



restores joint function
and relieves pain of osteoarthritis

Non Avian Derived (NAD)
Non Heat Degraded (NHD)
Sodium hyaluronate

Patient Information Leaflet



Manufactured in Ireland.
www.myknee.ie



What is a joint?



A joint is formed by the ends of two or more bones, normally covered with a thin, smooth layer of cartilage, which plays a protective role and allows smooth movement. Some parts of the joint are surrounded by a capsule called **synovium**. The inner layer or **synovial membrane** secretes a fluid which prevents friction inside the joint and is called **synovial fluid**. Bones are connected to one another by **ligaments**, composed mainly of **collagen fibers**, which have a certain level of elasticity. The main role of ligaments is to provide joint stability.

Joints are designed to allow smooth movements in various directions (depending on the type of joint) and also to provide mechanical support to the body.

What is osteoarthritis?

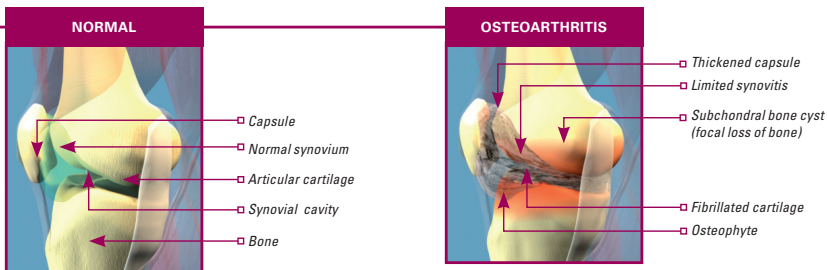
Osteoarthritis (often abbreviated OA) is a very common disease and a leading cause of disability in patients over 55. It is part of a group of conditions called arthritis. There are many forms of arthritis, the most common being OA. Osteoarthritis may be caused by previous joint injuries or surgery. It may affect weight bearing joints such as hip or knee, but also the shoulder or smaller joints in the hands and toes.

Risk factors for the development of OA include:

- Age (the incidence increases after 50)
- Gender (it is more common in women, especially over 60)
- Heredity
- Obesity
- Chronic joint overload
- Injuries or cartilage damaging diseases

In osteoarthritis, the cartilage covering the parts of the bones forming a joint tends to wear away, resulting over time in bones rubbing against each other, causing inflammation, pain and stiffness.

General Changes in an Idiopathic Osteoarthritis Joint



*Altered bone turnover, reflected by scintigraphy
or by «sclerosis» on radiograph*

What are the symptoms of osteoarthritis?

Osteoarthritis (OA) usually develops slowly, and gradually worsens over time. Symptoms, which may develop in one or several joints, range from mild to very severe and may include:

- Pain during movement and even at rest
- A grating sensation in the joint during movement
- Stiffness after periods of rest
- Joint swelling
- Loss of range of movement
- Loss of coordination
- Weakened posture due to pain and stiffness

How does your doctor make the diagnosis of osteoarthritis?

Your doctor will go through your medical history and will examine your affected joint. After the physical examination, an x-ray evaluation will usually be sufficient to make a diagnosis, although further tests might be necessary in some cases.

An x-ray of a joint with osteoarthritis may show the following signs: narrowing of the “space” inside the joint, irregularities on the edge of the bones, areas of bony thickening and even some deformities of the joint.

What are the treatment options for osteoarthritis?

Based on the examination and diagnosis, treatment options may vary. They depend on the extent of the disease and other factors, such as your age and your level of physical activity.

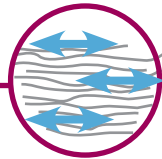
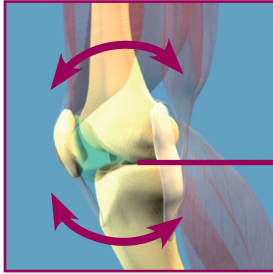
These options include:

- physical therapy / physiotherapy
- medication (such as analgesics, non-steroidal anti-inflammatory drugs or corticosteroids)
- visco-supplementation
- joint replacement (arthroplasty).



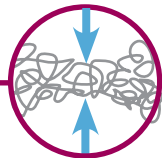
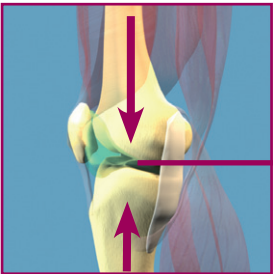
What is sodium hyaluronate (Na-HA)?

Sodium hyaluronate (or hyaluronan) is a natural component of all extracellular tissue structures, including cartilage and synovial fluid. Your body naturally contains approximately 15 g of Na-HA, half of which is found in the skin. Hyaluronan plays a central role in maintaining the physiological internal environment of joints and is responsible for the viscosity and elasticity of the synovial fluid.



Slow movement

When the joint is subject to small efforts (e.g. walking), Na-HA chains align in the direction of movement. This arrangement guarantees cartilage lubrication.



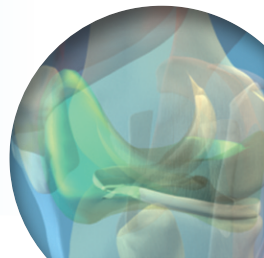
Quick movement

When the joint is subject to intense efforts (e.g. running, descending stairs), Na-HA chains gather in a «ball-like» fashion. This arrangement helps absorbing shocks during movements.

What is “visco-supplementation” ?

In osteoarthritis, hyaluronate (Na-HA) in the synovial fluid is reduced both quantitatively and qualitatively, causing a loss of shock absorbing and lubricating properties inside the joint. This results in joint pain, stiffness and possibly an onset or worsening of osteoarthritis.

With intra-articular Na-HA treatment (or visco-supplementation), the patient's natural synovial fluid is supplemented by injections of sodium hyaluronate, with the aim to restore the physiological environment of the joint. By naturally supplementing the patient's lubricants, viscosupplementation may reduce pain and stiffness in the treated joints for easier, more comfortable movement.



General information about Suplasyn®

Suplasyn® is a sterile solution of highly purified sodium hyaluronate (Na-HA or “hyaluronan”). It is produced by bio-fermentation, thereby minimizing the risk of cross-species contamination or allergy to foreign proteins. Suplasyn® is sterilized by aseptic filtration.

Suplasyn® is available in over 30 countries and benefits from an experience of over 10 years and millions of injections.

The treatment may consist of a single injection (SUPLASYN 1-Shot, for large joints) or repeated injections, usually 3, at weekly intervals (SUPLASYN and SUPLASYN m.d.). Your physician will decide if additional injections could be of benefit.

While symptoms may subside rapidly, the full benefits of the treatment are usually felt a few weeks after its completion.

The majority of patients experience pain relief and joint function improvement, lasting approximately 6 months, up to 12 months⁽¹⁻⁴⁾. This depends on the condition of the individual patient and the severity of the disease. Once the beneficial effects of a course of SUPLASYN wear off, it is possible and safe to repeat the injections^(4,7).

Ask your physician for advice.

Rest is recommended in the 48 hours following each injection and strenuous activity should be avoided during the full course of the treatment.

Possible undesirable effects of Suplasyn®

As with any intra-articular injection, there may be a mild and short-lasting discomfort during the actual procedure.

Following the injection, some patients may experience a mild local reaction like pain, feeling of heat, redness and swelling. Usually, these symptoms disappear quickly (within a few days) and without any consequence.

If these symptoms occur, rest and apply ice locally. If you feel that symptoms are severe or if they persist you should consult your physician. Do so immediately if you have fever following the injection.

Suplasyn® is CE marked in the EU as a Medical Device (CE 0473) and, as such, is not considered as a drug. It contains hyaluronan, a substance that is naturally present in your joint. Suplasyn® acts locally, directly within the affected joint and causes none of the gastrointestinal side effects associated with NSAIDs and analgesics.

References

1. B. Mazières et al. *Joint Bone Spine* (2007) 74: 453-460.
2. R. Petrella et al. *Arch Intern Med* Vol 162 Feb, 11 2002.
3. R.J. Petrella & M. Petrella. *The Journal of Rheumatology* 2006; 33:5.
4. R.J. Petrella. *Am J Phys Med Rehabil*. 2005; 84: 278-283.
5. Rodriguez et al. (2003) *EULAR poster* P237.
6. Petrella et al. *the Physician and Sports medicine* July 2004; Vol. 32 (7).
7. Petrella et al. *Orthopedic Research and Reviews* 2010; 2:5-9



When is Suplasyn® indicated?

As for any medical treatment, only a qualified medical professional will be able to tell you if Suplasyn® represents a good treatment option for you.

Suplasyn® has been shown to relieve pain and improve joint function in patients with mild to moderate osteoarthritis ⁽¹⁻⁶⁾.

It can be used as an alternative or supplement to treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics, the medicines most often used to treat the symptoms of osteoarthritis. These drugs sometimes cause unacceptable side effects. For example, patients under NSAID treatment are at risk of developing a gastric ulcer. Some patients do not wish to take these drugs; for other patients they are even contra-indicated.

Your doctor will decide whether Suplasyn® is right for you if you have recently been diagnosed with osteoarthritis, or if your current treatment needs to be changed or supplemented.

Suplasyn® is available in 2 sizes:

Your physician will decide which product and schedule is best for your individual condition.



- **Suplasyn® 1-Shot**
for the treatment of large joints in
one single injection
Available in 1 x 6ml syringe.



- **Suplasyn®**
for the treatment of large joints
such as knees.
Available in 1 x 2ml syringe.

About this leaflet: This leaflet gives you basic information about synovial joints, osteoarthritis, visco-supplementation and Suplasyn®. This information is intended to be general in nature and is not to be used as a basis for medical decision making. Only your doctor has the qualifications to propose the best treatment option for your condition and individual clinical profile. For questions or further information, please contact your doctor. Please also visit: www.suplasyn.com



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