

**PRODUCT NAME:**

Cingal®

(Cross-linked Hyaluronic Acid with ancillary Triamcinolone Hexacetonide)

**INGREDIENTS:**

The Cingal sterile suspension contains the following:

Water for Injection, Cross-linked Hyaluronic Acid (2.20%), Sodium Phosphate Dibasic (0.15%), Sodium Phosphate Monobasic, Monohydrate (0.03%), Triamcinolone Hexacetonide (0.45%), Polysorbate 80 (0.22%) and Sorbitol (5.30%).

Cingal contains materials derived from microbial origin.

**INDICATIONS:**

Cingal is indicated as a viscoelastic supplement or a replacement for synovial fluid in the knee. Cingal® is well suited for rapid and long-term relief of the symptoms of knee joint dysfunctions such as osteoarthritis.

**INSTRUCTIONS FOR USE:**

Cingal is injected through a sterile, disposable, hypodermic needle of suitable (18-21) gauge into the selected joint space. The sterile needle should be attached to the Cingal syringe by a health care professional using health care facility approved aseptic technique.

**INTENDED PERFORMANCE:**

The actions of Cingal are long term relief of symptoms by lubrication and mechanical support supplemented by short-term pain relief provided by triamcinolone hexacetonide.

**SIDE EFFECTS / UNDESIRABLE EFFECTS:**

*Effects associated with Hyaluronic Acid*

- Mild to moderate swelling
- Discomfort
- A risk of infection is possible with the procedure of injecting substances into joints

*Effects associated with Triamcinolone Hexacetonide*

*Possible (rare)*

The following side effects can occur with repeated injections into the joint:

- Pain
- Infection
- Excess injections into the same site may cause local tissue death
- Vertigo
- Cortisol suppression may be observed during the first week after injection. These symptoms may be extreme fatigue, darkening of your skin, low blood pressure, feeling faint, salt craving, low blood sugar, nausea, diarrhea or vomiting, or abdominal pain.

- The use of medications containing steroids prior to and after implantation may affect recovery. Inform your healthcare professional if you have or are intending to use any substances containing steroids.

**IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL.**

## **PRECAUTIONS**

Symptoms that could indicate that Cingal is malfunctioning:

- A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, are suggestive of septic arthritis. Tell your doctor if you notice anything else that is making you feel unwell.

## **EXPECTED DEVICE LIFETIME**

Cingal is intended to provide long lasting pain relief through 26 weeks for the pain and symptoms associated with knee osteoarthritis.

## **SERIOUS INCIDENTS**

Related to the use of Cingal, contact the Australian sponsor and the Australian Therapeutic Goods Administration at the below details:

### **AUSTRALIAN SPONSOR**

Surgical Specialties

1/17 Rodborough Road, Frenchs Forest

NSW, 2086.

[www.surgicalspecialties.com.au](http://www.surgicalspecialties.com.au)

1300 665 884

### **AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION**

[www.tga.com.au](http://www.tga.com.au)

### **MANUFACTURER**

Anika Therapeutics, Inc. Bedford, MA 01730 U.S.A