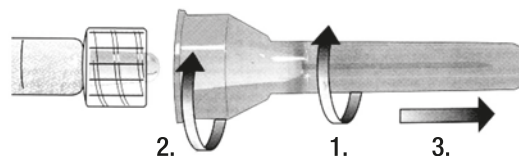
Remove any joint effusion before injecting HA1 MSM®; for the removal of the effusion and the injection of HA1 MSM® the same needle must be used. Remove the protective cap of the syringe, with particular attention to avoid contact with the opening. Firmly screw the needle, of diameter between 18 and 22 G, at the collar of Luer lock, following the instruction given below. Before injection, the site should be treated with appropriate disinfectant. Inject HA1 MSM® adopting aseptic technique. Inject only into the joint cavity. It is recommended to perform an initial cycle of 3 weekly treatments, possibly followed by maintenance sessions, according to the medical prescription.

## INSTRUCTIONS FOR ASSEMBLY OF THE SYRINGE NEEDLE:

A. Carefully unscrew the cap of the tip of the syringe, being particularly careful to avoid contact with the opening.



B. Gently grip the needle guard and mount the needle on the luer-lock mount, screwing it tight until a slight counter-pressure is felt in order to ensure an airtight grip and prevent leakage of the liquid during administration.



## STORAGE:

Store HA1 MSM® at 2–25°C (36–77°F) in a dry place in the original box. Protect from light, heat and frost. Keep out of reach of children.

## CONTENTS OF THE PACK:

Pre-filled syringe containing 2 ml of non pyrogenic gel, sterilised using moist heat.



Consult instructions for use



Store between +2°C and +25°C



Do not re-sterilise



Do not use if package is damaged



Sterilized using steam



Do not reuse



Keep dry



Manufacturer



Keep away from sunlight



Batch number



Use by

