

PATIENT INFORMATION

TRILURON™

(Sodium Hyaluronate)

Please make sure to read the following important information carefully. This information does not take the place of your doctor's advice. If you do not understand this information or want to know more, ask your doctor.

GLOSSARY

Hyaluronan is a natural substance that is present in very high amounts in joints, skin and eyes. It is a major part of the synovial (cushioning) fluid in your joints and functions as a lubricant and a shock absorber.

Non-steroidal anti-inflammatory drugs (NSAIDs) are medications used to treat pain. There are many examples of NSAIDs, including (but not limited to) aspirin and ibuprofen (e.g. Advil®, Motrin®, etc.). Some of these drugs are over-the-counter, while stronger, more potent versions can be obtained only by a doctor's prescription.

Osteoarthritis (OA) is a joint disease that shows itself as a type of arthritis that involves the wearing down of cartilage (the protective layer covering the ends of the bones) caused by loss of quality of the cushioning (synovial) fluid in the joint.

WHAT IS TRILURON™?

TRILURON™ is a sterile mixture that is made up mostly of a 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.

TRILURON™ is available in either 2 ml glass containers or 2 mL pre-filled syringes.

TRILURON™ is given in a shot directly into your knee.

WHAT IS TRILURON™ USED FOR?

TRILURON™ 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 TRILURON™?

A study of 373 patients with knee pain due to osteoarthritis was performed to collect information on the safety of TRILURON™ and how well it works to relieve pain. There were two groups of patients in the study. One group received 3 weekly knee injections of TRILURON™ at clinics in France and Germany and the other group received 5 weekly knee injections of Hyalgan at clinics in the United States. Joint pain was measured in all patients for 6 months after the first injection. Patients with pain from knee osteoarthritis, who did not get relief from simple painkillers or from exercise and physical therapy, got comparable pain relief, on average, from the TRILURON™ injections into the knee joint as did the patients who received Hyalgan injections into the knee joint.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

If you have osteoarthritis, there are several things you can do that do not involve TRILURON™ 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 TRILURON™?

- You should not take this product if you have had any previous allergic reaction to TRILURON™ 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 TRILURON™

- TRILURON™ 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 TRILURON™ did not suggest that it could affect your ability to have children or cause harm to your child if you are pregnant or nursing,
- TRILURON™ 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 TRILURON™ have not been shown in children.

POSSIBLE COMPLICATIONS

Side effects are sometimes seen when TRILURON™ is injected into the knee joint. These can include:

- Local signs and symptoms such as pain, swelling, fluid in the joint, warmth, or redness at the injection site. Usually such symptoms disappear within a few days by resting the injected knee and applying ice to it. Only sometimes have these events been more severe and longer lasting.
- Very rare cases of infection in the knee joint have been reported. Your physician knows to take care to prevent infection when injecting TRILURON™.
- Signs and symptoms of an allergic reaction have been reported. These may include rash, itching, hives, flushing (becoming red); swelling of your face, tongue, or throat; difficulty breathing or swallowing; and shortness of breath. Before you are injected with TRILURON™, tell your physician if you have already had similar signs or symptoms after an injection of TRILURON™, other hyaluronan products, or products from birds such as feathers, eggs, and poultry.

If any of the above symptoms or signs appear after you are injected with TRILURON™, or if you have any other problems, you should call your doctor.

WHAT DO YOU NEED TO DO AFTER RECEIVING TRILURON™ INJECTION?

It is recommended to avoid strenuous activities, such as high-impact sports (such as tennis and jogging) or prolonged weight bearing activities for approximately 48 hours following the injection. You should talk to your doctor regarding the appropriate time to resume such activities.

HOW IS TRILURON™ GIVEN?

Your doctor will give you an injection of TRILURON™ (20 mg/2 mL) into your knee. You will receive a total of 3 injections (1 a week).

MANUFACTURED BY

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