

## **Patient Information**

### **Gel-One<sup>®</sup>**

#### **Cross-linked Hyaluronate**

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

Be sure to read the following important information carefully. This information does not take the place of your doctor's advice. Your doctor has determined that the knee pain you are experiencing is caused by osteoarthritis and that you are a candidate for a non-surgical, non-pharmacological, pain-relieving therapy called Gel-One<sup>®</sup>. If you do not understand the following information or want to know more, ask your doctor.

#### **Glossary of Terms**

**Hyaluronan:** Hyaluronan is a natural substance found in the human body and is present in very high amounts in joints. The body's own hyaluronan acts like a lubricant and shock absorber in the joint and is needed for the joint to work properly.

**Non-steroidal anti-inflammatory drug:** Non-steroidal anti-inflammatory drugs are often abbreviated to "NSAIDs". NSAIDs are drugs for reducing pain, fever and inflammation, such as aspirin and ibuprofen.

**Osteoarthritis (OA):** Osteoarthritis is a condition that involves the wearing down of cartilage (the protective covering on the ends of your bones) and losing cushioning fluid in the joint.

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### **What is Gel-One®?**

Gel-One® is a transparent, sterile, and viscoelastic gel made from sodium hyaluronate (hyaluronan). Hyaluronan that is used to make Gel-One® comes from chicken combs and is highly purified. Hyaluronan is also a natural substance found in the human body and is present in very high amounts in joints. The body's own hyaluronan acts like a lubricant and shock absorber in the joint and is needed for the joint to work properly. OA is a condition that involves the wearing down of cartilage (the protective covering on the ends of your bones). In joints with OA, there may not be enough hyaluronan, and there may be lower quality of hyaluronan in joint fluid and tissues. Gel-One® is available in a 3.0 mL (approximately ½ teaspoon) pre-filled syringe. Gel-One® is injected directly into your knee joint.

### **What is Gel-One® used for?**

Gel-One® is used to relieve knee pain due to OA. It is used for patients who do not get enough relief from NSAIDs or from simple pain medications, such as acetaminophen, or from exercise and physical therapy.

### **Are there any reasons why I should not receive Gel-One®?**

- You should not receive a Gel-One® injection if you have had any previous allergic reaction to Gel-One® or similar material, i.e., 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 not have an injection into the knee if you have a skin disease or infection around the area where the injection will be given.

### **What should my doctor warn me about?**

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications:

- Gel-One® is only for injection into the knee, performed by a qualified doctor.
- Gel-One® has not been tested to show better pain relief or safety when combined with other injected medicines.
- Tell your doctor if you are allergic to hyaluronan products.
- Tell your doctor if you are allergic to cinnamon or products from birds such as feathers, eggs, and poultry.

- For 48 hours after you receive the injection, you should avoid any strenuous activities (such as jogging, tennis, other active sports, heavy lifting) and prolonged weight-bearing activities such as standing on your feet for more than one hour.
- The effectiveness of repeat treatment cycles of Gel-One<sup>®</sup> has not been established.
- Use of Gel-One<sup>®</sup> in joints other than the knee and for conditions other than OA has not been tested.
- Gel-One<sup>®</sup> has not been tested in pregnant or nursing women. You should tell your doctor if you think you are pregnant or if you are nursing a child.
- Gel-One<sup>®</sup> has not been tested in children (≤ 21 years of age).

### **What are the possible complications?**

- Common side effects (also called reactions) are sometimes seen when Gel-One<sup>®</sup> is injected into the knee joint. These can include: knee pain; swelling; and/or fluid build-up around the knee. These reactions are generally mild and do not last long. Reactions are generally treated by resting and applying ice to the injected knee. Sometimes it is necessary to give pain relievers by mouth, such as acetaminophen or NSAIDs, or to give injections of steroids, or to remove fluid from the knee joint. Patients rarely undergo arthroscopy (a surgical inspection of the knee joint) or other medical procedures related to these reactions.
- Other adverse events observed in the clinical study are shown in the section “What adverse events were observed in the clinical study?”
- Rare cases of allergic/non-allergic reaction to other hyaluronan preparations, accompanied by cold sweat, paleness and low blood pressure, have been reported.
- If any of these symptoms or signs appear after you are given Gel-One<sup>®</sup> or if you have any other problems, you should call your doctor.

### **What are the potential benefits of Gel-One<sup>®</sup>?**

The potential benefit of Gel-One<sup>®</sup> is that it may reduce knee pain due to OA for up to 26 weeks following treatment.

### **How is Gel-One<sup>®</sup> given?**

Your doctor will inject Gel-One<sup>®</sup> into your knee joint. Your doctor may recommend a local anesthetic to reduce the possible discomfort associated with an injection.

### **What do I need to do after I get Gel-One®?**

For 48 hours after you receive the injection, you should avoid any strenuous activities (such as jogging, tennis, other active sports, heavy lifting) and prolonged weight-bearing activities (such as standing on your feet for more than one hour).

### **What other treatments are available for OA?**

If you have OA, there are several things you can do besides getting a Gel-One® injection. These include:

#### Non-drug treatments

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

#### Drug Therapy

- Pain medications such as acetaminophen and narcotics
- Drugs that reduce inflammation, such as aspirin, and other NSAIDs such as ibuprofen and naproxen (signs of inflammation are swelling, pain, or redness)
- Corticosteroids that are injected directly into the knee joint

### **When should I call my doctor?**

If any of the side effects or symptoms described above appear after you are given Gel- One®, or if you have any other problems, you should call your doctor.

### **What did the clinical studies show?**

The studies of Gel-One® were conducted in the United States. In the first study, a total of 377 patients received treatments, 249 patients were injected with Gel-One® and 128 patients were injected with saline control. Patients were asked to rate their pain during 5 conditions of activity or rest: how much pain during walking on a flat surface, during going up or down stairs, at night in bed, during sitting or lying down, and during standing. Patients rated their pain from 0 to 100 (where 0 is “no pain” and 100 is “worst possible pain”) by marking on a 100-mm line. Pain was evaluated in this manner at 1, 3, 6, 9, and 13 weeks after injection. The pain scores were used to compare the effectiveness of Gel- One® injection to saline control injection. Patients receiving Gel-One® experienced more improvement in knee pain over 13 weeks than patients who received saline control injections. The pain score was reduced by an average of 39.3% and average pain score reduction of 27.8 mm (on the 100-mm pain scale) from the baseline score in patients receiving Gel-One®, whereas the pain score was reduced by an average of 33.2% with an average pain score reduction of 22.6 mm

in patients receiving saline as a control.

Patients involved in this study whose knee pain returned after 13 weeks were offered retreatment with Gel-One® in a second clinical study (extension study). For some of these patients, this was a second injection of Gel-One® (125 patients), while it was a first treatment with Gel-One® for those patients who had received a saline injection during the initial study (74 patients). Patients in the extension study were followed for 13 more weeks after this Gel-One® injection. The results of this study showed that retreatment with Gel-One® is well tolerated, as the patients who received two Gel-One® injections did not have different or more frequent complications compared with patients who had only one Gel-One® injection.

In a third clinical study of Gel-One®, a total of 814 patients received treatments; 404 were injected with Gel-One®, and 410 were injected with a saline control. Patients were asked to rate their pain from 0 to 100 (where 0 is “no pain” and 100 is “worst possible pain”) by marking on a 100-mm line after walking 50 feet on a flat surface. Pain was evaluated in this manner at 3, 6, 12, 18, and 26 weeks after injection. Both the Gel-One® treatment and saline control treatment groups showed a 43% improvement in their average pain scores over baseline for 26 weeks.

The results of this third clinical study of Gel-One® were compared to another marketed product. This analysis showed Gel-One® to have a comparable knee OA pain-relieving clinical benefit in reducing OA knee pain over 26 weeks following treatment.

### **What adverse events were observed in the clinical studies?**

The most common adverse events that were related to the Gel-One® injection were knee pain, swelling, and effusion. No device-related serious adverse events were observed in the clinical studies.

Other adverse events that were related to the Gel-One® injection were: injection site pain, swelling, bruising, redness, and reaction; knee stiffness, muscular weakness, spasms, synovitis, warmth, popping; hip pain; dizziness; skin redness; rash; hives; itching; back pain; headache; hypertension; swelling; effusion; migraine; contusion; burning sensation; leg edema; increased blood liver enzyme, alkaline phosphatase, urea; and increased or decreased white blood cell count.

### **How do I get more information about Gel-One®?**

If you have any questions or would like to find out more about Gel-One®, you may call xxx.

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