Cingal® Patient information leaflet

PRODUCT NAME
Cingal (Cross-linked Sodium Hyaluronate with ancillary Triamcinolone Hexacetonide)

INGREDIENTS:
Cingal is a sterile preparation containing the following:
Cross-linked Hyaluronic Acid (2.20%), Sodium Phosphate Dibasic (0.15%), Sodium Phosphate Monobasic (0.03%), Triamcinolone Hexacetonide (0.45%), Polysorbate 80 (0.22%), Sorbitol (5.30%) and water for injection (q.s. to 4 mL). 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 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 of knee joint dysfunctions such as osteoarthritis, by lubrication and mechanical support supplemented by short-term pain relief provided by triamcinolone hexacetonide.

SIDE EFFECTS / UNDESIRABLE EFFECTS:
Effects associated with Hyaluronic Acid
Hyaluronic acid is a naturally occurring component of the tissues of the body. Cingal is thoroughly tested to determine that each batch conforms to the product quality requirements. Mild to moderate swelling and discomfort have occasionally been observed following intra-articular injection of hyaluronic acid preparations. 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, diarrhoea 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 any of these symptoms or signs appear after you are given Cingal or if you have any other problems, you should tell your doctor.
IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL

PRECAUTIONS
- Cingal should be injected into the joint ONLY by a qualified physician or licensed healthcare practitioner.
- The safety and effectiveness of Cingal have not been studied in pregnant or nursing women or children. You should tell your healthcare professional if you are pregnant or nursing.
- For 48 hours after you receive the injection, you should avoid activities such as jogging, tennis, heavy

lifting or standing on your feet for a long time (more than one hour).

EXPECTED DEVICE LIFETIME
Once injected, the effect of Cingal will generally last about 6 months. Eventually the product is broken down and absorbed by the body, just like the hyaluronic acid already in your body.
Please follow your doctor's instructions regarding any follow-ups required

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION
https://www.tga.gov.au/

MANUFACTURER
Anika Therapeutics, Inc. Bedford, MA 01730, U.S.A
https://anika.com/

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