



RHEUMA LINE

NAME OF PRODUCT:

VISCOSEAL®

INTENDED USE:

Synovial fluid substitute.

COMPOSITION:**Active substance:**

Sodium hyaluronate.

Excipients:

Sodium chloride, sodium monohydrogenphosphate, sodium dihydrogenphosphate, water for injection.

INDICATIONS:

To relieve pain, improve mobility and promote joint recovery by flushing out irrigating solution and substituting the synovial fluid following arthroscopic procedures or joint lavage.

PRESENTATION:

Sterile 10 ml mono-use bottle containing 0.5% sodium hyaluronate as an isotonic solution, in a sterile sachet.

DOSAGE & ADMINISTRATION:

The contents and outer surface of the VISCOSEAL® mono-use container are sterile as long as the sachet remains unbroken. VISCOSEAL® should be used at the end of the arthroscopic procedure or joint lavage after the normal irrigating solution. Remove the container from the sachet. Twist off the cap and remove the air bubble by squeezing the container. Attach its luer tip to a portal already placed in the joint. Introduce VISCOSEAL® into the joint cavity by squeezing the container. This will help to wash out the remaining irrigating solution.

CHARACTERISTICS AND MODE OF ACTION:

Arthroscopy is a common procedure to visualise, diagnose and treat problems inside a joint. The joint is normally irrigated with solutions such as saline or Ringer lactate before and during arthroscopy in order to allow a clear view of the operation site and to rinse out debris. There is evidence that the presence of these solutions in the joint after irrigation may be detrimental to the cartilage¹. Furthermore, during the procedure the synovial fluid, which has particular viscoelastic and protective properties due to its hyaluronic acid (HA) content, is washed from the joint. Therefore, although the intervention may result in a long-term improvement of joint function, in the short term a majority of the patients may suffer from post-arthroscopy complaints like pain, swelling and impaired mobility of the joint.



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As well as acting as a lubricant and shock absorber^{2,3}, exogenous HA has been shown to have several other benefits when placed in the joint. Studies have demonstrated that it is able to provide pain relief⁴, stimulate endogenous HA synthesis⁵, and protect the cartilage and synovium by coating the surfaces⁶. There is evidence to suggest that introducing exogenous HA into the joint immediately after joint lavage will help to reduce the negative effects of the saline on the cartilage⁷. It has also been demonstrated that HA promotes the recovery of joint function after arthroscopy or joint lavage^{8,9}.

VISCOSEAL[®] has been developed to relieve the post-arthroscopic symptoms, i.e., pain, swelling and impaired joint mobility, and to promote joint recovery. It contains a highly purified specific fraction of HA produced by fermentation and is devoid of any animal protein. Flushing VISCOSEAL[®] through the joint cavity will help remove the remaining irrigating solution and efficiently coat all surfaces of the joint. The VISCOSEAL[®] left in the joint will act as a lubricant and a shock absorber and its macromolecular meshwork will prevent the free passage of inflammatory cells and molecules through the joint cavity. In addition, HA is able to promote wound healing.

REFERENCES

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BIOCOMPATIBILITY:

Results of acute, sub-acute and chronic toxicity studies together with the results of foetal toxicity, fertility, peri- and post-natal toxicity studies show that sodium hyaluronate is well tolerated.

INTERACTIONS:

No information on the incompatibility of VISCOSEAL[®] with other solutions for intra-articular use is available to date.

STORAGE:

Store at $\leq 25^{\circ}\text{C}$ in original sterile pack, away from heat sources and light. Do not freeze.

SHELF-LIFE:

3 years if stored in original unopened package at room temperature, $\leq 25^{\circ}\text{C}$.

To be used under the direction of a physician.
VISCOSEAL[®] is a medical device.



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