

VISCOSEAL[®]

SYRINGE Sodium Hyaluronate 0.5%

ACCELERATING POST-ARTHROSCOPY RECOVERY



TRB

Your experience
Your expertise
Your expectations



Our solution for joint recovery



Arthroscopy, particularly knee arthroscopy, is a commonly used technique worldwide. Nevertheless, patients may suffer from post-operative complications such as pain, swelling, and impaired mobility of the joint in the short-term due to the lack of synovial fluid in the joint.¹







Viscoseal has been specially developed to replace the synovial fluid post-arthroscopy and therefore to prevent post-operative complications.



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SYRINGE

Product characteristics

 <p>CONCENTRATION CLOSE TO THAT OF HEALTHY SYNOVIAL FLUID</p> <p>0.5% sodium hyaluronate (50 mg/10 ml)</p>	 <p>FREE OF ANIMAL PROTEINS</p> <p>Sodium hyaluronate obtained by biofermentation</p>	 <p>PHYSIOLOGICAL</p> <p>Isotonic solution with a physiological pH</p>
 <p>READY-TO-USE</p> <p>10 ml pre-filled syringe</p>	 <p>SAFE NEEDLE ATTACHMENT</p> <p>Latex-free syringe equipped with a Luer lock</p>	 <p>FACILITATION OF ASEPTIC USE</p> <p>Sterile in the blister</p>

The advantages of Viscoseal Syringe

Temporarily replaces the synovial fluid post-arthroscopy thanks to the lubricating and shock-absorbing properties of sodium hyaluronate²

Displaces the irrigating solution left in the joint space, therefore preventing cartilage metabolism impairment^{3,4}

Provides an alternative to local anaesthetics and corticosteroids, which have been shown to be chondrotoxic⁵⁻⁹

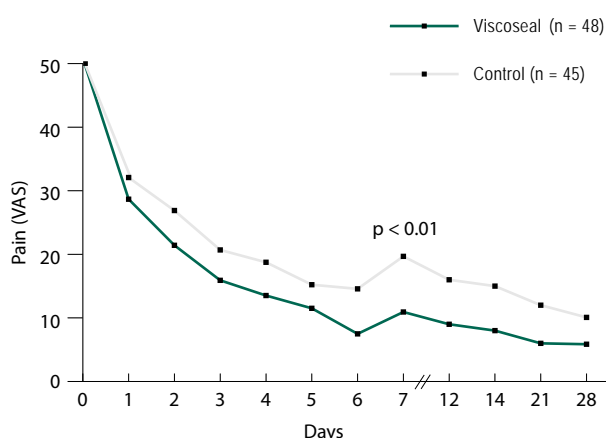
VISCOSEAL[®]

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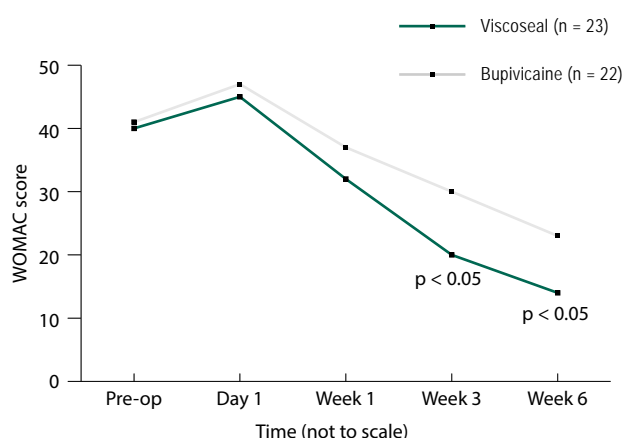


Proven efficacy and safety for patients

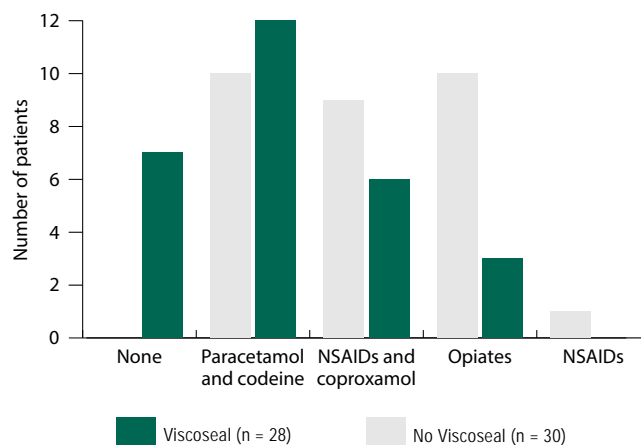
Less pain after surgery¹⁰



Improved joint function and mobility¹¹



Reduced analgesic consumption¹⁵



After arthroscopy, Viscoseal Syringe:

- Reduces post-operative pain^{1,10-16} and effusion^{1,11-13,16}
- Improves joint function and mobility^{11,16,17}
- Reduces analgesic consumption^{11,14,15}
- Reduces the time to discharge from hospital¹⁴⁻¹⁶
- Has an excellent safety profile^{1,10,12-19}



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SYRINGE

Instructions for use

VISCOSEAL[®] SYRINGE— Synovial fluid substitute
Sodium hyaluronate from fermentation 0.5%.
Synovial fluid substitute. 10 ml pre-filled syringe
in a sterile pack for single use. Sterile by moist
heat.

Composition:

1 ml isotonic solution contains 5.0 mg sodium
hyaluronate from fermentation, sodium chloride,
disodium phosphate, sodium dihydrogen
phosphate and water for injections.

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 of the
shoulder or knee joint.

Contra-indications:

Known hypersensitivity to any of the constituents
of the product.

Interactions:

Avoid using VISCOSEAL[®] SYRINGE with materials
disinfected with quaternary ammonium salt
solutions.

Undesirable effects:

No undesirable effects are expected with
VISCOSEAL[®] SYRINGE when used in the approved
indication and at the dosage prescribed. To date,
no cases of infections and allergic reactions
causally associated with the use of
VISCOSEAL[®] SYRINGE have been reported.
However, both risks cannot be completely
excluded. The contra-indications must be
considered.

Dosage and administration:

The contents and the outer surface of the

VISCOSEAL[®] SYRINGE pre-filled syringe are
sterile as long as the sterile pack remains intact.
VISCOSEAL[®] SYRINGE should be used at the
end of the arthroscopy after completion of the
normal irrigating procedure. Take the pre-filled
syringe out of the sterile pack. Remove the cap,
attach a suitable needle and secure it by turning
slightly. Remove any air bubble, if present, before
injection. Introduce VISCOSEAL[®] SYRINGE into the
joint cavity. Alternatively, the pre-filled syringe
may be placed directly into a portal in the joint.
The introduction of VISCOSEAL[®] SYRINGE into the
joint cavity will help to wash out the remaining
irrigation solution.

Precautions:

The general precautions for arthroscopic
procedures should be observed.
VISCOSEAL[®] SYRINGE should be instilled
accurately into the joint cavity. As no clinical
evidence is available on the use of sodium
hyaluronate in children, pregnant and lactating
women, treatment with VISCOSEAL[®] SYRINGE is
not recommended in these cases. Any solution
not used immediately after opening must be
discarded. Otherwise the sterility is no longer
guaranteed and this may be associated with a risk
of infection. Do not use if the pre-filled syringe
or the sterile pack are damaged. Store between
2 °C and 25 °C! Do not use after the expiry date
indicated on the box. Keep out of the reach of
children.

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 cartilage. Furthermore, during the
procedure the synovial fluid, which has particular
viscoelastic and protective properties due to its
hyaluronic acid content, is washed from the joint.
Therefore, although the intervention may result
in a long-term improvement of joint function,
in the short-term patients may suffer from
post-arthroscopy complaints like pain, swelling
and impaired mobility of the joint.
VISCOSEAL[®] SYRINGE has been developed to
relieve these symptoms and promote joint
recovery. It contains a highly purified specific
fraction of hyaluronic acid produced by
fermentation and is devoid of animal protein.
Flushing VISCOSEAL[®] SYRINGE solution through
the joint cavity will help remove the remaining
irrigating solution and efficiently coat all surfaces
of the joint. The VISCOSEAL[®] SYRINGE solution
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.

Presentation:

1 pre-filled syringe of 50 mg/10 ml
VISCOSEAL[®] SYRINGE in a sterile pack
for single use.

To be used by a physician only.

Last revision date: 2019-10


*The text of this information may vary depending on the
country where the product is authorised. In this case, the
national authorisation prevails.*

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