

STOP THE EVOLUTION OF OSTEOARTHRITIS!

**WE CANNOT IGNORE PAIN!
WHY HURT WHEN YOU CAN PREVENT IT?**

Product: ORTHOFLEX one®

Composition: hyaluronic acid+ chondroitin sulfate

Indication: osteoarthritis

Concentration: 60 mg/3 ml (2%) hyaluronic acid
90 mg/3 ml (3%) chondroitin sulfate

Treatment: 1 injection/treatment OA level 3 and 4

Molecular weight: 3 KDa

Effect: cartilage repair, mobility improvement,
pain relief

Packaging: 3 ml prefilled syringe in medical blister

Sterilization: autoclave

Shelf life: 2 year

Storage: between +2°C and +25°C

ORTHOFLEX one® is produced according to Good Manufacturing Practice (GMP) and ISO13485, being certified as a system with high quality ingredients, CE marked medical device, being in accordance with the European Directive 93/42/EE.

Storage: Store at 2- 25 degrees C, in the original package and do not freeze.

**Be responsible, respect yourself and prevent the degradation of cartilage,
by using ORTHOFLEX one® therapy.**



1 INJECTION PER TREATMENT

ORTHOFLEX one

INTRA ARTICULAR INJECTION FOR JOINT CARTILAGE REPAIR
**UNIQUE COMBINATION OF CROSS-LINKED
HYALURONIC ACID +CHONDROITIN SULFATE**

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What is ORTHOFLEX one®?

ORTHO FLEX one® is the first and alone commercial viscose supplement combining HA (hyaluronic acid) and CS (chondroitin sulfate) in the treatment of degenerative joint disease.

ORTHO FLEX ONE® is a sterile, viscoelastic solution, containing two highly purified cross-linked biological polymers: hyaluronic acid in concentration of 60 mg per 3 ml and chondroitin sulfate 90 mg per 3 ml. The solution has high molecular weight - 3,0 MilDa - which guarantees its excellent efficiency and a strong therapeutic effect.

ORTHO FLEX one® presents itself in a prefilled, sterile, single dose syringe, that will be injected as **1 dose per treatment**.



How does it work?

Hyaluronic acid is a major component of the synovial fluid and cartilage and is responsible for the lubrication and cushioning in joints.

It decreases friction between joint surfaces and protects soft tissue from trauma, by acting as a shock absorber.

Hyaluronic acid also has analgesic, anti-inflammatory and antioxidant effects, stimulates proteoglycan synthesis and facilitates the evacuation of cartilaginous remains.

Chondroitin Sulfate is a molecule that occurs naturally in the body. It is an important component of cartilage - the tough connective tissue that cushions the joints.

It delivers nutrients to the joint cartilage. The body needs nourishment to heal and repair itself and Chondroitin Sulfate has been proven to stimulate the growth of new joint cartilage.

It can also block the enzymes that degrade cartilage and provides the building blocks for the body to produce new cartilage.

Chondroitin sulfate also inhibits pro-inflammatory factors secretion.

The elasticity and plasticity, which are the functions of the joint cartilage, can be maintained through the use of Chondroitin Sulfate.

The adjunction of Chondroitin sulfate provides not only pain relief, mobility improvement and cartilage protection, but also cartilage regeneration.

This cartilage repair is particularly useful in severe OA (grade III and IV).

Using Chondroitin Sulfate as a **cross-linking agent** increases bio-compatibility and bio-degradability of the native polymer, creates the premises for delaying cartilage degeneration and supports regeneration.



The outstanding viscoelastic performance of **ORTHO FLEX one®** is due to the unique **cross-linking** process.

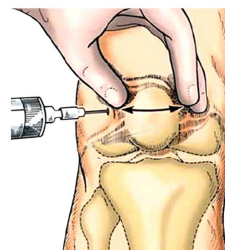
What are the indications of ORTHOFLEX one®?

ORTHO FLEX one® is a product for viscose supplementation, which is a safe, efficient and well established treatment in osteoarthritis, consisting of injecting a hyaluronic acid and chondroitin sulfate based solution into the affected synovial joint.



ORTHO FLEX one® acts as a temporary replacement and supplement for synovial fluid. It is also recommended for :

- post-arthroscopy pain relief,
- following meniscus repair procedure,
- following previous crossed ligament reconstruction
- as auxiliary treatment for patients with osteochondral defects.



What is the treatment with ORTHOFLEX one®?

Just one injection per treatment can treat the symptoms of osteoarthritis.

ORTHO FLEX one® is administered in the affected joint as a single dose per treatment.

If the treatment is bilateral, a separate syringe should be used for each knee.

Approved for all synovial joints (particularly the knee and hip, but also the ankle, shoulder, elbow, wrist, fingers, toes, the temporo mandibular and facet joints).

This effect can be maintained for up 1 year. In order to prevent complications, the treatment should be repeated.

Any joint effusion present should be removed by joint aspiration, before injecting **ORTHO FLEX one®**.



After the injection, an articular rest of approximately 24 hours is recommended (no strenuous exercise), in order to increase the duration of effect. General rest and applying ice to the injected joint are helpful.