

HYALGAN® (Sodium Hyaluronate) Complete Patient Information

WHAT IS HYALGAN?

HYALGAN is a sterile mixture that is made up mostly of a natural, highly purified sodium hyaluronate that comes from rooster combs. Hyaluronate is a natural chemical found in the body and it is present in a particularly high amount in joint tissues and in the fluid that fills the joints. The body's own hyaluronate acts like a lubricant and a shock absorber in the joint, and it is needed for the joint to work properly. In osteoarthritis, there may not be enough hyaluronate, and there may be a change in the quality of the hyaluronate in joint fluid and tissues.

HYALGAN is available in either 2 mL glass containers or 2 mL pre-filled syringes. HYALGAN is given in a shot directly into your knee.

WHAT IS HYALGAN USED FOR?

HYALGAN is used to relieve knee pain due to osteoarthritis. It is used for patients who do not get adequate relief from simple painkillers or from exercise and physical therapy.

WHAT ARE THE BENEFITS OF HYALGAN?

A study involving 495 patients with knee pain due to osteoarthritis was performed in the United States. This study investigated the safety and effectiveness of HYALGAN. The patients were placed in one of three groups. One group was given an injection of HYALGAN into one knee joint once a week for 5 weeks. The second group was given an injection of salt water into one knee joint once a week for 5 weeks. The third group received two naproxen tablets every day for 6 months. Joint pain was measured in all patients throughout the 6 months. Patients with osteoarthritic knee joint pain, who did not get relief from simple painkillers or from exercise and physical therapy, got pain relief from the HYALGAN injections into the knee joint. Pain relief was not seen in some patients until after the fifth injection.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

If you have osteoarthritis, there are several things you can do that do not involve HYALGAN injections. These include the following:

Non-drug treatments

- avoiding activities that cause excess pain in your joints
- exercise
- physical therapy

Drug therapy

- painkillers such as acetaminophen and narcotics
- drugs that reduce inflammation such as aspirin, and other nonsteroidal anti-inflammatory agents (NSAIDs) such as ibuprofen and naproxen
- corticosteroids that are injected directly into the joint

ARE THERE ANY REASONS WHY I SHOULD NOT TAKE HYALGAN?

- You should not take this product if you have had any previous allergic reaction to HYALGAN or similar material, i.e., hyaluronate products.
- You should not have an injection into the knee if you have infections or skin diseases around the injection site.

THINGS YOU SHOULD KNOW ABOUT HYALGAN

- HYALGAN is only for injection into the knee, performed by a qualified physician.
- Consult your physician if you are allergic to products from birds such as feathers, eggs, and poultry.
- Immediately after you have the injection and for the next 48 hours, you may need to avoid activities such as jogging, tennis, heavy lifting, or standing on your feet for a long time.
- Although results of studies in rats and rabbits with HYALGAN did not suggest that it could affect your ability to have children or cause harm to your child if you are pregnant or nursing, HYALGAN has not been tested in pregnant women, or women who are nursing. You should tell your doctor if you think you are pregnant, or if you are nursing a child.
- The safety and effectiveness of HYALGAN have not been shown in children.

POSSIBLE COMPLICATIONS

- HYALGAN has been used in a number of countries in Europe, South America, and Asia since 1987. During this time, two cases of serious, allergic-type events were reported right after the patients received the injection. For example, one patient experienced sweating, paleness, and a feeling of pressure in the chest and stomach. The patient's skin turned slightly blue, and blood pressure dropped. You should tell your doctor before you are given HYALGAN if something like this has ever happened to you after receiving an injection of HYALGAN or a similar material, i.e., hyaluronate products.
- Six cases of allergic reactions were reported in people outside of the United States after they had been given HYALGAN. These people reported that their pulse became quicker, they had a heavy feeling, there were changes in their blood pressure and circulation, and they shivered, had a fever, and sweated. You should tell your doctor before you are given HYALGAN if something like this has ever happened to you after receiving an injection of HYALGAN or a similar material, i.e., hyaluronate products.
- Seven cases of fever were reported.
- One case of abnormally low blood pressure was reported.
- One episode of fainting occurred.
- Side effects sometimes seen when HYALGAN is injected into the knee are pain, swelling, heat, and/or redness of the joint as well as rash, itching, or bruising where HYALGAN is injected. These reactions were generally mild and did not last long.
- If any of the above symptoms or signs appear after you are given HYALGAN, or if you have any other problems, you should call your doctor.

HOW IS HYALGAN GIVEN?

Your doctor will give you an injection of HYALGAN (20 mg/2 mL) into your knee. A treatment cycle consists of five injections given at weekly intervals. Some patients may experience benefit with three injections given at weekly intervals. This has been noted in studies reported in the literature in which patients treated with three injections were followed for 60 days.

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