

## PATIENT INFORMATION

**SYNIVISC**  
HYLAN G-F 20

Be 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.

### WHAT IS SYNIVISC?

Synvisc is a gel-like mixture that is made up of hylan A fluid, hylan B gel, and salt water. Hylan A and hylan B are made from a substance called hyaluronan (pronounced hye-a-loo-ROE-nan), also known as sodium hyaluronate that comes from chicken combs. This is a natural substance found in the body and is present in very high amounts in joints. The body's own hyaluronan acts like a lubricant and a shock absorber in the joint and is needed for the joint to work properly. Osteoarthritis (pronounced os-TE-o-ar-THRI-tis) (OA) is a type of arthritis that involves the wearing down of cartilage (the protective covering on the ends of your bones). In OA, there may not be enough hyaluronan, and there may be a decrease in the quality of the hyaluronan in the joint. Synvisc comes in syringes containing 2 mL (half a teaspoon) of product. Synvisc is injected directly into your knee.

### WHAT IS SYNIVISC USED FOR?

Synvisc is used to relieve knee pain due to OA. It is used for patients who do not get enough relief from simple painkillers, such as acetaminophen, or from exercise and physical therapy.

### WHAT ARE THE BENEFITS OF SYNIVISC?

Two medical studies involving a total of 132 patients were done in Germany. The patients in these studies were at least 40 years old and had knee pain due to OA. The patients were placed in one of two groups. One group was given an injection of Synvisc into one or both knees once a week for three weeks. The second group was given an injection of salt water once a week for three weeks. As part of the study, knee joint pain was measured for 26 weeks. Also, patients and doctors were asked to judge the success of the treatment for 26 weeks. Patients with OA knee pain, who did not get pain relief with other medicines, got pain relief with Synvisc. The patients given Synvisc had more pain relief than the patients given salt water. Some patients started to feel pain relief after the first week of Synvisc treatment. The most pain relief and the greatest amount of treatment success was seen 8 to 12 weeks after Synvisc treatment started.

A medical study done in the United States involved 90 patients. The patients were at least 40 years old and had knee pain due to OA. Patients were placed into one of two groups. One group was given Synvisc once a week for three weeks. The second group had a needle inserted into the knee to have any fluid removed (this procedure is called arthrocentesis [pronounced AR-thro-sen-TE-sis]) once a week for three weeks.

Patients improved after Synvisc treatment, but not more than patients who had arthrocentesis. This study was different from the German studies because the last time the two groups were compared was only two weeks after the last Synvisc injection. The study was also different in other ways, including length of time that patients had to stop taking medicines before they could start treatment. The length of time patients had to stop taking medicines was two weeks in the German studies and four weeks in the U.S. study.

### WHAT OTHER TREATMENTS ARE AVAILABLE FOR OA?

If you have OA, there are other things you can do besides getting Synvisc. These include:

#### Non-drug treatments

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

#### Drug therapy

- pain relievers such as acetaminophen and narcotics
- drugs that reduce inflammation (signs of inflammation are swelling, pain or redness), such as aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen
- steroids that are injected directly into your knee

### ARE THERE ANY REASONS WHY YOU SHOULD NOT RECEIVE SYNIVISC?

- You should not get this product if you have had any allergic

reaction before to Synvisc or hyaluronan products. Signs of an allergic reaction may include swelling of your face, tongue, or throat; difficulty breathing or swallowing; shortness of breath; wheezing; chest pain; a tightness in your throat; sleepiness; rash; itching; hives; flushing; and/or fever. You should call your doctor immediately if you develop any of these signs of an allergic reaction.

- You should not be given Synvisc if you have a knee joint infection or skin diseases or infections around the area where the injection will be given. Talk to your doctor if you have any questions about this information.

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

- Synvisc is only for injection into the knee, performed by a doctor or other qualified health care professional.
- Tell your doctor 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 for a long time.
- 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 tested in children.

#### **POSSIBLE SIDE EFFECTS:**

- The side effects (also called reactions) sometimes seen

when Synvisc is injected into the knee as a first or repeat set of injections were pain, swelling, heat, redness, and/or fluid build-up around the knee. These reactions were generally mild and did not last long, but sometimes fluid accumulation was considerable and painful; cases where the swelling is extensive and painful should be discussed with your doctor. The reactions seemed to occur more often when Synvisc was injected into the knee as a repeat set of injections than when Synvisc was injected as a first set of injections.

- These reactions were generally treated by giving pain relievers by mouth such as acetaminophen or by giving NSAIDs by mouth or injections of steroids, or by removing fluid from the knee joint. Patients have rarely undergone arthroscopy (a surgical inspection of the knee joint) and other medical procedures.
- Rare cases of knee joint infection have been reported after Synvisc injections.
- Rashes, hives and itching have been seen in patients after Synvisc treatment. Before you are given Synvisc, tell your doctor if something like this has ever happened to you after receiving an injection of Synvisc or other hyaluronan products.
- Other less common side effects have been: muscle pain/cramps, flushing and/or swelling of your face, fast heartbeat, nausea (or feeling sick to your stomach), dizziness, fever, chills, headache, difficulty breathing, swelling in your arms and/or legs, prickly feeling of your skin, and in rare cases a low number of platelets in the blood (platelets are a type of blood cell that are needed to help clot your

blood when you are cut or injured).

- 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 (2mL) into your knee once a week, for a total of three injections.

#### **MANUFACTURED AND DISTRIBUTED BY:**

Genzyme Biosurgery  
a division of Genzyme Corporation  
1125 Pleasant View Terrace  
Ridgefield, New Jersey 07657

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

If you have any questions or would like to find out more about Synvisc, you may call Genzyme Biosurgery at 1-888-3-SYNVISC (1-888-379-6847).

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