

# ALSAVIN Family

Intra-Articular Sodium Hyaluronate Injection Systems

Freedom to  
MOVE



**ALSANZA**  
Medizintechnik und Pharma GmbH



## **ALSAVIN**

Sodium Hyaluronate 20mg

20 mg HA (1.0%) in 2 ml solution  
3-5 injections with one week intervals  
Bacterial fermentation  
3.0 MDa molecular weight  
35.000 mPa.s viscosity



## **ALSAVIN SUPRA**

Sodium Hyaluronate 32mg

32 mg HA (1.6%) in 2 ml solution  
1-3 injections with one week intervals  
Bacterial fermentation  
3.0 MDa molecular weight  
250.000 mPa.s viscosity



## **ALSAVIN ONE**

Sodium Hyaluronate 48mg

48 mg HA (2.0%) in 2.4 ml solution  
1 injection  
Bacterial fermentation  
3.0 MDa molecular weight  
900.000 mPa.s viscosity

# FREEDOM OF MOVEMENT WITHOUT PAIN WITH ALSAVIN INTRA-ARTICULAR INJECTIONS

ALSAVIN Intra-Articular Injections (IAs) are used to restore the limited mobility of patients because of the discomfort experienced due to osteoarthritis and to help them move freely and maintain a quality life.

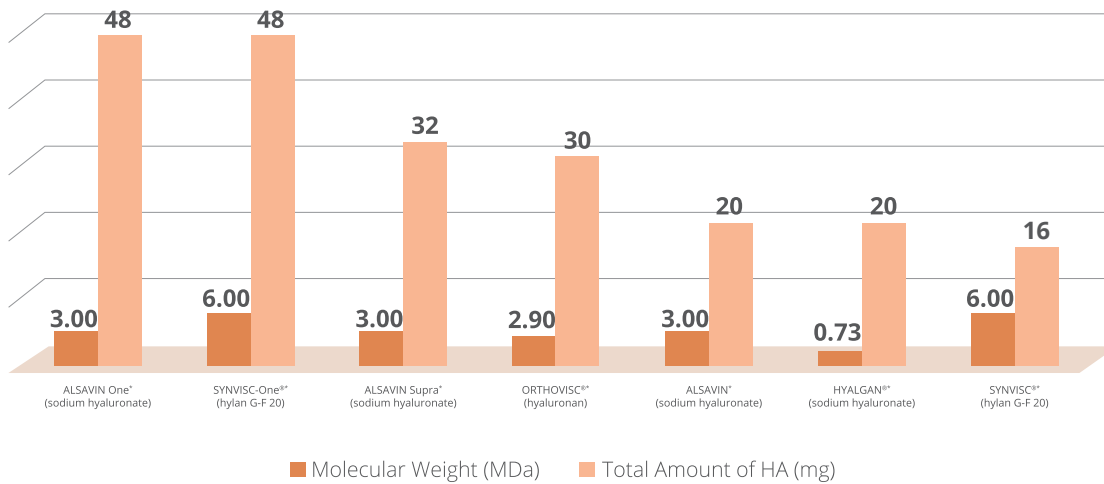


# HIGH MOLECULAR WEIGHT

ALSAVIN IAIs contain 3.0 MDa\* long and monotype HA chains prevent molecular separation and support stability for pain relief.

\* ALSAVIN IAIs manufacturer's full prescribing information

## Molecular Weight and Total Amount of HA Comparison



\* SYNVISIC-One® (hylan G-F 20) full prescribing information

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\* ORTHOVISC® (hyaluronan) full prescribing information

\* HYALGAN® (sodium hyaluronate) full prescribing information

\* ALSAVIN (sodium hyaluronate) full prescribing information

\* ALSAVIN Supra (sodium hyaluronate) full prescribing information

\* ALSAVIN One (sodium hyaluronate) full prescribing information



## SUSPENSIVE HA STRUCTURE

Well entangled ALSAVIN IAs exhibit suspensive properties and the distance between HA chains supports stress absorption at the molecular level.

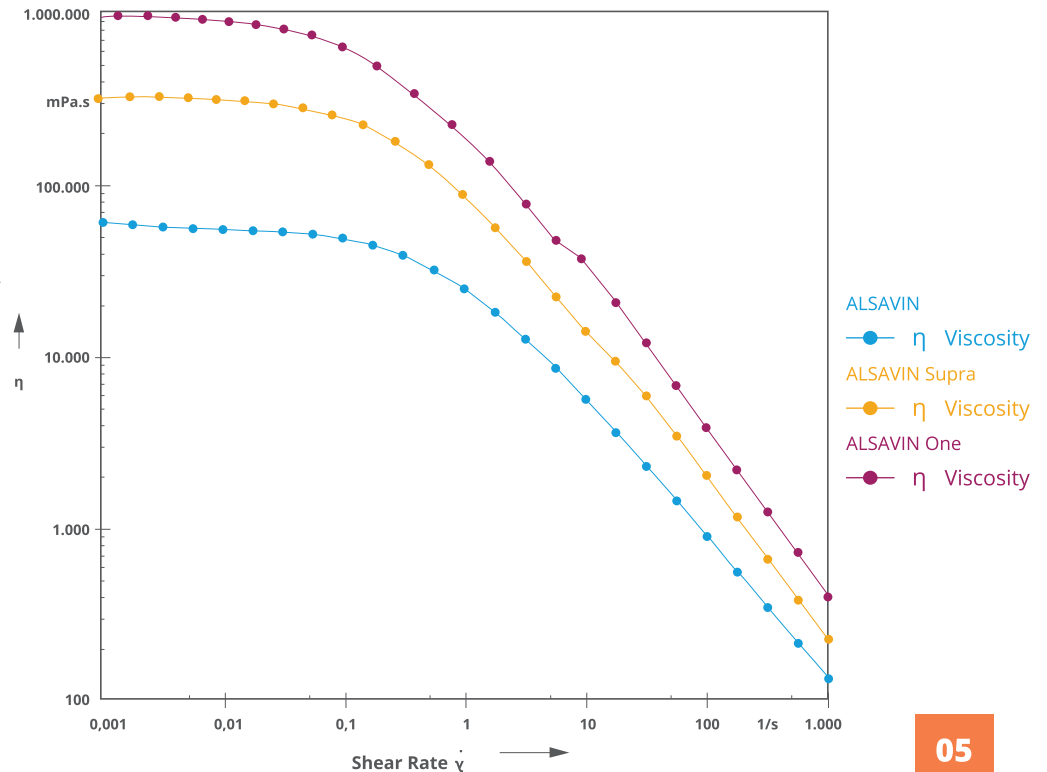


Low MW HA products have wide space between their chains but exhibit poor stability due to the lack of entanglement.

The well entangled HA structure of ALSAVIN provides suspensive behavior with wider distances between chains.



ALSAVIN - ALSAVIN Supra - ALSAVIN One



## HIGH DYNAMIC VISCOSITY

ALSAVIN IAs show 'shear thinning' like healthy human synovial fluid under increased mechanical stress frequency that provides articular motion compatibility and smooth movements.

Presenting High Dynamic Viscosity values even at higher shear rates;

- improves stability
- increases strength
- delays material degradation for both static and dynamic conditions

## ADAPTIVE ELASTICITY

Elasticity of intra-articular HA products plays a significant role in pain relief. The Adaptive Elasticity of ALSAVIN IAs is increased by the stress frequency. Provides progressive shock absorption while presenting highly elastic and suspensive responses.

**Exhibits a more elastic response than synovial fluid** in static conditions (0 - 0.5 Hz).

Protects total cartilage from gelling and stiffness while under static conditions or after long inactivity.

**More suspensive** than synovial fluid under dynamic conditions (2.5 Hz).

Higher elastic modulus of ALSAVIN at 2.5 Hz yields greater elastic behavior and enhanced **suspensive properties under dynamic conditions. Thus protecting the material and cartilage from deformations.**

## NON-ANIMAL BASED

ALSAVIN IAs are sterile, non-pyrogenic, clear, non-inflammatory, highly purified sodium hyaluronate of high molecular weight. The rigorously purified sodium hyaluronate is manufactured by bacterial fermentation.\*

\* ALSAVIN IAs manufacturer's full prescribing information





## TECHNICAL SPECIFICATIONS

ALSAVIN Family			
			
			
<b>Substance</b>	Sodium Hyaluronate	Sodium Hyaluronate	Sodium Hyaluronate
<b>Concentration</b>	20 mg HA (1.0%)	32 mg HA (1.6%)	48 mg HA (2.0%)
<b>Volume</b>	2 ml	2 ml	2.4 ml
<b>Frequency</b>	3-5 injections with one week intervals	1-3 injections with one week intervals	Single injection
<b>Origin</b>	Bacterial Fermentation	Bacterial Fermentation	Bacterial Fermentation
<b>Molecular Weight</b>	3.0 MDa	3.0 MDa	3.0 MDa
<b>Dynamic Viscosity</b>	35.000 mPa.s	250.000 mPa.s	900.000 mPa.s

## Description:

Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% is sterile, non-pyrogenic, clear, non-inflammatory, highly purified sodium hyaluronate of high molecular weight, dissolved in a buffered physiological saline solution. The highly-purified sodium hyaluronate is obtained from bacteria by fermentation. Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% is a product for the relief of the pain and stiffness of the knee joint and other synovial joints in patients with degenerative and traumatic changes to the synovial joint. Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% contains sodium hyaluronate, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate and water for injection.

	<b>ALSAVIN 1.0%</b>	<b>ALSAVIN Supra 1.6%</b>	<b>ALSAVIN One 2.0%</b>
<b>1.0 ml contains</b>	10,0 mg sodium hyaluronate	16,0 mg sodium hyaluronate	20,0 mg sodium hyaluronate
<b>pH</b>	6.8 - 7.6	6.8 - 7.6	6.8 - 7.6
<b>Osmolality</b>	300 - 350 mOsm/kg	300 - 350 mOsm/kg	300 - 350 mOsm/kg
<b>Molecular weight (App.)</b>	3.0 MDa	3.0 MDa	3.0 MDa

## Properties and Efficacy:

All synovial joints especially the weight – bearing joints, contain viscoelastic sodium hyaluronate. This substance has lubrication and shock absorbing properties, allowing these joints to move normally and painlessly. In patients with degenerative joint disease (osteoarthritis), the viscoelasticity of the synovial fluid is significantly impaired, causing the mechanical stress on the joint and the breakdown of the articular cartilage to greatly increase resulting in limited and painful joint movement. Intra-articular administration of high purity sodium hyaluronate, which has very good viscoelastic properties, can improve the quality of the joint's lubrication. The lubrication and shock absorbing properties of this product reduce pain and improve joint mobility. This effect may last for several months following recommended treatment cycle of intra-articular injections.

## Indications:

Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who

have failed to respond adequately to conservative non pharmacologic therapy and simple analgesics (e.g. acetaminophen (paracetamol)).

## Contraindications:

Do not administer to patients with known hypersensitivity to hyaluronate preparations. Intra-articular injections are contraindicated in cases of present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis.

## Side Effects:

Following the use Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0%, patients may experience local symptoms in the joint being treated (pain, sensation of heat, reddening and swelling). The following adverse events have been reported for similar products: mild or moderate arthralgia, in rare cases skin rash, aseptic joint effusions, pruritus and muscular cramps. Further adverse events that have been observed in very rare cases are: allergic reactions, anaphylactic shock, hemarthrosis, phlebitis, pseudosepsis, severe acute inflammatory reaction (SAIR), nasopharyngitis, joint stiffness, tendonitis, bursitis, fever and myalgia.







### **Warnings and Precautions:**

- Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% is intended for single use only. The reuse of the product creates a potential infection risks for patients or users.
- Sodium hyaluronate is manufactured by bacterial fermentation and rigorously purified. However the physician should consider the immunological and other potential risks that can be associated with the injection of any biological material.
- Do not reuse syringe. Any repeat usage of the syringe carries a risk of contamination and infection of the patient.
- Do not re-sterilize the pre-filled syringe. Performance will be impaired. Only the solution is sterile but not the outside of the syringe.
- Do not use if package is damaged or opened.
- Do not use after the expiry date printed on the pack.
- In order to avoid overuse of treated joints patients should be advised to relative rest (but no immobilisation) for 24h after each injection.
- Dispose of the syringe and cannula in accordance with accepted medical practice and applicable national, local and institutional requirements.
- There is no evidence concerning the safety of Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% in human pregnancy, lactation and the children under 18 years of age. Administration during pregnancy and lactation is at the discretion of the doctor.

### **Interaction with Other Agents:**

Sodium hyaluronate is incompatible with quaternary ammonium compounds such as benzalkonium chloride solutions. Therefore, Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% pre-filled syringes must never come into contact with surgical instruments rinsed with these solutions.

**Dosage and Administration:  
FOR INTRA-ARTICULAR INJECTION.  
FOR SINGLE USE ONLY.**

Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% should only be used by a physician for intra-articular injection. Use an appropriate size of the needle (19 to 20 gauge is recommended) and length of the needle depending on the joint to be treated. 3 to 5 injections performed one week apart are recommended (Alsavin 1.0%). 1 to 3 injections performed one week apart are recommended (Alsavin Supra 1.6%). 1-2 injections are recommended (Alsavin One 2.0%). Several joints may be treated simultaneously and treatment cycles may be repeated. In order to avoid intra-articular infection strict aseptic injection technique has to be applied. It is recommended that an ice-pack be placed on the joint undergoing treatment for 5 -10 minutes in order to prevent pain and swelling. In the case of effusion accompanied by severe pain the fluid must be removed from the affected joint.



**1. Twist and pull out**



**WRONG!**  
(Backstop opening at front)




**2. Insert and twist the cannula**




**CORRECT!**  
(Backstop opening at back)

**Storage:**


Store Alsavin 1.0% / Alsavin Supra 1.6% / Alsavin One 2.0% between 2°C and 25°C. Protect from light and shocks. Do not freeze.

-  Manufacturer


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-  Do not reuse


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-  Do not resterilize

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-  Sterilized using steam (Product)

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-  Consult instructions for use

-  Caution


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-  Keep away from sunlight

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-  Keep dry

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-  Do not use if package is damaged



**ALSAVIN**

[www.alsanza.com](http://www.alsanza.com)

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