

## **PATIENT INFORMATION**

### **DUROLANE<sup>®</sup>**

Please make 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.

#### **GLOSSARY**

**Hyaluronan** is a natural substance that is present in very high amounts in joints, skin and eyes. It is a major part of the synovial (cushioning) fluid in your joints and functions as a lubricant and a shock absorber.

**Non-steroidal anti-inflammatory drugs (NSAIDs)** are medications used to treat pain. There are many examples of NSAIDs, including (but not limited to) aspirin and ibuprofen (e.g. Advil<sup>®</sup>, Motrin<sup>®</sup>, etc.). Some of these drugs are over-the-counter, while stronger, more potent, versions can be obtained only by a doctor's prescription.

**Osteoarthritis (OA)** is a joint disease that shows itself as a type of arthritis that involves the wearing down of cartilage (the protective layer covering the ends of the bones) caused by loss of quality of the cushioning (synovial) fluid in the joint.

#### **WHAT IS DUROLANE<sup>®</sup>?**

DUROLANE<sup>®</sup> is a clear, viscous gel that contains highly-purified sodium hyaluronate. Sodium hyaluronate is found in the body, particularly in joint tissue and fluid surrounding the joint. This substance acts as a lubricant and shock absorber in the knee joint.

In joints affected by osteoarthritis, the concentration of sodium hyaluronate and its ability to lubricate and cushion may be reduced. Therefore, injection of sodium hyaluronate directly into the joint may increase lubrication and cushioning, relieving pain during physical activity.

The sodium hyaluronate in DUROLANE<sup>®</sup> is produced by bacterial fermentation. DUROLANE<sup>®</sup> is provided to your doctor as a single syringe containing 3 ml of gel.

#### **WHAT IS DUROLANE<sup>®</sup> USED FOR?**

DUROLANE<sup>®</sup> is used to relieve knee pain due to osteoarthritis, improving patient capacity for physical activity. It is used for patients who do not get enough pain relief from conservative therapies, such as exercise or physical therapy.

#### **HOW IS DUROLANE GIVEN?**

Your doctor will give you a single injection of DUROLANE<sup>®</sup> (3 ml, 20 mg/ml) into your knee joint.

#### **WHAT ARE THE POSSIBLE SIDE EFFECTS?**

Common side effects (also called reactions) that may occur during the use of DUROLANE<sup>®</sup> include pain, joint pain, joint swelling, and joint stiffness at the injection site.

The majority of reactions are mild to moderate in nature and do not last long. No treatment-related allergic reactions or acute-inflammatory reactions or hypersensitivity to DUROLANE<sup>®</sup> have been reported from the controlled clinical studies.

If any of the above symptoms or signs appear after you are given DUROLANE<sup>®</sup>, or if you are experiencing any other problems, you should call your healthcare professional.

### **WHAT SIDE EFFECTS WERE OBSERVED IN THE CLINICAL STUDIES?**

In the DUROLANE<sup>®</sup> treatment group for a clinical study performed in the People's Republic of China (PRC), the adverse events included injection site pain (2.3%), joint swelling (1.7%), and joint pain (8.6%). These adverse events were comparable to those reported in a control group that was treated with a commercially available 5-injection sodium hyaluronate, and adverse events in the control group included injection site pain (1.1%), joint swelling (1.7%), and joint pain (7.5%). Most of the reactions in both groups were mild to moderate in nature and did not last long.

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

Data from the clinical trial showed that a single injection of DUROLANE<sup>®</sup> provided comparable pain relief to patients with osteoarthritis of the knee to the pain relief provided by 5 injections of another commercially available sodium hyaluronate. The patients in the study had been diagnosed with OA of the knee associated with moderate to severe pain, and did not obtain sufficient relief with simple analgesics (e.g. acetaminophen) taken by mouth.

A total of 349 patients in the study were assigned by chance to receive either a single injection treatment of DUROLANE<sup>®</sup> (n=175 patients), or a 5-injection procedure using a commercially available hyaluronate (n=174 patients). Neither the patients nor the doctors evaluating them knew which treatment they received. Patients were observed by their doctor over 6 months. DUROLANE<sup>®</sup> demonstrated a similar safety profile to that of the 5-injection sodium hyaluronate product when injected in the knee.

The pain relieving benefits of DUROLANE<sup>®</sup> were compared with the same measures of a similar 5-injection sodium hyaluronate product that is manufactured by another company. The other product was approved in the US as a 5-injection regimen (treatment) and helped many patients with osteoarthritis. This comparison was used to show that DUROLANE<sup>®</sup> provides no inferior pain relief in a single injection. The main measure of the comparison was how much less pain the subjects had experienced over a 6 month time period.

### **WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?**

If you have osteoarthritis, a number of approaches to relieving the symptoms are available. These include:

Non-drug treatments:

- Avoidance of activities that cause knee pain
- Exercise
- Physical therapy

- Non-drug treatments (e.g. glucosamine, chondroitin)
- Removal of excess fluid from the knee
- Total knee replacement
- Arthroscopic surgery

**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 non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or naproxen
- Steroids that are injected directly into the knee

**ARE THERE ANY REASONS WHY YOU SHOULD NOT RECEIVE DUROLANE?**

- You should not be given this product if you have a knee joint infection or skin disease or infection around the area where the injection will be given.
- You should not use this product if you are allergic to sodium hyaluronate products.

**THINGS YOU SHOULD KNOW ABOUT DUROLANE®**

- DUROLANE® should only be injected by a doctor or other qualified healthcare professional.
- Tell your healthcare professional if you are allergic to sodium hyaluronate based products.
- As with other injection products, you may need to avoid activities such as jogging, tennis, standing for a long time (more than an hour) or heavy lifting for 48 hours after the injection.
- DUROLANE® has not been approved for use in joints other than the knee.
- The safety and efficacy of DUROLANE® have not been established in children (21 years of age or younger), pregnant women, or nursing mothers.
- The effectiveness of DUROLANE® has not been established for more than one course of treatment.
- No treatment-related allergic reactions or acute-inflammatory reactions or hypersensitivity to DUROLANE® have been reported from the controlled clinical studies.

**WHEN SHOULD YOU CONTACT YOUR DOCTOR?**

If any of the above symptoms or signs appear after you are given DUROLANE®, or if you are experiencing any other problems, you should call your healthcare professional.

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90-35807-01 Rev. (draft)

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