

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 knee joints. Monovisc is well suited for treatment of the symptoms of mild to moderate osteoarthritis of the human knee joints for patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics.

INSTRUCTIONS FOR USE:

Monovisc is injected through a sterile, disposable, hypodermic needle of suitable (18-21) gauge into the knee 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:

Monovisc® Patient information leaflet

AUSTRALIAN SPONSOR

Surgical Specialties

1/17 Rodborough Road, Frenchs Forest

NSW, 2086.

www.surgicalspecialties.com.au

1300 665 884

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

www.tga.com.au

MANUFACTURER

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