Autologous Protein Solution

Treating Osteoarthritic Knee Pain

Patient information to assist informed consent

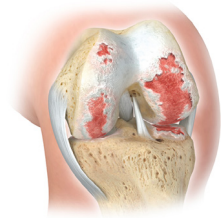
Do you have knee pain?

Knee pain is a common symptom experienced by people of all ages. It can be caused by a traumatic event, or by normal wear and tear that can become worse over time.[1] The knee is a type of hinge joint formed by the tibia (shinbone), femur (thighbone), and patella (kneecap).

The ends of the bones in the knee joint are covered with cartilage, a tough lubricating tissue that helps provide smooth, pain-free motion to the joint. When knee pain becomes worse over time, arthritis may be the cause.[2-3] Symptoms of arthritis are pain, swelling, or stiffness in the joint and may be caused by inflammation.[2,4]

What is Osteoarthritis (OA)?

OA is the most frequent type of arthritis and most commonly affects the knee joint.[2-3] Osteoarthritis is damage done to the joint over time.[2-4] In a normal joint, cartilage provides cushioning between bones. As wear or if a traumatic event occurs, the cartilage layer can become thinner or frayed resulting in knee pain.[3-4] Over time, pain increases as cartilage wears away and bones rub against each other.[3] Osteoarthritis negatively impacts quality of life through pain, limited mobility, reducing the ability to work and diminishing self-esteem.[3-4]



What are the Stages of OA?

OA symptoms can range from very mild to very severe and often limit your everyday activities:

Early[5]

Cartilage begins to wear down. Symptoms are generally mild, and may include pain that comes and goes.[5-6]

Moderate[5]

Joint fluid may lose its ability to lubricate and cushion the affected joint. You may have more pain and difficulty in movement.[5-6]

Late[5]

Areas of cartilage may totally wear away, causing bones to rub against each other.[5-6] You may experience significant pain.[5-6]

Once OA pain starts it is hard to stop

Autologous Protein Solution (APS) is a therapy designed to treat pain[7*] and slow the progression of cartilage degradation and destruction in the knee.[8^] APS processes an individual's blood to provide a novel output. The output is injected directly into the knee joint distributing beneficial and good proteins.[9] In laboratory testing, these "good" proteins block and slow the degradation of cartilage treating the underlying cause of OA knee pain.[8^] The results can differ than those obtained in the laboratory.

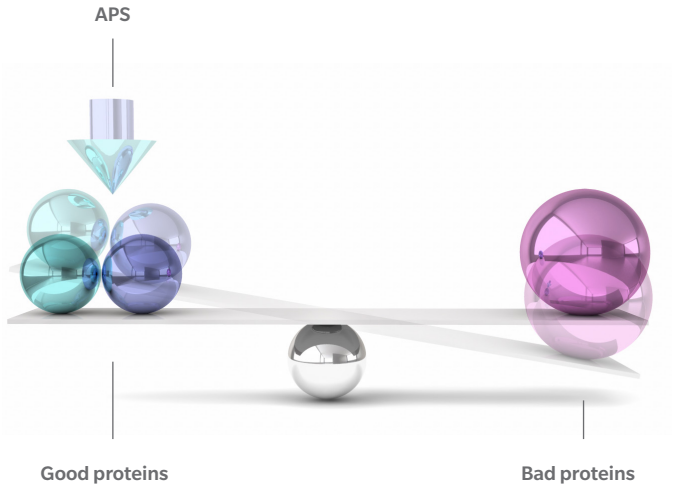
- **Designed to reduce pain associated with knee OA up to 2 years [7*,10, 14]**
- **Designed to improve mobility in the knee joint [7*,14,10] associated with OA**
- **Designed to improve knee pain at 2 years following a single injection[14]**

Science Behind APS

In an osteoarthritic knee, inflammatory cytokines ("bad" proteins) outnumber anti-inflammatory cytokines ("good" proteins) causing an imbalance resulting in knee pain and cartilage degeneration.[11]

The inflammatory proteins IL-1 and TNFα attack the cartilage.[11] These "bad" proteins must be stopped simultaneously to decrease pain and slow cartilage degeneration.[11]

APS introduces high levels of "good" proteins (IL-1ra, sIL-1R, sTNF-RI, and sTNF-RII)[9]. Animal and human studies have shown that APS has decreased pain.[8,10,14] In laboratory setting it has also has been associated with decreased cartilage degeneration.



However, do note that results differ in individuals, balance is being restored to the knee, anabolic (building) growth factors (IGF-1 and TGF-.1) are also introduced for beneficial cartilage health.[9] Therefore, APS creates a therapy which may reduce pain in the knee joint, may improve joint function and slow the destruction of cartilage.[8^] This therapy is provided in a non-surgical, single injection.

Post Treatment Guidance

What can you expect?

Day of the injection

Following the injection you may experience some side effects e.g. generalised swelling in the joint, bruising, local pain associated with the blood draw, or knee injection. For more complete product information on indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, please consult your doctor.

Immediate Post-Treatment Period

First 4-5 days you may experience pain in the injection site or in the knee or both. For pain management, nonsteroidal anti-inflammatory drugs (NSAIDs) are not recommended but other analgesics such as paracetamol can be taken.

Contact your doctor:
If you experience swelling with redness and warmness in the joint or at the injection site.

Post-Treament Period

There is no cure for OA.[13] But successful treatment with APS can reduce or relieve your pain, which may increase your mobility and comfort.[15, 14, 17]

APS may decrease or eliminate pain, reduce stiffness and help restore mobility and flexibility.[15, 14, 17] In general, it is recommended that you minimise your activity level for 14 days and not exceed pre-injection activity levels. At a minimum, activities, including walking, should be limited for the first 4-5 days or this could result in inflammation and swelling of the joint. Training and sports should be avoided for at least 4-5 days following treatment and ideally, throughout the entire post-treatment period (14 days). This is particularly important if you normally participate in high-intensity or long-distance sports or training.

Contact your doctor:
If at any time you experience pain that is different from the pain that you had prior to the injection.

Pain Reduction Period

Following the Immediate Post-Treatment Period (4-5 days) you can expect a small reduction in swelling, stiffness and pain. Pain relief may be expected after one to two weeks,[15, 14, 17] but for most patients, pain relief normally occurs between 4-8 weeks after treatment.

A significant reduction in pain may take up to 8 weeks to appear and can occur suddenly or gradually.

Contact your doctor:
If you do not have pain relief after 8 weeks.

Frequently asked questions

about APS

What is APS?

APS is an autologous (from an individual's own body) therapy which is designed to treat joint pain associated with knee osteoarthritis. In laboratory testing, APS has been shown to protect cartilage tissue.^
This protective quality may slow the progression of osteoarthritis as well.[8^]

How does APS work?

APS will be injected directly in the knee joint. Positive outcomes are possible due to the presence of high concentrations of anti-inflammatory proteins.[12] These "good" proteins may help stimulate a biologic cascade which has been shown to block cartilage destruction in osteoarthritis.8^ The pain in the joint may be reduced, and the joint function may be improved. The ongoing destruction of cartilage may also be slowed.[8^] The treatment is designed to be a single injection therapy.

What is APS made of?

APS processes the patient's own blood to concentrate white blood cells, platelets, and plasma proteins into a small volume of plasma. The output is approximately 2 to 3 cc of anti-inflammatory solution

How is APS given?

2-3 cc of final output will be injected directly in the knee joint.

Are there side effects?

You may experience side effects (e.g., bruising, local pain or swelling) associated with the blood draw, knee injection, MRI or X-Ray procedures.

Will APS cure my OA?

There is no cure for OA.[13] But successful treatment with APS may reduce or relieve your pain which may increase you your mobility and comfort.[10]
Your osteoarthritis may not improve or may get worse.

What are the main benefits of APS?

APS may significantly decrease or eliminate pain, reduce stiffness and help restore mobility and flexibility.[7*, 10]

When will the treatment start to work?

Pain relief may be expected after one to two weeks.[7*, 10]

Is APS safe?

Yes. Studies have demonstrated the safety of APS.[7*, 10]

Will I be able to be active as usual during the course of my treatment?

It is recommended that you minimise your activity level for 14 days (but not to exceed pre-injection levels).

How long can I expect the benefits to last?

Based on pre-clinical and early clinical results, patients may expect to see benefits for up to 24 months.[7*,10,14]

Who can be treated with APS?

Patients with mild to moderate knee osteoarthritis can receive APS therapy.

How many injections of APS are required?

Clinical studies have demonstrated the effectiveness of one injection. Studies suggest one injection can last up to 24 months. [7,10,14,*]

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* Animal studies are not necessarily indicative of clinical performance.
^ Laboratory testing is not necessarily indicative of clinical outcomes.
\# As measured by WOMAC pain scores reported by patients continuing follow-up through 2 years (n = 22).

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