

# Joint Fluid Therapy — Important Medical Information

**BRIEF SUMMARY FOR THE PHYSICIAN** (CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION)

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

**INDICATIONS AND USAGE:** Treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics, e.g., acetaminophen.

**CONTRAINDICATIONS** • Do not administer to patients with known hypersensitivity (allergy) to sodium hyaluronate preparations. • Do not inject this product in the knees of patients with infections or skin diseases in the area of the injection site.

**WARNINGS** • Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because sodium hyaluronate can precipitate in their presence.

**PRECAUTIONS General** • The effectiveness of a single treatment cycle of less than 5 injections has not been established. • Strict aseptic administration technique must be followed. • Remove joint effusion, if present, before injecting SUPARTZ. • 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 concomitantly with other intra-articular injectables have not been established. • Use caution when injecting SUPARTZ into patients who are allergic to avian proteins, feathers and egg products. • **STERILE CONTENTS.** The prefilled syringe is intended for single use. The contents of the syringe must be used immediately once the container has been opened. Discard any unused SUPARTZ. • Do not use SUPARTZ if the package is opened or damaged. Store in the original packaging below 77°F (25°C). **DO NOT FREEZE.** Do not use after expiration date indicated on package. Shelf life is 42 months.

**INFORMATION FOR PATIENTS** • Provide patients with a copy of the Patients' Information prior to use. • Transient pain and/or swelling of the injected joint may occur after intra-articular injection of SUPARTZ. • As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities or prolonged (i.e., more than 1 hour) weight-bearing activities such as jogging or tennis within the 48 hours that follow the intra-articular injection. • The safety and effectiveness of repeat treatment cycles of SUPARTZ have not been established.

**Use in Specific Populations** • **Pregnancy:** The safety and effectiveness of

SUPARTZ have not been established in pregnant women. • **Nursing Mothers:** It is not known if SUPARTZ is excreted in human milk. Excretion has been seen in rat milk. The safety and effectiveness of SUPARTZ have not been established in lactating women. • **Pediatrics:** The safety and effectiveness of SUPARTZ have not been demonstrated in children.

## ADVERSE EVENTS

The evaluable for safety population included all patients receiving at least one injection (619 SUPARTZ; 537 control injection) in five well controlled clinical trials. The most common adverse events (occurring in greater than 4% of SUPARTZ-treated patients) were arthralgia, defined as joint pain with no evidence of inflammation, arthropathy/arthrosis/arthritides, defined as joint pain with evidence of inflammation, back pain, pain (non-specific), injection site reaction, headache, and injection site pain. There were no statistically significant differences in the incidence rates of these adverse events between treatment groups.

Five (5) allergic reactions were reported in the SUPARTZ group. All five events were classified as mild to moderate. These were: hayfever (2), reaction on face and neck, cutaneous reaction forearms and knees, and an undefined mild allergy reaction. No anaphylactic reactions were observed in any study patients. Other adverse events occurring in 4% or less but not less than 1% of the SUPARTZ treated patients included upper respiratory tract infection, influenza-like symptoms, nausea, sinusitis, urinary tract infection, bronchitis, abdominal pain, diarrhea, inflicted injury, leg pain, discomfort in legs, dyspepsia, dizziness, rhinitis, and fall.

## DETAILED DEVICE DESCRIPTION

Each 2.5mL prefilled syringe of SUPARTZ contains:

Sodium Hyaluronate	25.0mg
Sodium Chloride	21.25mg
Dibasic Sodium Phosphate Dodecahydrate	1.343mg
Sodium Dihydrogen Phosphate Dihydrate	0.04mg
Water for Injection	q.s.

**HOW SUPPLIED** SUPARTZ is supplied as a sterile, non-pyrogenic solution in 2.5mL pre-filled syringe.

**DIRECTIONS FOR USE** SUPARTZ is administered by intra-articular injection once a week (1 week apart) for a total of 5 injections. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of SUPARTZ.

**Warning:** Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because sodium hyaluronate can precipitate in their presence.

**Precaution:** Do not use SUPARTZ if the package is opened or damaged. Store in the original packaging below 77°F (25°C). **DO NOT FREEZE.** Do not use after expiration date indicated on package. Shelf life is 42 months.

**Precaution:** Strict aseptic administration technique must be followed.

**Precaution:** Remove joint effusion, if present, before injection of SUPARTZ.

Take care to remove the tip cap of the syringe and needle aseptically. Inject SUPARTZ into the joint through a 22-23 gauge needle.

Inject the full 2.5mL in one knee only. If treatment is bilateral, a separate syringe should be used for each knee.

**Precaution:** The prefilled syringe is intended for single use. The content of the syringe must be used immediately once the container has been opened. Discard any unused SUPARTZ.

This Brief Summary is based upon the current circular revised February 2001.

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