

Profound tendon protection

Sodium hyaluronate 32 mg
2 ml of 1.6% gel in a pre-filled syringe

Composition

Each 1 ml contains:

Sodium hyaluronate	16.000 mg
Sodium chloride	8.500 mg
Disodium hydrogen phosphate	0.563 mg
Sodium dihydrogen phosphate	0.045 mg
Water for injection	q.s.

Description

Biolevox™ HA Tendon with pH 6.8-7.4 contains high molecular weight sodium hyaluronate produced by bacterial fermentation, non-animal origin. It is sterile and non-pyrogenic. The product is intended for injection around the tendon or into the tendon sheath.

Indications

Pain and limitation of mobility in tendon diseases caused by injuries (e.g. strained tendon) or overload changes (e.g. tennis elbow, rotator cuff tendinopathy).

Contraindications

The product should not be administered to patients:

- with known hypersensitivity to any of the components of the product;
- with septic tendonitis;
- with dermatosis at the injection site;
- who are using anticoagulants.

Precautions

All safety precautions during procedure should be taken to prevent occurrence of septic tendonitis.

The product is intended only for injection around the tendon or into the tendon sheath.

Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation as hyaluronan can precipitate in their presence.

Children, pregnant or nursing women should not be treated with this product as there are no clinical data available on its use in these patients.

The product should not be used if a sterile pre-filled syringe is damaged.

The product must be used before the expiration date indicated on the packaging.

Do not re-sterilize. It is to be used on one patient during a single appointment. Store at temperature between +2°C and +25°C.

Keep away from sunlight. Protect from moisture.

The product must be kept out of the reach of children.

Biolevox™

HA tendon

Potential side effects

Biocompatibility studies have confirmed high safety of the product. Transient local reactions, such as pain, redness and swelling, may occur after injection.

These effects can be reduced by cooling the site with cooling bags for 5 to 10 minutes after the injection. Simultaneous oral intake of analgesics and antiinflammatory drugs (NSAIDs) may be beneficial for pain relief.

Interactions

No incompatibility with other solutions administered around the tendon or into the tendon sheath has been reported so far.

Administration and dosage

Disinfect the skin at the site of planned injection. Take the prefilled syringe from the packaging, remove the Luer-lock closure and screw a suitable sterile needle (25G or 27G) onto the syringe. Remove air bubbles before injection.

The therapy consists of a series of two injections, administered at weekly intervals.

The beneficial effects of the treatment last for at least 6 months.

Treatment cycle may be repeated, if required.

Properties and mode of action

Sodium hyaluronate contained in Biolevox™ HA Tendon increases the level of sodium hyaluronate naturally occurring in the soft tissues surrounding the tendons, enabling strengthening and moisturizing the affected area, thus creating an excellent environment for regeneration. Because of its action, it relieves pain and limitation of mobility caused by injuries or overloads of tendons.

Packaging

A sterile pre-filled syringe, containing 2 ml of transparent gel, placed in a blister and two sterile needles (25G and 27G).

To be used exclusively by a medical doctor.



Advanced medical biotechnology



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references

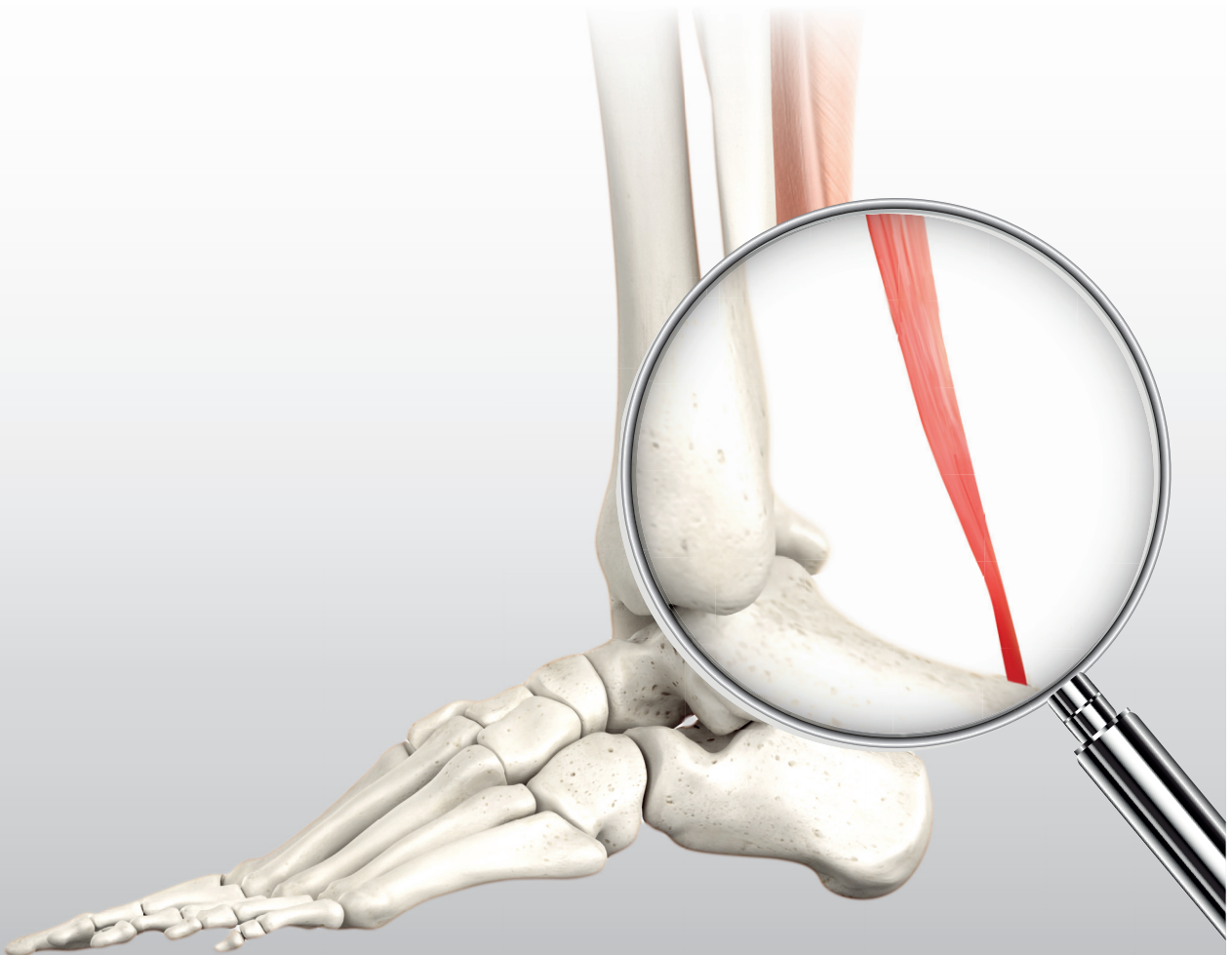


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BioleVox™

HA tendon

Profound tendon protection



Advanced
medical
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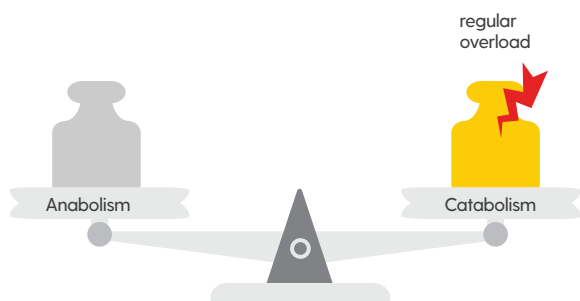
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Biolevox™ HA Tendon inhibits catabolic processes associated with tendinopathies.



Healthy tendon

– anabolism and catabolism in balance^[1,2]



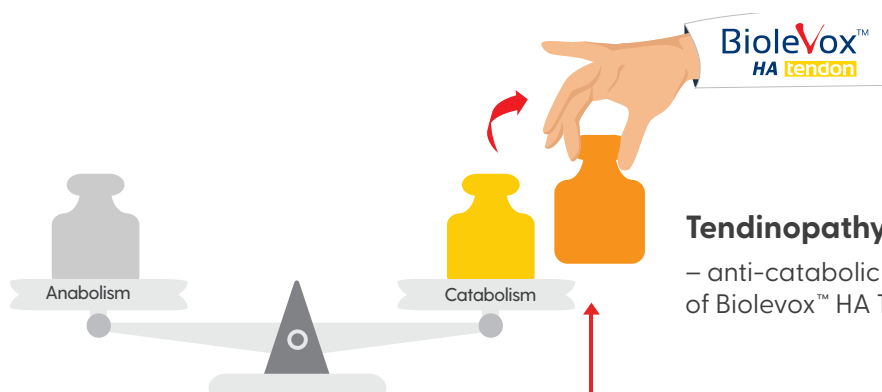
Healthy tendon

– regular overload^[3]



Tendinopathy

– dominance of catabolic over anabolic processes^[3,4,5]



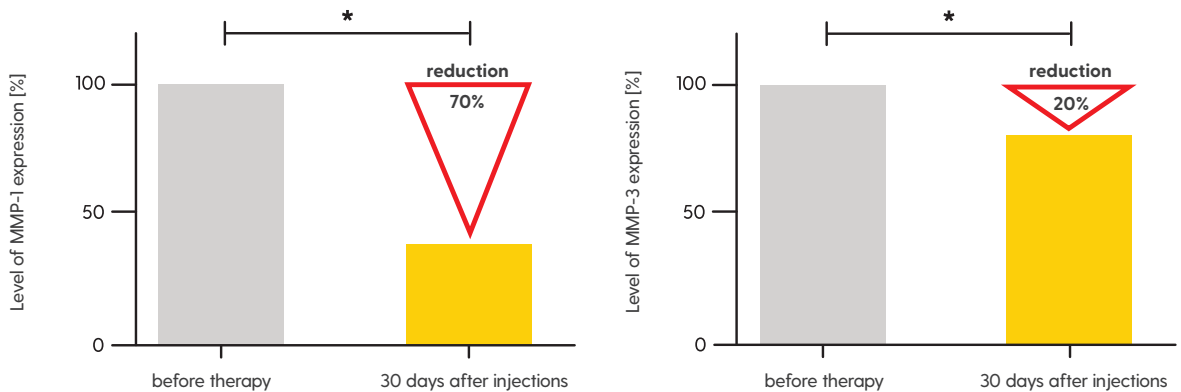
Tendinopathy

– anti-catabolic action of Biolevox™ HA Tendon^[6]

Biolevox™ HA Tendon contains hyaluronic acid which:

- effectively restrains production of catabolic enzymes;
- reduces clinical symptoms of tendinopathy.

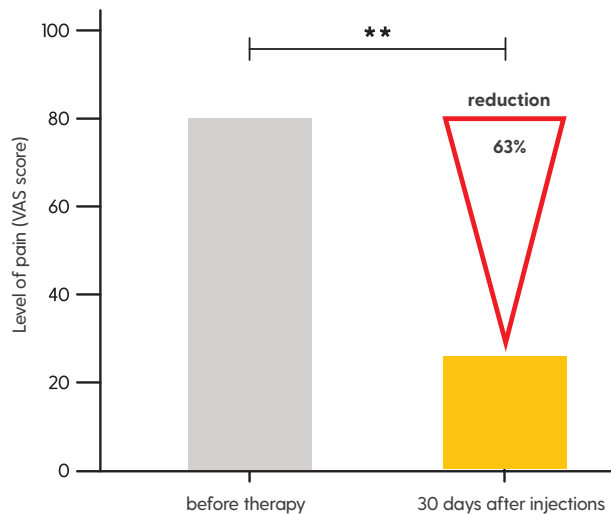
Effective reduction of tendon tissue degrading enzymes MMP-1 and MMP-3 expression^[6]



The influence of HA on the level of MMP-1 and MMP-3 degrading enzymes expression, measured in peritendinous effusion from patients with long head of biceps (LHB) tendinopathy.

MMP-1 - metalloproteinase 1, MMP-3 - metalloproteinase 3. *p<0.05

Effective pain reduction^[6]

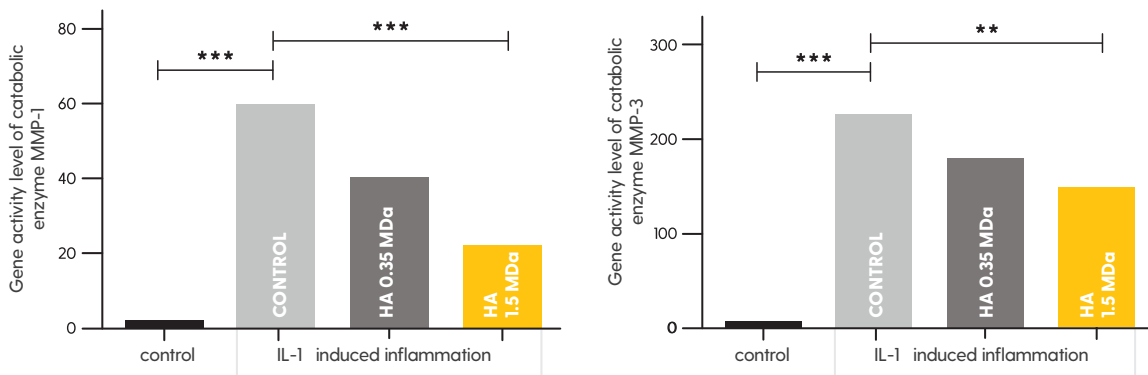


Change in level of pain in patients with tendinopathy treated with hyaluronic acid injections.

VAS – Visual Analogue Scale 100 mm. **p<0.01

Biolevox™ HA Tendon possesses optimal polymer chain length in order to effectively induce cell mechanisms that inhibit catabolic processes.

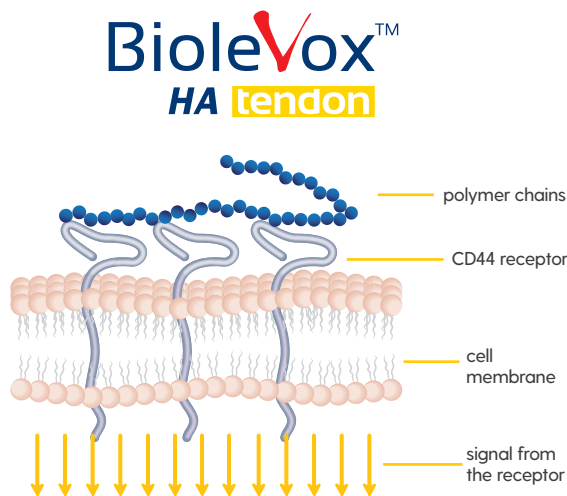
The influence of hyaluronic acid molecular weight on inhibition of MMP-1 and MMP-3 gene activity^[6,7]



The influence of HA molecular mass on MMP-1 and MMP-3 gene activity level after induction of inflammation with IL-1 in tenocytes. IL-1 – interleukin 1 beta; HA 0.35 MDa - hyaluronic acid with molecular weight of 0.35 mln Da; HA 1.5 MDa – hyaluronic acid with molecular weight of 1.5 mln Da. **p<0.01, ***p<0.001

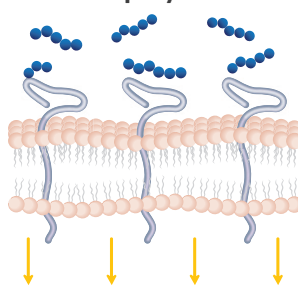
Polymer chain length in Biolevox™ HA Tendon effectively groups CD44 receptors in order to provide adequate cell response^[8,9,10]

Optimal polymer chains length



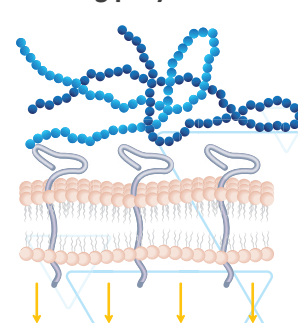
Only hyaluronic acid with an optimally high molecular weight (Biolevox™ HA Tendon) has the appropriate polymer chain length in order to effectively group many CD44 receptors. This leads to the induction of a properly efficient cell response to given hyaluronic acid signal. As a result, Biolevox™ HA Tendon is able to effectively induce cellular processes that inhibit catabolism associated with tendinopathy.

Too short polymer chains



Hyaluronic acid with too low molecular weight has short polymer chains, what prevents them from grouping many CD44 receptors. Hence, the receptors will not induce an efficient cellular response.

Too long polymer chains



Hyaluronic acid with too high molecular weight is not able to group many CD44 receptors, because their long polymer chains block each other (steric hindrance). Therefore, the receptors will not be able to induce an adequately efficient cellular response.