

Patient Information SUPARTZ®

(Sodium Hyaluronate)

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 SUPARTZ.

SUPARTZ is used for the treatment of pain in osteoarthritis of the knee in patients who have failed to get adequate relief from simple painkillers or from exercise and physical therapy.

What is SUPARTZ?

SUPARTZ is a solution made of highly purified, sodium hyaluronate (hyaluronan). Hyaluronan is a natural chemical found in the body and is found in particularly high amounts in joint tissues and in the fluid (synovial fluid) that fills the joints. The body's own hyaluronan acts like a lubricant and shock absorber in synovial fluid of a healthy joint. Osteoarthritis reduces your synovial fluid's ability to protect and lubricate your joint.

SUPARTZ is available in 2.5 mL pre-filled syringes. SUPARTZ is given in a shot directly in your knee.

What are the benefits of SUPARTZ?

The safety and effectiveness of SUPARTZ were studied in five clinical trials. These studies were conducted in Germany (1991); Sweden (1993); France (1995); the UK and Australia (1996). Patients received, in one knee joint, 5 weekly injections of SUPARTZ or salt water. In the French study there were 3 treatment groups: 5 SUPARTZ injections per patient, 3 SUPARTZ injections followed by 2 injections of the salt water per patient, or 5 injections of the salt water per patient. The results of these five studies (619 patients received SUPARTZ, 537 received salt water) have shown that five weekly injections of SUPARTZ into the knee is both safe and effective for the relief of pain associated with osteoarthritis of the knee that was not relieved by simple painkillers or by exercise and physical therapy.

Additionally, SUPARTZ(ARTZ) has been in use in Japan since 1987. A prospective post-market surveillance study conducted from 1987 to 1993 evaluated safety on 7404 knees treated from a total of 675

medical institutions. A subset of 7155 knees was treated with 3 or more consecutive injections. There were 58 cases of adverse reactions in 37 knees (0.50% - 37/7404). The most frequently observed were 29 cases of pain at the injection site, 16 cases of swelling, and 3 cases of redness. Other adverse reactions were 3 cases of rash, and 6 cases of increased liver enzymes suggesting abnormal liver function. The incidence of adverse reactions was not related to the number of injections. There was no increase in adverse events in patients requiring 3 or more injections.

How is SUPARTZ given?

Your doctor will give you an injection of SUPARTZ (25mg/2.5mL) into your knee once a week for 5 weeks (a total of 5 injections). Your doctor may recommend a local anesthetic to reduce the possible discomfort associated with an injection.

What should you expect following your series of injections?

The goal of SUPARTZ is the relief of pain. You may experience some pain relief before you receive the full series of 5 injections. While

studies suggest that most patients experiencing relief do so after the full series of 5 injections, some patients may experience benefit with 3 injections given at weekly intervals. The actual amount and duration of pain relief varies from patient to patient. Immediately after you have the injection and for the next 48 hours, you may need to avoid activities such as jogging, tennis, heavy lifting or standing on your feet for a long time. Please note that no treatment, including SUPARTZ, helps in every single patient.

What other treatments are available for osteoarthritis?

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

Non-drug treatments

- Avoiding activities that cause excess pain in your joints
- Exercise
- Physical therapy

Drug Therapy

- Painkillers such as acetaminophen and narcotics
- Drugs that reduce inflammation, such as aspirin, and other nonster-

oidal 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 utilize SUPARTZ?

- You should not use this product if you are allergic to products from birds such as feathers, eggs and poultry.
- You should not have the injection if you have infections or skin diseases in the area the injection will be given.
- You should not take this product if you have had any previous allergic reaction to SUPARTZ or similar material, i.e., hyaluronate products.
- The safety and effectiveness of SUPARTZ have not been established in pregnant women, in lactating women, and in children.

Possible complications:

- In the studies mentioned above, the following were the most common adverse events (occurring in greater than 4% of SUPARTZ-treated patients): joint pain with no evidence of inflammation, joint pain with evidence of inflammation,

back pain, pain (non-specific), injection site reaction, headache, and injection site pain.

However, these adverse events also occurred at similar rates in the patients treated with salt water.

- In the five studies, five (5) allergic reactions were reported in the SUPARTZ group. No severe allergic reactions were observed in any study patients.
- The following possible side effects have been reported as post-market experience worldwide. The most common side effects include: Injection site reactions (pain / swelling / effusion (an abnormal collection of fluid in a body cavity or space) / redness / warmth). These reactions were generally mild and did not last long. Other side effects include: Itching; swelling of face, eyelids, mouth, and/or extremities; rash; hives; redness in face; nausea; vomiting and fever.

Rare cases of allergic/non-allergic reactions accompanied by cold sweat, paleness and low blood pressure, have been reported.

- If any of the above symptoms or signs appear after you are given

SUPARTZ, or if you have any other problems, you should contact your doctor.

Other things you should know about SUPARTZ:

- Supartz is only for injection into the knee, performed by a qualified physician.
- Pain and/or swelling of the injected joint may occur after injection of Supartz.
- The safety and effectiveness of repeat treatment cycles of Supartz have not been established.
- The effectiveness of a single treatment cycle of less than 3 injections has not been established.
- The safety and effectiveness of the use of Supartz in joints other than the knee have not been established.
- The safety and effectiveness of the use of Supartz given at the same time as other injectables have not been established.

How can you get more information about SUPARTZ?

- Ask your doctor.
- Call Smith & Nephew Customer Service at 800 821 5700.
- Consult the Supartz internet site at www.supartz.com.

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