

GenVisc® 850

(sodium hyaluronate)

Patient Information

Product Information

GenVisc 850 (sodium hyaluronate)

Be sure to read the following important information carefully. This information does not take the place of your doctor's advice. Your doctor has determined that the knee pain you are experiencing is caused by osteoarthritis and that you are a candidate for a non-surgical, non-pharmacological, pain-relieving therapy called GenVisc 850. If you do not understand this information or want to know more, ask your doctor.

Glossary of Terms

Hyaluronate: Hyaluronate is a natural substance found in the human body and is present in very high amounts in joints. The body's own hyaluronate acts like a lubricant and shock absorber in the joint and is needed for the joint to work properly.

Non-steroidal anti-inflammatory drug: Non-steroidal anti-inflammatory drugs are often abbreviated to "NSAIDs". NSAIDs are drugs, such as aspirin, naproxen, ibuprofen, and Celebrex, for reducing pain, fever and inflammation.

Osteoarthritis (OA): Osteoarthritis is a condition that involves the wearing down of cartilage (the protective covering on the ends of your bones) and loss of cushioning fluid in the joint.

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For more Information, please refer to the Full Prescribing Information for GenVisc 850.

General

WHAT IS GENVISC 850 (SODIUM HYALURONATE)?

GenVisc 850 is a product from the class of products known as hyaluronic acid, sodium hyaluronate, or hyaluronan (HA), and also known as viscosupplementation therapy. It helps supplement the viscous properties of the fluid in your knee joint. It is approved for treatment of pain due to osteoarthritis of the knee in patients who do not get adequate relief from simple painkillers like acetaminophen or from exercise and physical therapy.

WHAT IS GENVISC 850 USED FOR?

GenVisc 850 is used to relieve knee pain due to OA. It is given to patients who do not get enough relief from non-steroidal anti-inflammatory drugs (NSAIDs) or from simple pain medications, such as acetaminophen, or from exercise and physical therapy.

HOW IS GENVISC 850 GIVEN?

GenVisc 850 is administered by intra-articular injection. Intra-articular means your healthcare professional will insert a needle into the space in your knee joint that contains fluid used for lubrication and cushioning.

HOW DOES GENVISC 850 WORK?

The precise mechanism by which GenVisc 850 works is unknown. The fluid (synovial fluid) in your knee helps to lubricate and cushion the joint during movement. The major component in the synovial fluid is hyaluronic acid, the same active component of GenVisc 850. One of the early effects of OA is to break down this fluid, making it less effective. It is thought that GenVisc 850 injection helps restore the synovial fluid to a more healthy state, thereby reducing the pain of OA.

ARE THERE ANY REASONS WHY I SHOULD NOT RECEIVE GENVISC 850?

Your doctor will determine if you are a candidate for GenVisc 850 treatment, but you should also be aware that GenVisc 850 should not be administered to patients who:

- have ever had an allergic response to hyaluronate-containing products such as a rash, itching, hives, flushing, swelling of the face, tongue or throat, and/or difficulty breathing;
- have a knee joint infection or skin disease, or infection around the area where the injection will be given, or circulatory problems in the legs.

WHAT SHOULD MY DOCTOR WARN ME ABOUT?

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications:

- GenVisc 850 is only for injection into the knee, performed by a qualified healthcare professional.
- GenVisc 850 has not been tested to show better pain relief or safety when combined with other injected medicines.
- Tell your doctor if you are allergic to hyaluronate products.
- For 48 hours after you receive the injection, you should avoid any strenuous activities (such as jogging, tennis, other active sports, heavy lifting) and prolonged weight-bearing activities such as standing on your feet for more than one hour.
- The effectiveness of repeat treatment cycles of GenVisc 850 has not been established.
- Use of GenVisc 850 in joints other than the knee and for conditions other than OA has not been tested.
- GenVisc 850 has not been tested in pregnant or nursing women. You should tell your doctor if you think you are pregnant or if you are nursing a child.
- GenVisc 850 has not been tested in children (21 years of age or younger).

WHAT ARE THE POSSIBLE SIDE EFFECTS?

- Some side effects (also called reactions) may occur during the use of GenVisc 850, with symptoms such as knee pain, inflammation, reddening, swelling appearing at the injection site, joint pain. If any of these symptoms or signs appears after you are given GenVisc 850 or if you have any other problems, you should call your doctor.
- Because GenVisc is administered through a needle you may experience some local pain or discomfort when it is administered, as may be expected with all injections.

WHAT ARE THE POTENTIAL BENEFITS OF GENVISC 850?

A clinical study was conducted in the People's Republic of China involving 229 patients with knee pain due to degenerative osteoarthritis (OA) of the knee. The result of this study showed that patients treated with GenVisc 850 experienced the same amount of improvement in knee pain over 6 weeks as those treated with Supartz®/Supartz FX™ (sodium hyaluronate, Seikagaku Corp.), a similar product that has been sold in the U.S. since 2001. The overall average reduction of mean pain scores was 49 mm for the GenVisc 850 treatment group and 48 mm for the Supartz/Supartz FX group.

Four additional clinical studies involving 804 patients with knee pain due to OA were performed, three in Europe and one in Australia. Patients received five injections of GenVisc 850, Supartz/Supartz FX, or saline into the knee joint. Pain of the knee joint was measured at various times, 5, 6, 10, 13, 14, 17, 18, 20, 26, and 30 weeks. Analysis of the results of these four studies demonstrated that those patients given five injections of GenVisc 850 achieved greater pain relief up to 30 weeks than those patients given five injections of saline for the same time period. The difference in pain reduction from baseline to 30 weeks was significantly greater for the GenVisc 850 patients versus those receiving saline injections.

WHAT ADVERSE EVENTS WERE OBSERVED IN THE CLINICAL STUDIES?

In the GenVisc 850 treatment group for one of the clinical studies performed in Spain, 15 reported adverse events included pain at the injection site (6), allergic reaction (3), arthralgia (2), bleeding at the injection site (2), bleeding (1) and heaviness (1). In the GenVisc 850 treatment group for the clinical study performed in the People's Republic of China, two adverse events were reported, 1 report of local pain and 1 report of rash. There were no significant differences in the rate of occurrences of adverse events between patients injected with GenVisc 850 and patients injected with Supartz/Supartz FX or saline.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OA?

If you have OA, there are other things you can do besides getting GenVisc 850. These include:

Non-drug treatments

- Avoiding activities that cause knee pain
- Exercise
- Weight loss
- Physical therapy
- Removal of excess fluid from your knee

Drug therapy

- Pain relievers such as acetaminophen and narcotics
- Drugs that reduce inflammation and pain (signs of inflammation are swelling, pain or redness), such as aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen and Celebrex
- Steroids injected directly into your knee

THINGS YOU SHOULD KNOW ABOUT GENVISC 850.

- GenVisc 850 is only for injection into the knee, performed by a doctor or other qualified health care professional.
- If you have pain in both knees, the effects of pain relief on the knee opposite to the one injected have not been evaluated. Your doctor may recommend that both knees be injected.
- After you receive the injection, you may need to avoid strenuous activities such as jogging, tennis, heavy lifting, or standing for a long time for approximately 48 hours.
- If any of the above symptoms or signs appear after you are given GenVisc 850, or if you have any other problems, you should call your doctor.

WHY IS MY DOCTOR RECOMMENDING I RECEIVE GENVISC 850?

GenVisc 850 is indicated for patients with osteoarthritis knee pain who do not obtain adequate relief from simple painkillers, like acetaminophen (Tylenol®), or from exercise and physical therapy. Ask your doctor for additional information and discuss your treatment options.

IS GENVISC 850 APPROVED FOR USE IN THE U.S.?

GenVisc 850 was approved for use in the United States in September, 2015. GenVisc 850 has demonstrated a very favorable safety profile, with over 35 million doses administered worldwide since its first approval, and has been studied in over 30 clinical trials for use in relieving osteoarthritis knee pain.

WHAT IS GENVISC 850 MADE FROM?

Hyaluronic acid is a natural chemical found in almost all species and various parts of your body. It is in high amounts particularly in joint tissues and in the fluid that fills the knee joint space (synovial fluid). GenVisc 850 is made from an extraction and purification of hyaluronic acid from fermentation of bacteria that make hyaluronic acid identical in chemical composition to human hyaluronic acid.

WILL MY INSURANCE COVER GENVISC 850?

Most insurance carriers and Medicare cover GenVisc 850. The process of obtaining reimbursement varies from plan to plan so talk with your doctor's office and your insurance provider before you begin treatment to find out if GenVisc 850 is covered.

Treatment

ARE FIVE INJECTIONS REQUIRED?

Clinical investigations with GenVisc 850 have demonstrated that five injections one week apart provide optimal pain relief. Some patients have derived benefit following the third injection. The effectiveness of less than three injections has not been evaluated. You should discuss this with your doctor. Completion of the full injection treatment course is recommended to achieve the greatest therapeutic benefit.

HOW DO I KNOW IF GENVISC 850 IS RIGHT FOR ME?

A doctor is the best person to advise you on any course of treatment. GenVisc 850 is approved for the treatment of pain due to osteoarthritis of the knee in patients who do not get adequate relief from simple painkillers or from exercise and physical therapy.

AM I TOO OLD FOR GENVISC 850 INJECTIONS?

There are no specific precautions or contraindications regarding the use of GenVisc 850 in older patients.

CAN I TAKE OTHER MEDICATIONS WITH GENVISC 850?

Because GenVisc 850 is injected directly into the joint rather than administered systemically and there are no known drug interactions, you may be able to take other medications with it. It is not known to interfere with other pain relievers and anti-inflammatory drugs. The safety and effectiveness of the use of GenVisc 850 at the same time as other intra-articular injections, such as steroids, have not been established. Because it is administered locally it is unlikely that you will observe any benefit in joints not specifically injected. You should discuss all of your current medications and vitamin supplements with your physician on a periodic basis.

CAN I RECEIVE GENVISC 850 IN BOTH OF MY KNEES?

Yes, if both knees have pain. GenVisc 850 treatment may be given in both knees simultaneously or separately, according to your physician's recommendations. Because GenVisc 850 is only injected locally into the knee joint and not administered systemically, it is not likely that injections into one knee will have an effect on the opposite knee if it is not injected. In addition, it is unknown whether a good response in one knee is a good predictor of an equivalent response in the opposite knee should you decide to have this therapy.

SHOULD I MODIFY MY LEVEL OF PHYSICAL ACTIVITY AFTER RECEIVING GENVISC 850 TREATMENT?

It is recommended that you avoid strenuous activities such as jogging, tennis, and heavy lifting for at least 48 hours after receiving an injection. Your doctor will advise you about the level of activity that is right for you, but in general, patients are able to maintain their normal daily activities after receiving GenVisc 850 treatment.

CAN GENVISC 850 BE USED IN JOINTS OTHER THAN THE KNEE?

The U.S. Food and Drug Administration has only approved GenVisc 850 for use in the treatment of OA of the knee. The FDA has not approved or made an evaluation regarding the safety and effectiveness in other joints.

IS GENVISC 850 A CURE FOR OSTEOARTHRITIS OF THE KNEE?

There is no cure for osteoarthritis. GenVisc 850 is a treatment for the symptoms of knee pain of osteoarthritis.

Benefits

WHEN CAN I EXPECT TO EXPERIENCE PAIN RELIEF?

Each patient's response to GenVisc 850 may vary, depending on severity of your OA, degree of pain, and pre-existing medical conditions. In some patients, successful treatment may reduce pain within the first week after treatment begins. However, based upon clinical trials, most patients experienced pain relief after their third injection of GenVisc 850.

IS GENVISC 850 TREATMENT EFFECTIVE IN KNEES WITH ADVANCED OSTEOARTHRITIS AND LOSS OF CARTILAGE?

Most of the clinical studies with GenVisc 850 have selected patients with mild to moderate OA.

WHAT ARE THE BENEFITS OF RECEIVING GENVISC 850 TREATMENT?

Successful treatment with GenVisc 850 should reduce pain in an osteoarthritic knee. Because it is a local treatment, GenVisc 850 should not interfere with any medicine that the patient may take.

HOW LONG CAN I EXPECT THE BENEFIT OF GENVISC 850 TO LAST?

Each patient reacts differently to GenVisc 850 treatment. Five injections given at weekly intervals can provide most patients up to 30 weeks of pain relief. The duration of pain relief you experience may vary.

Safety

HOW SAFE IS GENVISC 850?

Extensive safety and toxicity tests were performed on GenVisc 850. GenVisc 850 is approved in over 60 countries worldwide. GenVisc 850 has been in use since 1995 in Japan, 1997 in Europe, and 2015 in the U.S., with over 4 million injections given worldwide. In clinical trials, transient

local pain or swelling occurred with some patients with injections of GenVisc 850. Since introduction into the global market, GenVisc 850 has not been withdrawn in any market because of safety concerns.

For more Information, please ask your doctor or refer to the Full Prescribing Information for GenVisc 850.