

**PRODUCT NAME:**

Monovisc® (Cross-linked Hyaluronic Acid)

**INGREDIENTS:**

The Monovisc sterile suspension contains the following:

Hyaluronan (88 mg), Sodium Chloride (36 mg), Potassium Chloride (0.8 mg) Sodium Phosphate, Dibasic (4.6 mg), Potassium Phosphate Monobasic (0.8 mg USP), water for injection (q.s. to 4 mL).

Monovisc contains materials derived from microbial origin.

**INDICATIONS:**

Monovisc® is indicated as a viscoelastic supplement or a replacement for synovial fluid in human joints. Monovisc® is well suited for treatment of the symptoms of human joint dysfunctions such as osteoarthritis.

**INSTRUCTIONS FOR USE:**

Monovisc 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 Monovisc syringe by a health care professional using health care facility approved aseptic technique.

**INTENDED PERFORMANCE:**

The actions of Monovisc are long term relief of symptoms by lubrication and mechanical support.

**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

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

**PRECAUTIONS**

Symptoms that could indicate that Monovisc 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**

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

**SERIOUS INCIDENTS**

Related to the use of Monovisc, 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