

## PATIENT INFORMATION

PI 5015-1  
7023US-01

## SYNVISC® HYLAN G-F 20

### WHAT IS SYNVISC?

Synvisc is a viscous and elastic sterile mixture that is made up of hylan A fluid, hylan B gel, and salt water. The two hylans are manufactured from hyaluronan (sodium hyaluronate) that comes from chicken combs. Hyaluronan is a natural chemical found in the body and is present in a particularly high amount in joint tissues and in the fluid that fills the joint. The body's own hyaluronan acts like a lubricant and a shock absorber in the joint, and is needed for the joint to operate properly. In osteoarthritis, there may not be enough hyaluronan, and there may be a change in the quality of the hyaluronan in joint fluid and tissues.

Synvisc is available in 2.25 mL pre-filled syringes containing 2 mL of Synvisc. Synvisc is given in a shot directly in your knee.

### WHAT IS SYNVISC USED FOR?

Synvisc 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 SYNVISC?

Two studies involving a total of 132 patients who were at least 40 years old and who had knee pain due to osteoarthritis were performed in Germany. The patients were placed in one of two groups. One group was given an injection of Synvisc into one or both knee joints once a week for 3 weeks. The second group was given an injection of salt water once a week for 3 weeks. Joint pain and patients' and physicians' ideas of the success of treatment were measured for 12 weeks.

Patients with osteoarthritic knee joint pain, who had not obtained pain relief with other

medications, experienced pain relief from the Synvisc injections into the knee joint. Patients who had been given Synvisc experienced more pain relief than patients who had received salt water. Some pain relief occurred within the first week after Synvisc treatment began. The most pain relief and the greatest amount of treatment success occurred 8 to 12 weeks after Synvisc treatment began.

A study in the United States evaluated 90 patients who were at least 40 years old and who had knee pain due to osteoarthritis. Patients improved after Synvisc treatments, but not significantly more than those who simply had a needle inserted into the knee to have fluid removed if any was present. This study was different from the German studies because the last comparison between Synvisc and control was only two weeks after the last Synvisc injection. It also differed in several other ways, including the length of time that patients had to stop taking medications before they could start treatment. This length of time was two weeks in the German studies and four weeks in the U.S. study.

### WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

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

#### Non-drug treatments

- avoiding activities that cause pain in your joints
- exercise
- physical therapy
- removal of excess fluid from the knee

#### Drug therapy

- pain killers 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 YOU SHOULD NOT TAKE SYNVISC?**

- You should not take this product if you have had any previous allergic reaction to Synvisc® or hyaluronan products.
- You should not have an injection into the knee if you have a knee joint infection or skin diseases or infections around the injection site.

## **THINGS YOU SHOULD KNOW ABOUT SYNVISC:**

- Synvisc 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.
- After you receive the injection, you may need to avoid activities such as jogging, tennis, heavy lifting, or standing on your feet for a long time.
- The safety and effectiveness of repeat treatment cycles of Synvisc have not been established.
- Synvisc 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 Synvisc have not been shown in children.

## **POSSIBLE COMPLICATIONS:**

- Synvisc has been used in Sweden since 1995 and Canada since 1992. Hives and itching have been reported to occur in patients soon after they have received Synvisc injections. No serious allergic-type events (difficulty breathing, drop in blood pressure, and skin turning blue) have been reported after patients have been given Synvisc injections. You should tell your doctor before you are given Synvisc if something like this has ever happened to you after receiving an injection of Synvisc or other hyaluronan products.
- Side effects sometimes seen when Synvisc is injected into the knee were pain, swelling, heat, and/or redness of the knee joint. These reactions were generally mild and did not last long. The reactions were treated by giving oral analgesics

such as acetaminophen or by giving oral NSAIDs or injections of steroids, or by removing fluid from the knee joint.

- Rare cases of joint infection, pain on one side of the body with nausea, anxiety and listlessness; facial flush with swelling of lips; rapid heartbeat, nausea, dizziness, shivering with headache, respiratory difficulties, and prickling in body have been reported after Synvisc injections.
- If any of the above symptoms or signs appear after you are given Synvisc, or if you have any other problems, you should call your doctor.

## **HOW IS SYNVISC GIVEN?**

Your doctor will give you your injection of Synvisc (16 mg/2 mL) into your knee once a week, for a total of three injections.

## **DISTRIBUTED BY:**

Wyeth Laboratories Inc.  
A Wyeth-Ayerst Company  
Philadelphia, Pennsylvania 19101  
Telephone: 1-800-99-WYETH  
Fax: (610) 964-5999

## **DEVELOPED BY:**

Biomatrix, Inc.  
65 Railroad Avenue  
Ridgefield, New Jersey 07657  
Telephone: (201) 945-9550  
Fax: (201) 945-0363

## **MANUFACTURED BY:**

Biomatrix Medical Canada Inc.  
275, avenue Labrosse  
Pointe-Claire, Québec  
Canada H9R 1A3

## **HOW CAN I GET MORE INFORMATION ABOUT SYNVISC?**

If you have any questions or would like to find out more about Synvisc, you may call Wyeth Laboratories Inc., at 1-800-99-WYETH or fax (610) 964-5999.

Synvisc® is a registered trademark of Biomatrix, Inc.

Synvisc® is covered by U.S. patents.

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