

Patient Information

MONOVISC™ High Molecular Weight Hyaluronan

What is MONOVISC™?

MONOVISC™ is a viscous (thick) sterile mixture made from highly purified hyaluronan from bacterial fermentation. Hyaluronan is a natural chemical found in the body. High amounts of hyaluronan are found in the joint tissues and in the fluid that fills the joints. The body's own hyaluronan acts like a lubricant and a shock absorber in the joint. It is needed for the joint to work properly. When you have osteoarthritis, there may not be enough natural hyaluronan in the joint, and the quality of that hyaluronan may be poorer than normal. MONOVISC™ is given in a shot (injection) directly into the knee joint.

What is MONOVISC™ used for?

MONOVISC™ is used to relieve knee pain due to osteoarthritis. It is used for patients who do not get adequate pain relief from simple pain relievers like acetaminophen or from exercise and physical therapy.

What are the benefits of MONOVISC™?

Data from clinical trials conducted in the U.S. have shown that MONOVISC™ provides pain relief to a proportion of patients who have not been able to find pain relief with simple pain medication or exercise.

What other treatments are available for osteoarthritis?

If you have pain due to osteoarthritis of the knee, there are things you can do that do not involve MONOVISC™ injections.

These include:

Non-drug treatments:

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

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 any reasons why you should not take MONOVISC™?

- You should not take this product if you are allergic to hyaluronate products.
- If you have any known allergies, you should consult with your healthcare professional to determine if you are able to take MONOVISC™.
- 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 MONOVISC™

- MONOVISC™ should be injected by a qualified physician or properly licensed practitioner.
- Tell your healthcare professional if you have any known allergies before MONOVISC™ is administered.
- For 48 hours after you receive the injection, you should avoid activities such as jogging, tennis, heavy lifting or standing on your feet for a long time (more than one hour).
- The safety and effectiveness of MONOVISC™ in joints other than the knee has not been demonstrated in U.S. studies.
- The safety and effectiveness of MONOVISC™ has not been shown in pregnant or nursing women. You should tell your healthcare professional if you are pregnant or nursing.
- The safety and effectiveness of MONOVISC™ has not been shown in children.
- The effectiveness of MONOVISC™ has not been established for more than one course of treatment.

Possible complications

- Side effects are sometimes seen when MONOVISC™ is injected into the knee joint. These can include: pain, swelling, heat, rash, itching, bruising and/or redness. You may also feel achy. These reactions are generally mild and do not last long.
- If any of these symptoms or signs appear after you are given MONOVISC™ or if you have any other problems, you should call your healthcare professional.

How is MONOVISC™ given?

Your healthcare professional will give a single injection of MONOVISC™ (88 mg/4 mL) into your knee.

MONOVISC™ Manufacturer

MONOVISC™ is manufactured by Anika Therapeutics, Inc., 32 Wiggins Avenue, Bedford, MA 01730.

MONOVISC™ Distributor

MONOVISC™ is distributed by DePuy Mitek, Inc., 325 Paramount Drive, Raynham, MA 02767.