orto brand
enjoy your life

ORTHOFLEX PRODUCTS

ORTHOFLEX one®
ORTHOFLEX tendon®
ORTHOFLEX forte®
ORTHOFLEX gel®

www.ortobrand.com

ORTOBRAND INTERNATIONAL

Manufactures and distributes products based on hyaluronic acid (HA), a naturally occurring polymer found throughout the body, used for the affected synovial joint.
It all started with a desire to help people in need and to be able to understand that a medical device is not just a product, but rather a chance to return to a normal life.
ORTOBRAND team's objective is to develop international business by establishing partnerships with specialized foreign distributors all over the world.

Thank you for your interest in our products and services.

https://www.ortobrand.com/

facebook.com/OrthoflexForte

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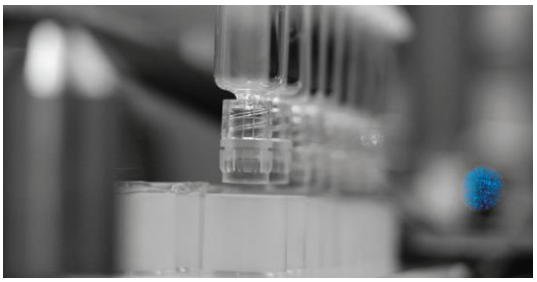

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ORTHOFLEX®
Medical Report

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

Advanced Technology

The manufacturing in compliance with Romanian law no 95/2006 regarding medicines for human use. Valid Manufacturing Authorization, in full compliance with GMP issued by the National Medicine and Medical Devices Agency.
Manufacturing operations for investigational medicinal products include total or partial, certification and batch release, import, storage and distribution and tests (microbiological and physical-chemical) for quality control.

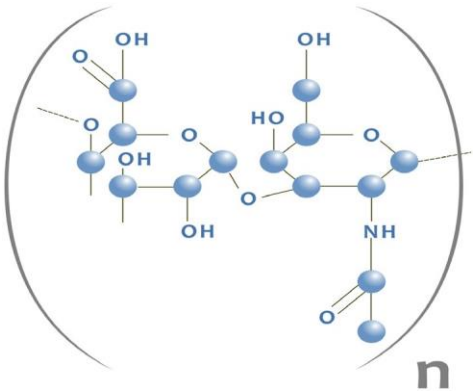
Medical investigation, approved result.

ORTOBRAND has a method that is currently unique with regard to the combination of its advantages. The raw material selected according to the highest quality aspects is cross-linked in a special way. The products are thus particularly stable in the human

body. Natural enzymatic degradation processes are slowed down by the cross-linked and gel-like substance, and by the associated reduction in the molecule surface of the products. Processes are slowed down by the cross-linked and gel-like substance, and by the associated.

The extraction of hyaluronic acid (non-animal origin) through biofermentation also reduces the likelihood of immune responses to a minimum. ORTOBRAND products have an optimized injection behavior that is reflected in the of the hyaluronic acid from ORTOBRAND.

SODIUM HYALURONATE



•Hyaluronan (also known as sodium hyaluronate or hyaluronic acid) is a natural and linear glycosaminoglycan, and is ubiquitous in all the tissues and fluids of animals, with the highest concentrations in soft connective tissues.
•In 1934, Karl Meyer and his assistant John Palmer first announced the discovery of HA. They purified HA from bovine vitreous and showed that it contained a hexuronic acid and a hexosamine. They proposed "for convenience, the name hyaluronic acid, from hyaloid (vitreous) + uronic acid." Up to the mid-1940s, HA had been isolated successfully from other sources- synovial fluid, skin, umbilical cord, cock's comb, etc.
•In 1980s, Dr. Endre Balazs and his coworkers developed a procedure to isolate, purify and identify hyaluronic acid from rooster combs and human umbilical cords. Since then, HA has been produced at industrial scale from rooster combs and human umbilical cords.
•Discovered from bacteria.It is known that the capsules of some bacteria contain HA, therefore, HA can also be isolated from certain strains of bacteria, such as streptococci, which was first reported in 1937 by Kendall et al. They cultured Group A streptococci and then the mucoid polysaccharide was precipitated with ethanol. This polysaccharide which was composed of N-acetyl glucosamine and glucuronic acid units was identical with that occurring in bovine vitreous humor and human umbilical cord. The bacterial production of HA involving a Streptococcus zooepidernicus strain was first described in 1989, giving rise to the first commercialization of HA produced by fermentation.
•By the end of the 20th century, bacterial fermentation had become the leading production technique for sodium hyaluronate, and it has led to great changes in the sodium hyaluronate industry. The industry is now able to produce a higher quality HA product on an industrial scale necessary to support the continued expansion of HA applications into new areas of science. The techniques have also lowered the cost of HA production to a point that has allowed many applications to go mainstream that might have proved too costly for markets previously.
•Commercial HA is commonly presented as the form of sodium salt.
•During the manufacture of HA, sodium salts (such as sodium chloride or sodium hydroxide) are often used to increase ionic strength or to adjust pH value, therefore, most of HA products is presented as the form of sodium salt, named sodium hyaluronate.

Joint Pain and Arthritis

With overuse or injury, cartilage on the end of the joints can break down, causing a narrowing of the joint space and the bones to rub together. Painful bony growths, or spurs, may form. This can lead to swelling, stiffness, and possibly osteoarthritis, the most common type of arthritis. Another type of arthritis is rheumatoid arthritis, an auto-immune disease characterized by extreme inflammation.

What is Osteoarthritis?

- Osteoarthritis is a disease that affect the joints in your body.

•While it can affect any joint , osteoarthritis most commonly in the hands , hip, Knees, neck and lower back.

•Osteoarthritis (OA) is the most common joint disease and cause of disabilities, especially in the elder people (more than 80 percent of the population over 55 years of age is affected by osteoarthritis).

•Also known as degenerative arthritis, degenerative joint disease or OA, it occurs when the cartilage that normally covers and cushions the ends of bones wears down over time. It is characterized by cartilage erosion, changes in subchondral bone, osteophyte formation and synovial inflammation.

- The main symptoms of OA are chronic pain, stiffness and loss of mobility.

How does OA develops?

Osteoarthritis is caused by cartilage resulting in a joint pain.

•The smooth cartilage surface wear down. Then this happens, the cartilage loses its elasticity and more easily damage by excess use or injury.

•With time section of cartilage may wear away completely. As a result the bone rub together.

•As the cartilage wear down , the join may lose its normal shape. The bone end thicken. The bone at the edge of the joint mat grown outward and form body spurs.

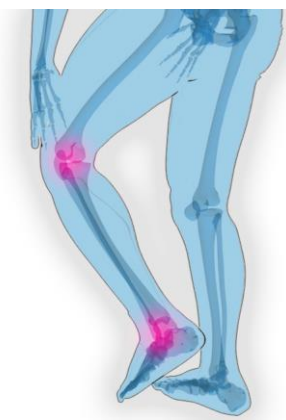
•Fluid – filled cysts may form in the bone near the joint . Bit of bone or cartilage may float loosely in the joint space.

Osteoarthritis of the Knee

When osteoarthritic joints became swollen and damaged , they can be painful and difficult to move.

- If you have OA of the knee the symptoms pain, stiffness limited range of motion.

•In the arthritic joints , the normal concentration and molecular weight of hyaluronate (HA) is decreased by 33% to 50%, limiting its role in maintaining normal joint biomechanics.



VISCOSUPPLEMENTATION

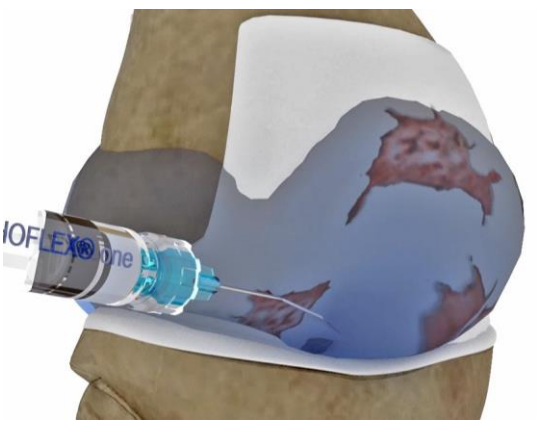
What is Viscosupplementation?

•Viscosupplementation refers to a procedure that involves the use of HA solution to supplement or replace synovial fluid in joint with pathological conditions to alleviate pain and promote the healing of intra-articular wounds. The viscosupplementation should improve the physiological environment of an osteoarthritic joint by restore the protective viscoelasticity of synovial fluid, reduce friction, and improve mobility.
•Studies have confirmed the satisfactory effect of HA to treat lameness in race horses and osteoarthritis (OA) in human knees, hips, shoulders, and temporo-mandibular joint, and so forth. The use of HA solution in OA treatment is considered to be the most successful medical applications of HA.
•Viscosupplementation has as its therapeutic goal the restoration of rheological homeostasis in pathological structures such as osteoarthritic joints. When the normal viscoelasticity of a solid tissue compartment or the elastoviscosity of a liquid tissue compartment is decreased under pathological conditions, normal function and regenerative processes are impaired. By introducing viscosupplementary devices, the normal rheological state of such compartments is restored or augmented. These devices stay in the tissue compartment for various periods of time, depending on the nature of the viscosupplement and the pathophysiology of the tissue compartment.

Mechanism of action

•Viscosupplimentation with HA hasvarious mechanism of actions on the osteoarthritic knee. In addition to repletion of intra -articular HA and its viscous and elastic properties , HA also have anti inflammatory, anabolic and analgesic properties.

•HA has been identified as the molecule responsible for imbuing the knee with this rheostatic properties. HA is polysaccharide chain composed of repeating disaccharide units of glucuronic acid and N –acetylglucosamine. HA is normally synthesized by tipe B synoviocytes or fibroblasts and is secreted into the joints. In the osteoarthritic knee the concentration of HA is decresed to nearly one half of normal, the MW is reduced (as polysaccharide chains are cleaved) and this is decreased interaction between HA molecules. These changes after the inherent viscous and elastic properties of HA and reduces the ability of the joint to resist stress and shear forces.
•HA is viscoelastic substance because it exhibits both viscous and elastic properties. This allows the joint optimally adapt to different externally applied forces. The knee experiences low shear loads during simple range of motion. Under these conditions , viscous properties predominate and the HA molecules line up and act as a lubricants . under high shear loads , HA molecules behave and an elastic substance and absorb energy that is transmitted across the joint.
•Because native HA is decreased in the osteoarthritic knee and HA restores these lost viscoelastic properties , descriptions of these product as viscosupplements seems reasonable .



ORTHOFLEX® one

Intra articular injection for joint cartilage regeneration

Help your joints to repair cartilage

Prefilled syringes

Natural cross-linked Hyaluronate 60 mg +
Chondroitin Sulfate 90 mg/3 ml

The first and alone commercial viscose supplement combining HA (hyaluronic acid) and CS (chondroitin sulphate) with ORTHOFLEX ONE in the treatment of degenerative joint disease.

What is it?

Orthoflex one® is a prefilled sterile syringe , a viscose elastic 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. with **high molecular weight** that guarantees its excellent efficiency and a strong therapeutic effect **3,0 million daltons**

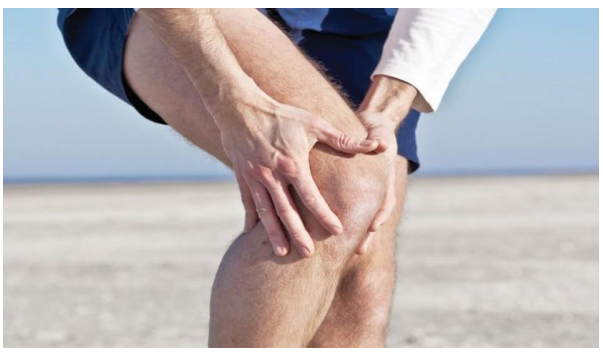
The injection is to be administered intra articular for the treatment of arthrosis and it will definitely lead to an improvement in the functioning of the joint bones and to the recovery of the cartilage.

What is hyaluronic acid?

Hyaluronic acid is a naturally occurring protein in the body, it is concentrated in synovial fluids and is a key component of cartilage which ensures lubrication and shock damping in a normal joint.

What is chondroitin sulfate?

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



How does it work?

The functions of chondroitin sulfate:

- It delivers nutrients to the joint cartilage, helps to inhibit the enzymes that decompose the joint cartilage and speeds up the formation of a new joint cartilage.
- the elasticity and plasticity, which are the functions of the joint cartilage can be maintained through the use of Chondroitin Sulfate.

Why use chondroitin sulfate?

- ✓ Chondroitin Sulfate is widely used in the treatment of osteoarthritis
- ✓ It can also block the enzymes that degrade cartilage, and it provides the building blocks for the body to produce new cartilage.
- ✓ Chondroitin Sulfate appears to be very important in keeping joints healthy by means of its unique ability called chondro protection, retention or stimulation of repair function in cartilage cells.
- ✓ The body needs nourishment to heal and repair itself and Chondroitin Sulfate has been proven to stimulate the growth of new joint cartilage.
- ✓ Using Chondroitin Sulfate as a cross-linking agent increases bio compatibility and biodegradability native polymer and creates premises to delay the cartilage degeneration and even supports regeneration cartilage structure.
- ✓ ORTHOFLEX one® –improved by cross linking , preponderantly elastic, confers capacity, mechanic protection, increased and improved lubrication.

Treatment

- ORTHOFLEX one is administered in the affected joint as a single injection. If the treatment is bilateral, a separate syringe should be used for each knee.
- This effect can be maintained for up 1 year; in order to prevent complications the treatment must be repeated.
- ORTHOFLEX one is administered only by medical professionals trained for intra articular administration techniques.
- Any joint effusion present should be removed by joint aspiration before injecting ORTHOFLEX one
- ORTHOFLEX one must be administered strictly intra articular.
- Do not administer intravenously.

What are the indications ?

- ORTHOFLEX ONE is a product for viscose supplementation, which is a safe, efficient and well established treatment in osteoarthritis consisting in injecting a hyaluronic acid based solution into the affected synovial joint.
- ORTHOFLEX ONE acts as a temporary replacement and supplement for synovial fluid, it treats pain and restricted mobility and elasticity , protects cartilage as a result of traumatic pathology in the knee joint and other synovial joints
- It is also indicated for the reduction of post–arthroscopy pain. following meniscus repair; following previous crossed ligament reconstruction; auxiliary treatment for patients with osteochondral defects;
- Orthoflex one is natural cross linked hyaluronate , it is recommended in osteoarthritis level 3 and 4 , molecular weight 3 mil Da
- The beneficial effects of ORTHOFLEX one® can last up to 1 year and after this period the treatment should be repeated..
- After the injection, an articular rest of approximately 24 hours is recommended (no strenuous exercise) in order to augment the duration of the effect, resting and applying ice to the injected joint.
- Obtained by bio ferment process, its synthetic origin gives it a complete safety, eliminating any allergic reactions.
- ORTHOFLEX one® is a pre filled sterile syringe that has a 3 year term of validity and it is sterilized by autoclave.

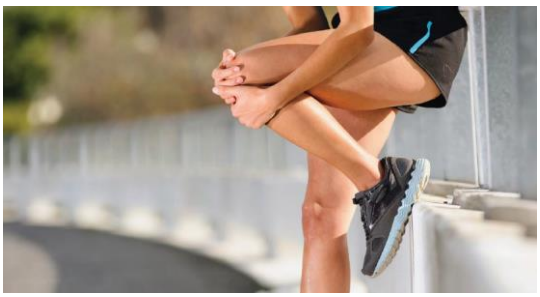
ORTHOFLEX® forte

Viscose-supplement intra articular injection.

Protect cartilage and greatly improve the joints mobility.

What are the infiltrations with hyaluronic acid? What is ORTHOFLEX FORTE?

It is a pre filled sterile syringe which contains an injectable viscose elastic solution with a high level of hyaluronic acid and which is to be administered intra articular and which is used to treat arthrosis leading to the improvement of the joint function.



Prefilled syringes

Sodium Hyaluronate 30 mg/2ml

Description

ORTHOFLEX FORTE is a sterile, viscose elastic solution of sodium hyaluronate contains 30 mg/2 ml of sodium hyaluronate with a high molecular weight of 2.4 million daltons obtained by bio ferment process, and its synthetic origin offers a complete safety eliminating any allergic reactions

Indications

ORTHOFLEX FORTE is indicated in Osteoarthritis, a disease of joints characterized by a progressive degradation of the cartilage and bone deformation, showing symptoms like knee pain, stiffness, articular limited mobility, crack, swelling.

ORTHOFLEX FORTE is indicated as a viscose elastic supplement or a replacement for synovial fluid in the human knee joint, it has an analgesic, anti inflammatory, antioxidant effect , it stimulates proteoglycan synthesis and facilitates the evacuation of cartilaginous remains

ORTHOFLEX FORTE is indicated for symptomatic treatment of knee osteoarthritis the actions of the product are lubrication and mechanical support.

What does the treatment consist of?

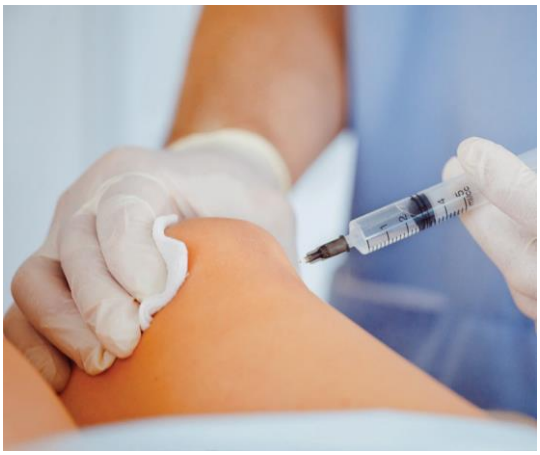
· When it comes to arthrosis, once the cartilage is damaged there is also a change in the composition of the synovial fluid as it loses its capacity to lubricate and as a consequence pain finds its place in the joints and in time a person's ability to move decreases. It is an irreversible disease, it progresses slowly but its evolution can be slowed down with the ORTHOFLEX FORTE therapy.

- ORTHOFLEX FORTE is administered in the affected joint once a week for 3 consecutive weeks. If treatment is bilateral, a separate syringe should be used for each knee.
- This effect can be maintained for 6 months following a treatment cycle of 3 intra articular injections and in order to prevent complications the treatment must be repeated.
- ORTHOFLEX FORTE is administered only by medical professionals trained for intra articular administration techniques.
- Any joint effusion present should be removed by joint aspiration before injecting ORTHOFLEX FORTE.
- ORTHOFLEX FORTE must be administered strictly intra articular.
- Do not administer intravenously.

What are the effects of ORTHOFLEX FORTE therapy?

· After the treatment the patients can immediately notice a pain relief and this can last for a few months. Repeating the injections slows down the arthrosis process as the hyaluronic acid stimulates the body to produce more synovial fluid.

· Local reactions may appear – pain, heat sensation, articular swelling but these can be ameliorated by applying local cold bandages. Within the first 48 hours after the injection it is recommended to avoid excessive movements of the joints, one should not stand up too much or one should not lift weights.



What are the benefits of ORTHOFLEX forte?

- Re establishes the level of hyaluronic acid in the joint.
- Decreases pain and improves the joint mobility. When the articular surfaces rub on each other then the molecules of hyaluronic acid from the synovial fluid act as a lubricant, protecting the articular surfaces from being mechanically damaged.
- Under the joint loading pressure the hyaluronic acid acts as a shock dumper, thus protecting the cartilage against the compression trauma.
- It feeds the cartilage and protects the synovial fluid as the hyaluronic acid represents a protective barrier for the synovial fluid.
- Maintains the balance of fluids within the joint and it helps the joint regain its normal function. Easy to administer.
- It directly treats the affected joint.
- Helps avoiding and preventing surgical interventions.

Counter indications

Orthoflex is not to be injected if the injection skin area is sore, infected or if it shows signs of an acute or chronic affection.

· ORTHOFLEX is obtained through bio ferment which confers safety, eliminating the risk of any side effect; it is under the form of a pre filled sterile syringe, it is completely sealed, it is sterilized through auto clave and it has got a 3 year term of validity.

ORTHOFLEX® tendon

Restore mobility in damaged tendon.

What is a tendon?

A tendon is a fibrous connective tissue which attaches muscle to bone

What is ORTHOFLEX tendon?

ORTHOFLEX tendon® is a viscose elastic gel for peritendinous or intra sheath injections. ORTHOFLEX tendon® is an injectable prefilled syringe 40mg/2ml natural solution of highly purified sodium hyaluronate obtained by biofermentation devoid of animal protein + 10 mg mannitol , a free radical scavenger which help to stabilize the chains of sodium hyaluronate

ORTHOFLEX tendon is used for the treatment of pain and reduced mobility due to tendon disorders.

It is injected around the affected tendon or into the tendon sheath

Prefilled syringes

Sodium Hyaluronate 40 mg/2ml + 10mg mannitol

What is tendinopathy?

Tendinopathy is a disease of the tendon caused by wear and tear, overuse, or incorrect use of the joints in the body.

Tendons connect muscle to bones, and although tendinopathy, or tendinosis or tendon disorder as it is sometimes referred to, is generally non-inflammatory, it can lead to pain and reduced mobility

What is a tendon injury?

Tendons are the tough fibres that connect muscle to bone. Most tendon injuries occur near joints, such as the shoulder, elbow, knee, and ankle. A tendon injury may seem to happen suddenly, but usually it is the result of repetitive tendon overloading.

The most well-known tendons are the Achilles tendon (the largest tendon in the human body found at the heel), the biceps tendon, the tendons in the hand, and the elbow tendon.

Effects

- acts as a lubricant when applied into the tendon sheath or peritendinously.
- enhance tendon gliding effect and reduce adhesion.
- prevents the free passage of inflammatory cell and molecules through the tendon sheath due to its macro molecular mesh work.
- promotes tendon recovery and would healing process.
- is a good transport medium for nutrients
- reduces pain and increases joint function.

How to use?

Intrasheath injection
in tendon with a sheath, inject ORTHOFLEX tendon into the tendon sheath in the affected area
Peri tendinous injection
in tendon without a sheath inject ORTHOFLEX tendon
along the affected tendon nut not in tendon
The content and outer layer of the ORTHOFLEX tendon syringe are sterile, provided that the packaging has not been opened or damaged
Inject ORTHOFLEX tendon around the affected tendon or into the affected tendon sheath 2 injections per week.
Several tendons may be treated in the same time , repeated treatment may be administered as required.

ORTHOFLEX tendon should be administered only by a medical specialist in peri tendinous or intra sheath injection techniques.

ORTHOFLEX® gel

Intra-articular injection for osteoarthritis. New injection for restoration of articular cartilage .

Regenerative cartilage
Love your joints
Be responsible and respect yourself
Use natural ingredients for joint pain and to prevent cartilage degeneration by injecting ORTHOFLEX gel intra articular.

What is ORTHOFLEX gel?

ORTHOFLEX gel is a bio- matrix in the form of a sterile, viscose elastic solution consisting of highly purified cross linked bio polymers ,sodium hyaluronate and chondroitin sulfate and n-acetylglucosamine.

Indications

Orthoflex gel is a product for viscose supplementation which is safe ,efficient and well established treatment in osteoarthritis consisting in injecting a hyaluronic acid based solution into the affected synovial joint.
Any joint in the body may be affected (hand, hip, knee, lower back, shoulder, elbow).
Orthoflex gel acts as a temporary replacement supplement for synovial fluid.

Prefilled syringes

Sodium Hyaluronate 36 mg/2,25 ml
Chondroitin sulfate 67,5 mg/2,25 ml
N-acetylglucosamine 67,5 mg/2,25 ml

Effect and mode of action

ORTHOFLEX gel is a bio- matrix in the form of a sterile, viscose elastic solution consisting of highly purified cross linked bio polymers ,sodium hyaluronate and chondroitin sulfate and n-acetylglucosamine.
A single injection of Orthoflex gel relieves long term pain, helps improve the movement of joints and protects the cartilage.
The unique combination between Glucosamine, chondroitin with hyaluronic acid can provide a complete product for maintaining healthy joints.
These three closely related compounds are components of glycoaminoglycans (GAGS) found in articular cartilage.
Hyaluronic acid is a major component of the synovial fluid and cartilage and thanks to its viscose elastic and rheological properties it is responsible of the lubrication and cushioning in joints. It decreases friction between joint surfaces and protects soft tissues from trauma by acting as a shock damper.
It provides not only special protective properties between the joints but also movement of the joints fluid itself, it also transports nutrients and helps reduce inflammation within the joints .
The quantity and quality of hyaluronic acid in the synovial fluid are reduced in the patients who have osteoarthritis because its synthesis by the synovial and cartilage cells is disturbed.

The protection of articular surface is thus strongly altered, the cartilage becomes vulnerable and exposed to structural damage due to the forces of friction and compression.

Chondroitin sulfate is another natural substance found in the body.
Chondroitin sulfate ,a sulfate glycosaminoglycan, is an important structural component of the extracellular cartilage matrix .The role of chondroitin sulfate is to optimize the rheological behavior of hyaluronic acid , due to specific interactions.
It prevents other body enzymes from degrading the building blocks of joint cartilage.
Chondroitin sulfate also inhibits pro inflammatory factors secretion. These data support the observed clinical activity as a symptomatic slow –acting for osteoarthritis with pain improvement and enhancement function.
Glucosamine is found naturally in the body. It stimulates the formation and repair of articular cartilage.
Together with the chondroprotective effect of the hyaluronic acid, N-acetylglucosamine which has stimulatory effect on hyaluronic acid synthesis in human articular chondrocytes and synovial fibroblast inhibits nitric oxide which in turn reduces apoptosis in cultured human chondrocytes.
Chondoitine sulfate can also reduce apoptosis of chondrocytes via mitochondrial pathway.
ORTHOFLEX gel , administered as a single injection , restores good lubrication and shock absorption in the joint , and provides significant improvement of symptoms.
The cross-linked hyaluronate- chondroitine sulfate increases the biocompatibility and biodegradability of the native polymer and creates premises to delay cartilage degeneration and supports the regeneration of the cartilage structure.

How do glucosamine sulfate and chondroitin sulfate work?

Glucosamine and chondroitine are 2 molecules that make up the type of cartilage found within joints.

Joints affected by DJD (degenerative joint diseases) show joint space narrowing.
This is a decrease in the thickness of the cartilage around the ends of the bones. Cartilage is made by cells called chondrocytes. As we age, the chondrocytes produce less cartilage. Glucosamine sulfate increases production of cartilage.
Glucosamine sulfate stimulates the chondrocytes to manufacture more cartilage and to replace unhealthy cartilage with fresh, healthy cartilage. Healthy cartilage, in turn, allows more good nutrients to reach the chondrocytes, and thus continue the cycle of creating more healthy cartilage. Glucosamine sulfate also inhibits the breakdown of cartilage.
Chondroitin sulfate, help the joints, by increasing the viscosity and amount of joint fluid (hyaluronic acid), inhibiting the breakdown of cartilage, and reducing joint inflammation.
Glucosamine is considered to be very safe and when combined with chondroitine and hyaluronic acid is a properly balanced formula which can be very efficient in treating joint pain.
Using ORTHOFLEX gel injection more of the cartilage building block will be available for cartilage repair.

Administration

Must be administered strictly intra articular, 2 treatments per year, every 6 months according to the doctors recommendation.

Love your joints

Be responsible, respect yourself and prevents the degradation of cartilage using
ORTHOFLEX hyaluronic acid
www.ortobrand.com

How to use ORTHOFLEX®

ORTHOFLEX® one, ORTHOFLEX® forte and ORTHOFLEX® gel

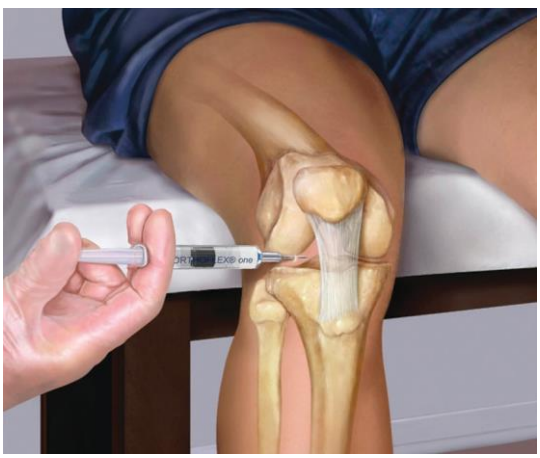
Injection

•The affected knee is first aspirated to remove any effusion that may be present, decreasing the concentration of inflammatory mediators that may be present and limiting the dilution effect the effusion would have on the injected material.
•Superolateral or lateral midpatellar injection site is the most reliable for reaching the synovial joint space of the knee.

Method of administration and dosage

- ORTHOFLEX® one, ORTHOFLEX® forte and ORTHOFLEX® gel is administered only by medical professionals trained for Intra - articular administration tech- nique.
- ORTHOFLEX® one, ORTHOFLEX® forte and ORTHOFLEX® gel must be administered strictly intra-articular.
- Do not administer intravenously.
- The volume will vary depending upon the
- size of the joint space , not to exceed 2ml
- for the knee and other large joints or 1ml for small joints.

•It is the physician‘s responsibility to determine the appropriate volume and ensure that the joint is not overfilled.
•ORTHOFLEX® forte is administered in the affected joint once a week for 3 consecutive weeks.
•Several joints may be treated simultaneously.
•Not to exceed one treatment course for any individual joint in any 6- month periods.
•Any joint effusion present should be removed by joint aspiration before injecting ORTHOFLEX® forte.

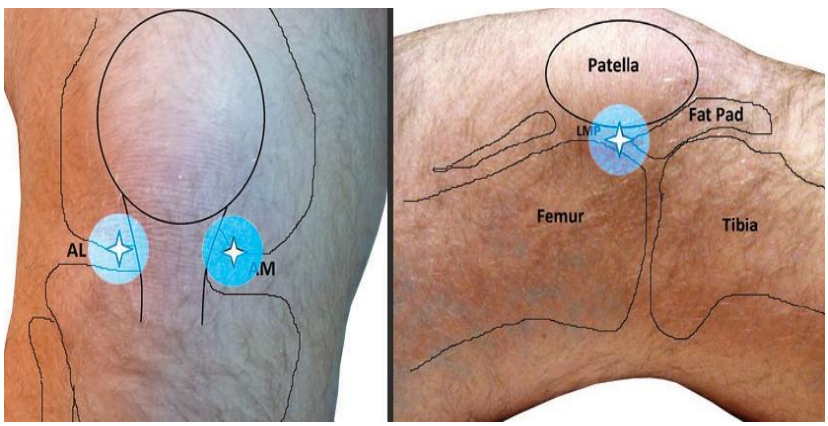


The intra -articular space should not be overfilled.

- - ORTHOFLEX® one, ORTHOFLEX® forte and ORTHOFLEX® gel is available as a ready to use pre-filled syringe and must not be diluted. The content of a pre- filled syringe ORTHOFLEX® is sterile and must be used immediately after the packaging has been opened.
- ORTHOFLEX® one, ORTHOFLEX® forte and ORTHOFLEX® gel should be injected slowly into the joint space using a standard intra – articular injections technique.
- Remove the pre-filled syringe from the package. Before administration break the visible seal and remove the cap of the pre-filled syringe. Attach the hypodermic needle and make sure you have it properly fixed by turning it slightly.
- Remove the air from syringe before the injection.

Precautions

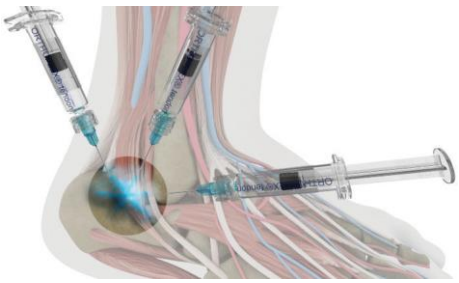
•General precautions should be observed for the intra-articular injection administration. Sodium hyaluronate should be administered in the synovial space only by medical professionals trained in intra-articular administration technique.
•An excess amount of sodium hyaluronate is not to be used and the patient should be monitored closely. The intra- articular space should not be overfilled.
•If pain increase during the injection procedure, the injection should be stopped and the needle withdrawn.
•Patient should be carefully examined prior to administration to determine signs of acute inflammation and the physician should evaluate whether Orthoflex forte treatment should be initiated in this case. As in any invasive joint procedure it is recommended caution to avoid over using the joint immediately after the intra-articular injection. To date, there are insufficient data to recommend the use in children and adolescents. Orthoflex forte should not be intra- articularly administered simultaneously or mixed with other products.



HOW TO USE ORTHOFLEX® tendon

•Inject ORTHOFLEX®tendon around the affected tendon once a week for a total of two injections. Several tendons can be treated simultaneously. Repeat treatment as needed.
•The content and outer layer of the ORTHOFLEX®tendon syringe is sterile, provided that the packaging has not been opened or damaged. Remove the prefilled syringe from the packaging, unscrew the Luer-Lok, attach a suitable needle (for example, 25-27 G), and twist to secure.

- Remove all air bubbles prior to injection.
- ORTHOFLEX®tendon should be instilled accurately into the tendon sheath or around the affected tendon, if necessary under imaging control. Avoid nerve lesions and injections into blood vessels!



Quality:

® ORTHOFLEX HA 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

Love your joints

Be responsible, respect yourself and prevents the degradation of cartilage using ORTHOFLEX hyaluronic acid
Thanks for your interest in our products and service.
Keep in touch

www.ortobrand.com

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enjoy your life

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