

Product Information

1. What is HYALGAN[®] (sodium hyaluronate)?

HYALGAN is a product from the class of products known as hyaluronic acid, sodium hyaluronate, or hyaluronans.¹ It 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.²

2. How is HYALGAN administered?

HYALGAN is administered by intra-articular injection. (Intra-articular injection directly into the knee joint.)

3. How does HYALGAN work?

The precise mechanism by which HYALGAN 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. One of the early effects of osteoarthritis (OA) is to break down this fluid, making it less effective. It is thought that HYALGAN injection helps restore the synovial fluid back to a more healthy state, thereby reducing the pain of OA.^{1,3}

4. Why is my doctor recommending I receive HYALGAN?

HYALGAN 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.² Ask your doctor for additional information and discuss your treatment options.

5. Is HYALGAN approved for use in the U.S.?

HYALGAN was the first hyaluronic acid to be approved in the United States in 1997.⁴ It has a long history of use worldwide with a very favorable safety profile, with over 38 million doses administered, and has been studied in 90 clinical trials.⁴

6. What is HYALGAN made from?

Hyaluronic acid is a natural chemical found in almost all species and various parts of your body. It is particularly in high amounts in joint tissues and in the fluid that fills the knee joint (synovial fluid).^{1,3} HYALGAN is made from an extraction and purification of hyaluronic acid from rooster combs, where it is also found in particularly high amounts.

7. Will my insurance cover HYALGAN?

Most insurance carriers and Medicare cover HYALGAN. 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 HYALGAN is covered.

Treatment

8. Why are three or more injections required?

Clinical investigations with HYALGAN have demonstrated that three⁵ to five⁶ injections one week apart provide optimal pain relief and restoration of joint mobility. Completion of the full injection treatment course is recommended to achieve the greatest therapeutic benefit.²

9. How do I know if HYALGAN is right for me?

A doctor is the best person to advise you on any course of treatment. HYALGAN 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 physician therapy.²

10. Am I too old for HYALGAN injections?

There are no specific precautions or contraindications regarding the use of HYALGAN in older patients. During clinical trials, the safety profile of HYALGAN was well established in older patients (greater than 60 years old).⁷

11. Can I take other medications with HYALGAN?

Because HYALGAN is injected directly into the joint and not administered systemically and there are no known drug interactions,⁸ you may be able to take other medications as well. It is specifically not known to interfere with other pain relievers and anti-inflammatory drugs. The safety and effectiveness of the use of HYALGAN concomitantly with other intra-articular injections, such as steroids, have not been established. You should discuss all of your current medications and vitamin supplements with your physician on a periodic basis.

12. Can I receive HYALGAN in both of my knees?

Yes, if both knees have pain. HYALGAN treatment may be given in both knees simultaneously or separately, according to your physician's recommendations. Because HYALGAN 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 of both of your knees.

13. Should I modify my level of physical activity after receiving HYALGAN 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.² Your doctor will advise about what level of activity is right for you, but in general, patients are able to maintain their normal daily activities after receiving HYALGAN treatment.

14. How often can HYALGAN be injected into my knee?

The number of courses/injections is a decision you and your doctor need to make. Your doctor may recommend three or five HYALGAN injections and repeat treatment based upon their clinical assessment and discussions with you. Studies show that retreatment with HYALGAN is safe following the initial treatment period.^{2,7} Some insurance plans restrict the frequency at which you can receive additional injections. Consult your doctor's office or insurance provider to find out about coverage for any retreatments you may receive.

15. Can HYALGAN be used in joints other than the knee?

The U.S. Food and Drug Administration has only approved HYALGAN for use in the treatment of OA of the knee.² The FDA has not approved or made an evaluation regarding the safety and effectiveness in other joints.

16. Is HYALGAN a cure for osteoarthritis of the knee?

There is no cure for osteoarthritis. HYALGAN is a treatment for the symptoms of knee pain of osteoarthritis.²

Benefits

17. When can I expect to experience pain relief?

Each patient's response to HYALGAN 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 HYALGAN.⁶

18. Is HYALGAN treatment effective in knees with advanced osteoarthritis and loss of cartilage?

Clinical studies with HYALGAN have been primarily done in patients with mild to moderate OA.⁶

19. What are the benefits of receiving HYALGAN treatment?

Successful treatment with HYALGAN should reduce pain in an osteoarthritic knee, resulting in increased mobility.⁶ Because it is a local treatment, HYALGAN should not interfere with any medicine that the patient may take.

20. How long can I expect the benefits of HYALGAN to last?

Each patient reacts differently to HYALGAN treatment. Five injections given at weekly intervals can provide most patients with long-lasting pain relief for up to 6 months. The duration of pain relief you experience may vary.

Some patients may experience benefit with three injections given at weekly intervals. This has been noted in studies of patients receiving three injections who were followed for 60 days.

Safety

21. How safe is HYALGAN?

Extensive safety and toxicity tests were performed on HYALGAN before the first clinical trials. HYALGAN has been in use since 1987 in Europe and 1997 in the U.S., with 38 million injections given worldwide.⁴ In clinical trials, transient local pain or swelling occurred with some patients with injections of HYALGAN.^{2,6}

22. What are the side effects of HYALGAN?

Because HYALGAN is injected directly into the joint, some patients may feel localized discomfort after treatment.^{2,6,8} Some pain, swelling, and effusion may occur in and around the knee. Both usually go away within a short period and do not interfere with the success of the treatment. If you continue to feel discomfort or notice other problems, you should consult your physician.

23. Are there any allergies that may affect HYALGAN treatment?

Consult with your doctor if you have a history of hypersensitivities (allergies), especially if you have had a reaction to intra-articular hyaluronic acid preparations or are allergic to bird proteins, feathers, and egg products. There are reports of patients reporting allergic reactions to HYALGAN injections.² There are rare reports of patients reporting allergic reactions.

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