

**SYNOJOYNT<sup>TM</sup>**  
**(1% sodium**  
**hyaluronate)**

**Patient Information**

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 SYNOJOYNT?**

SYNOJOYNT is a gel-like, elastic, sterile product containing highly purified hyaluronan (pronounced hye-a-loo-ROE-nan). Hyaluronan is a natural substance found in the body. It is present in particularly high amounts in 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 function properly.

**WHAT IS SYNOJOYNT USED FOR?**

SYNOJOYNT is used to help relieve knee pain due to osteoarthritis. It is used for patients who do not get enough relief from simple pain medications such as acetaminophen or from exercise and physical therapy.

Osteoarthritis is a condition that involves the wearing down of cartilage (the protective covering on the ends of your bones). In osteoarthritis, there may not be enough, or a decrease in the quality, of the gel-like substance in the joint and surrounding tissues for the joint to work properly.

**HOW IS SYNOJOYNT GIVEN?**

SYNOJOYNT comes in pre-filled syringes containing 2 ml (about half a teaspoon) of product. SYNOJOYNT is given by injection directly into the knee joint by a doctor or other qualified healthcare professional in his/her office. SYNOJOYNT is injected into your knee once a week for three weeks, for a total of three injections.

**ARE THERE ANY REASONS WHY I SHOULD NOT TAKE SYNOJOYNT?**

- Your doctor will determine if you are an appropriate candidate for SYNOJOYNT.
- Do not take SYNOJOYNT if you have had previous allergic reactions to SYNOJOYNT or hyaluronan products.
- SYNOJOYNT should not be injected into the knee if you have a knee joint infection or skin diseases or infections around the injection site.

**WHAT SHOULD MY DOCTOR WARN ME ABOUT?**

- After you receive an injection of SYNOJOYNT, you may experience temporary pain or swelling of the injected joint.
- SYNOJOYNT has not been tested in pregnant women or women who are nursing. Tell your doctor if you think you are pregnant or nursing a child before agreeing to be injected with SYNOJOYNT.

- SYNOJOYNT has not been tested in children less than 18 years of age.

### **WHAT ARE SOME OF THE POSSIBLE SIDE EFFECTS OF SYNOJOYNT?**

Some side effects (also called reactions) may occur during the use of SYNOJOYNT, with symptoms such as knee pain, reddening, swelling, and fluid collection appearing at the injection site, joint pain. If any of these symptoms or signs appears after you are given SYNOJOYNT or if you have any other problems, you should call your doctor. Incidences of rash, headache, dizziness, chills, hives, nausea, muscle cramps, peripheral edema, and malaise have also been reported in association with injections of hyaluronan into the knee joint.

The following are the most common adverse events that occurred during the clinical trial of SYNOJOYNT:

- Pain in the knee or at the injection site
- Swelling and discomfort of the joint

### **WHAT ARE THE BENEFITS OF SYNOJOYNT?**

Based on the results from a clinical study, subjects with knee pain due to osteoarthritis experienced relief of this pain as well as improvement in knee function lasting up to 6 months after receiving SYNOJOYNT.

A total of 396 patients in the study were assigned by chance to receive either a three weekly-injection treatment of SYNOJOYNT® (n=197 patients), or the same three-injection procedure using salt water (a “saline control”) (n=199 patients). Neither the patients nor the doctors evaluating them knew which treatment they received. Patients receiving SYNOJOYNT had an average reduction in pain scores of 36 mm (on a 500 mm scale) greater than patients receiving the saline control. In addition, the average percentage changes in stiffness scores were significantly better for patients receiving SYNOJOYNT in comparison to those patients that received the saline control.

### **WHAT SHOULD I DO AFTER RECEIVING A SYNOJOYNT INJECTION?**

- After receiving your injection, limit physical activity. Someone may need to drive you home from the doctor's office.
- Avoid strenuous physical activity for 48 hours following the injection to help keep your knee from swelling. Some examples of activities to avoid include:
  - Running-Tennis-Hiking
  - Jumping-Swimming-Heavy lifting (weight lifting)
  - Jogging-Bicycling-Aerobic exercise
- Do not stand on your feet for more than one hour at a time during the first 48 hours following your injection.
- You should ask your doctor when you should begin major physical activities again.

### **WHEN SHOULD I CALL MY DOCTOR (TROUBLESHOOTING)?**

If you experience any of the adverse effects or symptoms described earlier or if you have any other problems, you should call your doctor immediately.

### **ARE THERE OTHER NON-SURGICAL TREATMENTS AVAILABLE FOR OSTEOARTHRITIS?**

Yes, there are other non-surgical treatments available. Some of them include, but are not limited to:

- **Non-drug treatments**
  - Avoiding activities that cause pain in your knee
  - Exercise
  - Physical therapy
  - Weight loss (if overweight)
  - Removal of excess fluid from the knee
- **Drug Therapy**
  - Pain medications such as acetaminophen or stronger prescription medications
  - 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

Talk to your healthcare professional about non-surgical treatment options that may be appropriate for you.

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