

## What is Cingal®?

Cingal is a novel combination hyaluronic acid (HA) viscosupplement plus corticosteroid single-injection treatment for the pain of osteoarthritis (OA) of the knee.

## How is Cingal different than other treatment options?

Cingal is the first and only CE mark approved hyaluronic acid (HA) and corticosteroid combination product. First in its class, Cingal is a unique product that combines an HA viscosupplement to provide long-term pain relief with a well established corticosteroid to treat inflammation and provide rapid pain reduction.

## How does it work?

Hyaluronic acid (HA) is vital for maintaining the function and elasticity of the synovial fluid in human joints. Osteoarthritis (OA) causes the natural HA to break down, leaving lower concentrations of HA in the synovial fluid. Cingal is designed to supplement the reduced amount of natural HA in synovial fluid in osteoarthritic knee joints. The formulation of Cingal allows for long-term relief of the symptoms of OA through lubrication and mechanical support from the viscosupplement component, enhanced by short-term pain relief provided by triamcinolone hexacetonide (TH) corticosteroid.

## Is Cingal safe?

Cingal demonstrated a very good safety profile in its clinical study as a combination hyaluronic acid (HA) plus corticosteroid product in the treatment of knee pain due to osteoarthritis (OA). In addition, both HA viscosupplements and corticosteroids are individually well established with proven track records supporting their safety and performance in the treatment of the pain of osteoarthritis.<sup>12</sup> HA viscosupplements have been proven to be a safe, targeted therapy for osteoarthritis with minimal side effects. HA injections have been used for more than 25 years<sup>3</sup> to reduce pain associated with OA and to improve viscoelastic properties of the synovial fluid. Corticosteroid injections have been used for over 45 years<sup>4</sup> in the treatment of the symptoms of osteoarthritis for their potent anti-inflammatory effects to reduce pain quickly and allow earlier motion.

# Cingal®

## One-Injection Combination Hyaluronic Acid and Triamcinolone Hexacetonide

### FAQ

## What can I expect from the procedure?

Cingal is injected directly into the knee joint space where it supplements the hyaluronic acid (HA) in the synovial fluid. It is a simple procedure that may be done in a physician's office.

## Are there side effects?

In a Cingal clinical study, a low number of patients experienced minor side effects. All were common side effects seen with viscosupplement injections, including injection site pain, joint pain, rash, redness or swelling, and all were resolved naturally without treatment.<sup>5</sup> For additional details and information about the product, please refer to the Instructions for Use that are included in the product's packaging.

## When can I expect to feel pain relief?

Every patient's experience is slightly different. For some, pain relief happens almost immediately, while it may take a few days for others. In a clinical study, Cingal patients experienced statistically significant reduction in knee pain in the first week.<sup>5</sup>

## How long does it last?

In a Cingal clinical study, significant knee pain relief was sustained through six months. Although there were no time points measured after 26 weeks, clinical results show that the effects of Cingal lasted and appeared to get stronger at six months, allowing patients to continue to experience maximum pain relief.<sup>5</sup>

## Can I get repeat injections?

Yes. The safety of receiving a repeat injection of Cingal was confirmed in a follow-up clinical study.<sup>6</sup> In this study, patients received a second injection six months after their initial injection of Cingal. Repeated treatments can be performed as directed by a physician.

## Who should consider a Cingal injection?

Patients who have mild to moderate osteoarthritis (OA) and whose conservative treatments such as lifestyle changes or pain medications no longer effectively manage their pain due to OA may benefit from a Cingal injection. Cingal is designed for patients who demand quick results, want to remain active, prefer a single-visit treatment, or are looking to delay reconstructive surgery.

## What is Cingal made from?

Cingal is a transparent gel that contains natural, non-animal-sourced hyaluronic acid (HA), combined with a corticosteroid.

## What is a hyaluronic acid viscosupplement?

Viscosupplementation is a procedure where hyaluronic acid (HA) is injected into the synovial fluid surrounding the knee joint for the treatment of the pain associated with OA. In osteoarthritic joints, the natural HA found in the synovial fluid, the thick liquid that helps lubricate and cushion the joint, begins to break down. As a result, the synovial fluid becomes thinner and less effective at cushioning and lubricating the knee, causing pain, swelling, and loss of motion. Hyaluronic acid viscosupplements are designed to replace some of the natural HA that has been lost due to OA, providing pain relief, joint lubrication, and increased mobility.

## What is a corticosteroid?

Corticosteroids are naturally occurring hormones that mimic the anti-inflammatory effects of the hormone cortisol in the body, and are used to reduce inflammation in the treatment of a range of orthopaedic problems including osteoarthritis. Corticosteroids should not be confused with anabolic steroids, which are known for their use (or abuse) by athletes who take them for their muscle and strength building properties.

# The Patient Experience

Cingal® is a simple, physician-administered injection that delivers fast-acting and long-lasting pain relief for osteoarthritis so patients can once again enjoy daily physical activities with reduced pain.

## Simple Procedure

Cingal is a simple injection that may be done in the convenience of a clinician's office. The physician injects Cingal directly into the knee joint space where it combines with the synovial fluid to relieve the pain of osteoarthritis (OA) in the knee.

Cingal has been specially formulated as a single-injection procedure. Unlike other hyaluronic acid (HA) viscosupplementation treatment regimens that may require up to five injections, Cingal only requires a single injection to achieve fast-acting and long-lasting pain relief.

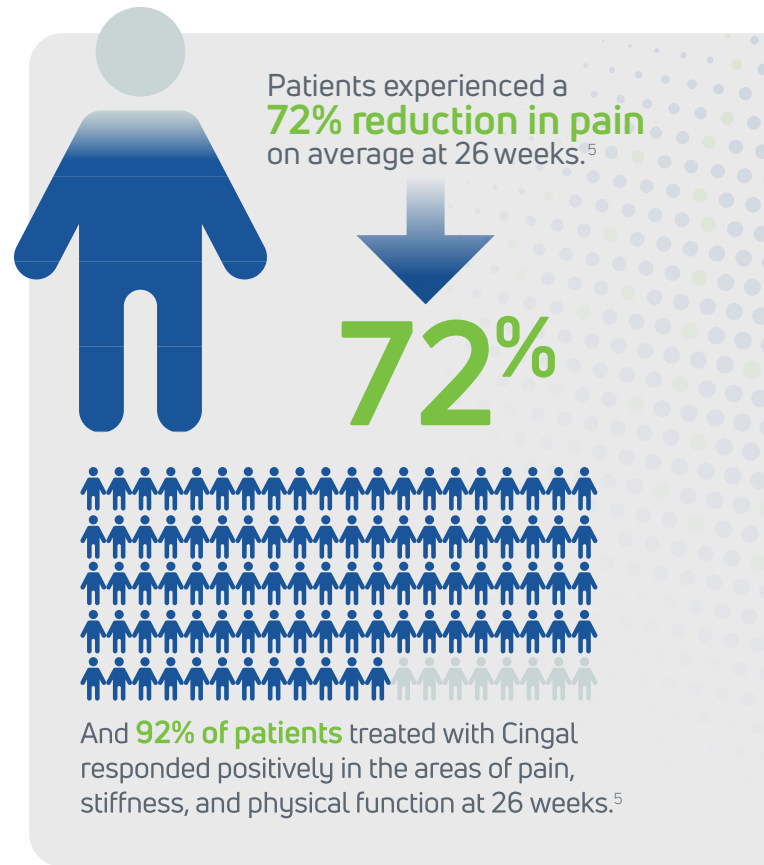
The Cingal injection may be administered by an orthopaedic surgeon, rheumatologist, or other qualified health professional.

## How Quickly Will Pain Relief Occur?

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## How Long Will Pain Relief Last?

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1. Bellamy N, Campbell J, Robinson V, et al. Intraarticular corticosteroid for treatment of osteoarthritis of the knee. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD005328. 2. Ozturk C, Atamaz F, Hegguler S, et al. The safety and efficacy of Intra-articular hyaluronan with/without corticosteroid in knee osteoarthritis: 1-year, single-blind, randomized study. Rheumatol Int. 2006 Feb;26(4):314-9. 3. Ault A. From the Head of a Rooster To a Smiling Face Near You. New York Times, 2003 Dec. 4. Zoorob R., Cender D. A Different Look at Corticosteroids. Am Fam Physician. 1998 Aug 1;58(2):443-450. 5. Cingal 13-01, a randomized, double-blind, placebo-controlled, active comparator Phase III study. Anika Therapeutics, Inc.: study sponsor, Dr. Laszlo Hangody: global principal investigator, SynteractHCR: CRO. 6. Cingal 13-02, an open-label, follow-on study to Cingal 13-01. Anika Therapeutics, Inc.: study sponsor, Dr. Laszlo Hangody: global principal investigator, SynteractHCR: CRO. 7. Mazzara, J, MD. Cortisone Injections. Connecticut Center for Orthopedic Surgery, LLC., Web: [http://www.orthoontheweb.com/pdfs/about\\_cortisone\\_injections.pdf](http://www.orthoontheweb.com/pdfs/about_cortisone_injections.pdf) 8. Cingal 13-01, a randomized, double-blind, placebo-controlled, active comparator Phase III study. Anika Therapeutics, Inc.: study sponsor, Dr. Laszlo Hangody: global principal investigator, SynteractHCR: CRO.

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