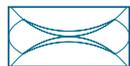


MOVEMENT IS LIFE™



ANTALVISC®  
Cross-Linked Hyaluronic Acid + Mannitol

THE WINNING  
COMBINATION.



## WHAT IS ANTALVISC® ?

ANTALVISC® is a single injection medical device indicated for the prevention and treatment of osteoarthritis (OA). It is injected in joints to relieve pain, restore articular function and protect cartilage.



ANTALVISC® is made of non-animal, high molecular weight, cross-linked hyaluronic acid and mannitol. Hyaluronic acid (HA) is a molecule that occurs naturally in the body, especially in cartilage and synovial fluid. HA provides the lubrication and cushioning in a normal joint. Mannitol, a natural sugar alcohol, is a strong antioxidant and free radical scavenger that protects HA from chemical degradation and rapid depolymerisation.

The intraarticular injection of HA, called viscosupplementation, is commonly used in clinical practice for the management of OA. Its effectiveness has been demonstrated by extensive clinical trials, and it is recommended by different scientific advisory bodies like EULAR (European League Against Rheumatism), OARSI (Osteoarthritis Research Society International), ACR (American College of Rheumatology) and APS (American Pain Society).

ANTALVISC® replaces and supplements the unhealthy synovial fluid to increase the quality and quantity of the endogenous HA and to restore its viscoelastic properties.

ANTALVISC® lubricates and cushions the joint and protects the cartilage, thereby improving mobility and articular function, reducing pain and retarding structural progression of OA.

# BE ACTIVE. BE ALIVE.

ANTALVISC<sup>®</sup> is an injectable treatment that reduces joint pain and stiffness to help osteoarthritis patients to regain their active lifestyles.

## Specifications

COMPOSITION	CROSS-LINKED HYALURONIC ACID + MANNITOL
ORIGIN	NON-ANIMAL (BIOFERMENTATION)
HA CONCENTRATION	20 MG/ML
HA MOLECULAR WEIGHT	> 4 MILLION DALTON IN THE STERILIZED PRODUCT
INDICATION	MILD-TO-SEVERE OA
EFFECTS	PAIN RELIEF, MOBILITY IMPROVEMENT, CARTILAGE PROTECTION
DURATION OF EFFECT	UP TO 15 MONTHS*
ADMINISTRATION	SINGLE INTRAARTICULAR INJECTION
NEEDLE SIZE	18 TO 22 G
PRIMARY PACKAGING	STERILE 3 ML BD GLASS PREFILLED SYRINGE WITH FINGER GRIP
SECONDARY PACKAGING	STERILIZED MEDICAL GRADE BLISTER IN CARTON BOX
SHELF LIFE	3 YEARS
STORAGE	BETWEEN +2°C AND +25°C

\* depending on several factors such as the severity of the osteoarthritis, the type and size of the affected joint, the patient's condition and age, the patient's lifestyle, the patient's genetic profile and the technique of injection.



# A SINGLE INJECTION. A LONG DURATION.

The formulation makes it possible to reduce the number of injections while increasing the duration of effect.

## RESISTANT

The molecule of HA is very sensitive to enzymes, free radicals, heat and mechanical constraints. Once injected it is rapidly degraded and absorbed within few hours. Therefore, in order to increase the residence time of HA and its beneficial action it is crucial to protect it against these chemical degradations. This problematic is particularly important in the joint because of the high mechanical degradation during the articular movement.

The HA in ANTALVISC® is protected from enzymatic, oxidative, thermal and mechanical degradations thanks to 4 factors:

### Adjuvanted

ANTALVISC® is a viscosupplement adjuvanted with mannitol. This natural sugar alcohol is a strong antioxidant and free radical scavenger that protects HA from chemical degradation and rapid depolymerization to enhance its intraarticular residence time.

### Cross-linked

ANTALVISC® is naturally cross-linked thanks to a proprietary technology. This natural cross-linking makes it possible to stabilize the HA polymers for more durability and to increase its rheological properties while keeping the biological and hygroscopic properties of a linear HA.



### High molecular weighted

ANTALVISC® is made of a very high molecular weight HA. Protected by mannitol from thermal degradation during the final manufacturing process of the gel, the HA molecular weight after sterilization is not less than 4 millions Dalton, which corresponds to that of a healthy synovial fluid. This large size of HA molecules increases the rheological properties of the gel and reduces its intraarticular chemical degradation. As thermal stabilizer, mannitol will maintain this very high molecular weight during the storage of ANTALVISC® at room temperature.

### Highly concentrated

ANTALVISC® has a high HA concentration of 20 mg/ml which corresponds to the double of the concentration usually found in the viscosupplements administered by 3-5 injections. This large number of molecules increases the viscosity and elasticity of the injected gel as well as its resistance and duration of effect.

# NATURAL AND SAFE

ANTALVISC® is a drug-free treatment made of non-animal, high purity hyaluronic acid and mannitol which are both non-toxic, non-allergenic and fully biocompatible ingredients.

## SAFE

ANTALVISC® is a natural, biocompatible, bioresorbable, non-allergenic, drug-free and non-systemic treatment.

ANTALVISC® has a well established safety profile and tolerability supported by clinical trials and patient experience.

Only non-serious, transient and spontaneously resolved adverse events can occur at a very low frequency.

### No animal origin

Several competing products, including the actual world's leading brands, are manufactured from a HA of animal origin (cock's comb) which has a high animal protein content, leading to possible allergic reactions and to a higher rate of adverse events. ANTALVISC® is made of a non-animal HA obtained by biofermentation which is the today's source of choice due to its high purity and full biocompatibility.

### No toxic agent

Unlike other visosupplements, ANTALVISC® contains no toxic substances such as 1,4-butanediol diglycidyl ether (BDDE), formaldehyde, divinyl sulfone etc. ANTALVISC® is naturally cross-linked without any chemical agent. Mannitol, like hyaluronic acid, is a natural substance that benefits from a perfect safety proven by extensive clinical studies for more than 60 years.

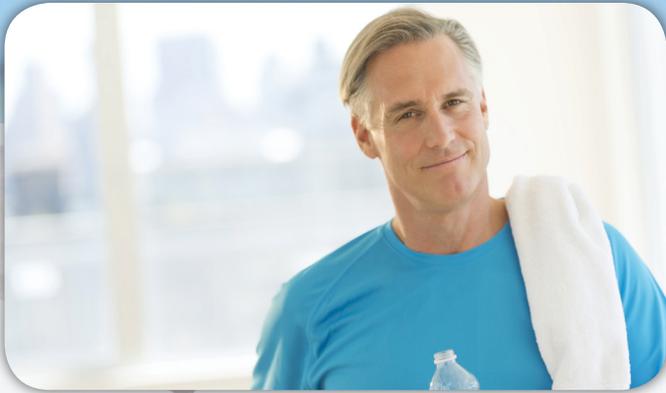


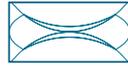
### Single injection

Unlike other viscosupplements, ANTALVISC® requires only one office visit of few minutes for a complete, simplified osteoarthritis treatment with no downtime. This single injection regimen decreases patient inconvenience and reduces the risk associated with multiple injections

### Quality control

ANTALVISC® is manufactured in France under strict quality control and meets the requirements of the highest technical standards. It conforms to the European Medical Devices Directive 93/42/EEC and an optimized risk management process that goes above and beyond regulatory compliance has been implemented.





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Cross-Linked Hyaluronic Acid + Mannitol



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