

HYMOVIS® ONE Viscoelastic Hyaluronan

PATIENT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician.

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 HYMOVIS® ONE?

HYMOVIS® ONE is a viscous (thick) gel-like sterile solution made from highly purified chemically modified hyaluronan supplied in a pre-filled syringe. The syringe contains 4 mL (less than 1 teaspoon) of HYMOVIS® ONE. It is injected in the knee by a trained clinical professional in a single injection regimen. Hyaluronan is a substance naturally present in the body and is present in high amount in the fluid that fills the joints. The body's own hyaluronan acts like a lubricant and a shock absorber in the joint, and it is needed for the joint to work properly. When you have osteoarthritis, the quality of the hyaluronan may be different from normal. If you do not understand this information or want to know more, please consult with your doctor.

WHAT IS HYMOVIS® ONE USED FOR?

HYMOVIS® ONE is used to temporarily relieve knee pain caused by osteoarthritis. It is intended for patients who do not get adequate pain relief from simple pain relievers like acetaminophen or from exercise and physical therapy.

HOW IS THE HYMOVIS® ONE PRODUCT GIVEN?

Your doctor will inject HYMOVIS® ONE (4 mL) into your knee in a single injection.

WHAT ARE THE POSSIBLE SIDE EFFECTS?

Some side effects (also called reactions) may occur with the use of HYMOVIS® ONE, including symptoms such as knee pain, inflammation, reddening, and swelling appearing at the injection site. If any of these symptoms or signs appear after you are given HYMOVIS® ONE, or if you have any other problems, you should call your doctor. Occurrences of rash, headache, dizziness, chills, hives, nausea, muscle cramps, peripheral edema (fluid buildup), and malaise (feeling of discomfort) have also been reported in association with intra-articular injections of hyaluronic acid in the knee. Temporary increases in inflammation (redness and swelling) following injections have occurred in some patients with inflammatory joint conditions.

WHAT SIDE EFFECTS WERE OBSERVED IN THE CLINICAL STUDY?

In patients who were treated with HYMOVIS® ONE in a clinical study, there were reported a low number of anticipated side effects, joint swelling (1 event), as well as a low number of unanticipated events, including pain/inflammation in the ball of the foot (metatarsalgia, 1 event), neck pain (1 event) and headache (1 event). Furthermore, patients who were treated with a different hyaluronic acid injection in this clinical study, MONOVISC®, experienced some side effects such as discomfort (1 event), thirst (1 event), joint contracture (1 event), muscle aches and pains (myalgia, 2 events), headache (2 events), redness (erythema, 1 event) and immune sensitivity (1 event).

WHAT ARE THE BENEFITS OF HYMOVIS® ONE?

A clinical trial conducted using HYMOVIS® ONE demonstrated that HYMOVIS® ONE provides temporary pain relief to patients with osteoarthritis of the knee. The patients in the study had been diagnosed with OA of the knee associated with pain and did not have sufficient relief with simple analgesics (e.g., acetaminophen) taken by mouth.

A total of 347 patients in the study were assigned by chance to receive either a single intra-articular injection of HYMOVIS® ONE or to receive the same treatment with a comparator hyaluronic acid, MONOVISC®. Neither the patients nor the doctors evaluating them knew which treatment they received. Patients were observed by their doctor over 6 months. HYMOVIS® ONE demonstrated the same benefit in terms of safety and effectiveness as MONOVISC® when injected in the knee.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

If you have pain due to osteoarthritis of the knee, there are treatments that do not involve injections of HYMOVIS® ONE into the joint. These include:

Non-drug treatments:

- Avoiding activities that cause pain in your knee
- Physical therapy
- Removal of excess fluid from the knee

- Weight loss
- Total or partial knee replacement surgery

Drug therapy:

- Pain medication 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 knee joint

ARE THERE REASONS WHY YOU SHOULD NOT TAKE HYMOVIS® ONE?

Your doctor will determine if there is any reason why you should not be treated with HYMOVIS® ONE. You should be aware that HYMOVIS® ONE:

- Should not be used in patients who have had any prior allergic reactions to any hyaluronan-based products or have an allergy to gram positive bacterial proteins. Signs of an allergic reaction may include swelling of your face, tongue, or throat; difficulty breathing or swallowing; shortness of breath; wheezing; chest pain; tightness in your throat; sleepiness; rash; itching; hives; flushing and/or fever.
- Should not be used in patients with a knee joint infection, skin disease or infection around the area where the injection will be given. If you have circulatory problems in your legs, be sure to talk to your doctor about them.

WHAT SHOULD YOU KNOW ABOUT HYMOVIS® ONE?

The following are important considerations to discuss with your doctor:

- HYMOVIS® ONE should be injected in the knee by a qualified physician or properly licensed practitioner.
- HYMOVIS® ONE was not tested in combination with other products injected in the knee.
- Tell your physician if you are allergic to hyaluronan products or have an allergy to gram positive bacterial proteins.
- HYMOVIS® ONE was not tested in pregnant or nursing women. Please tell your physician if you are pregnant or nursing a child.
- HYMOVIS® ONE was not tested in children (21 years of age or younger).
- The safety and effectiveness of HYMOVIS® ONE in joints other than the knee have not been demonstrated in U.S. studies.
- The effectiveness of repeat treatments of HYMOVIS® ONE has not been established.

RISKS OF USING HYMOVIS® ONE

The side effects sometimes seen after any joint injection, including HYMOVIS® ONE, may include: pain, swelling, warmth and redness. These symptoms are generally mild and do not last long. If needed, your doctor will recommend appropriate treatment.

If any of these symptoms or signs appear after you are given HYMOVIS® ONE, or if you have any other problems, you should call your doctor.

WHAT DO YOU NEED TO DO AFTER RECEIVING HYMOVIS® ONE 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.

WHEN SHOULD YOU CONTACT YOUR DOCTOR?

If any of the side effects or symptoms described above are noticed after you are injected with HYMOVIS® ONE.

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