ArtiAid®

CE 2797 | 2℃ 25℃ | STERILE A Sterilization using aseptic

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Description

ArtiAid® is a sterile, non-pyrogenic, synovia viscosupplementation aid prepared of the non-inflammatory, viscous, aqueous solution of a defined molecular weight (600,000~1,200,000 Dalton) fraction of highly purified sodium hyaluronate. Hyaluronate, a natural polymer of the glucosaminoglycan family, is a mucopolysaccharide consisting of repeating disaccharide units of N-acetylglucosamine and glucuronate linked by β 1-3 and β 1-4 glycosidic bonds. Each pre-filled syringe contains 10 mg/ml (1.0%) sodium hyaluronate dissolved in buffered physiological saline solution. The viscoelastic solution has a pH of 6.8 ~ 7.5, and an osmolality of approximately 290 mOsm/kg.

Indications

Symptomatic treatment of mild to moderate knee osteoarthritis, in patients who failed to respond adequately to conservative nonpharmacologic therapies, and to simple analgesics, e.g., acetaminophen.

Contraindications

- Do not administer to patients with known hypersensitivity to hyaluronate preparations.
- Intra-articular injections are contraindicated in cases of infections or skin diseases in the area of the injection site.
- At present, there are no other known contraindications to the use of ArtiAid® when used as recommended as an intra-articular injection.

Precautions

- Do not use ArtiAid® if package is opened or damaged.
- The product contents are sterile unless the package is opened or damaged. The syringe contents must be used immediately once the container has been opened. The syringe is intended for single use only. Discard any unused ArtiAid®.
- Strict aseptic administration technique must be followed.
- ArtiAid® is prepared from a biological source. It is a highly purified fraction but may still contain minute amounts of proteins. The physician should be aware of potential risks that can be occurred with the injection of any biological materials. Be careful of use of ArtiAid® in the patients with severe allergy diseases.
- ArtiAid® should be used with caution when there is evidence of venous or lymphatic stasis in that leg.
- Transient pain and swelling of the injected joint may occur after intra-articular injection of ArtiAid®. The physician might treat with appropriate medication.
- Remove joint effusion, if present, before injecting ArtiAid®. Inject ArtiAid® into the joint through a 20-gauge needle. Do not use the same syringe for removing joint effusion and for injecting ArtiAid®. Take care to remove the tip cap of the syringe and needles aseptically.
- As with any invasive joint procedure, it is recommended that care be taken not to overburden the joint immediately following the intra-articular injection and that the procedure not be performed if the patient does not have access to medical attention for the subsequent 48 hours.
- The efficacy of a single treatment cycle of less than 5 injections has not been established. Pain relief may not be seen until after the third injection.
- The safety and efficacy of repeat treatment cycles of ArtiAid® have not been established.
- The safety and efficacy of the use of ArtiAid® in locations other than knee and for conditions other than osteoarthritis have not been established.
- The safety and efficacy of use of ArtiAid® concomitantly with other intra-articular injections has not been established.
- Although animal studies with ArtiAid® that evaluated its potential reproductive and developmental toxicity were negative, the safety and efficacy of ArtiAid® has not been tested in pregnancy, nursing or children.
- Procedures to maintain the sterility of the injection site and use of proper technique for injection must be followed.
- In vitro, laboratory studies have shown opalescence of sodium hyaluronate when mixed with solutions containing quaternary ammonium compounds. Hence, sodium hyaluronate should not be injected through a device used in conjunction with such solutions.

Adverse Reaction

Sodium hyaluronate is a natural component in the tissues of the body and is extremely well tolerated in human. Transient postoperative inflammatory reactions have been reported. Some of the patients were reported to develop adverse reactions such as injection site pain, knee swelling and/or effusion, local skin reactions (rash, ecchymosis), and pruritus. Transient increase in phlogistic response in the injected knee following ArtiAid® injection in some patients with inflammatory arthritis such as rheumatoid arthritis or gouty arthritis have been reported.

Administration

Inject ArtiAid®, using a suitable needle (for example 20G), in the affected joint at weekly interval for 5 weeks.
Product administration should be performed exclusively by qualified physicians.
All the rules regarding the asepsis and the injection technique should be followed.
Remove any joint effusion, if present, before injecting ArtiAid®.
Take care to remove the tip cap of the syringe and needle aseptically. Inject ArtiAid® into the joint through a suitable needle (for example 20G).
Inject the full of ArtiAid® in one knee only. If treatment is bilateral a separate syringe should be used for each knee.
For patients who respond to treatment, the effect of treatment lasts for 6 months.

Storage Conditions and Shelf Life

Shelf life is 3 years if stored below 25°C. Protect against sunlight and heat. Do not freeze.

Supplied

ArtiAid® is manufactured using aseptic filling techniques.
ArtiAid® is a sterile, non-pyrogenic solution of sodium hyaluronate, using sodium hydroxide and/or hydrochloric acid for pH adjustment (when necessary). Supplied in a disposable syringe
Each syringe contains (AA-25):

Sodium hyaluronate	25.0 mg
Sodium chloride	22.5 mg
Dibasic sodium phosphate (heptahydrate)	1.0 mg
Sodium dihydrogen phosphate (dihydrate)	0.035 mg
Sterile water for injection	q.s.
Sodium hydroxide and /or hydrochloric acid for pH adjustment (if necessary)	

Catalogue No.	Product spectrum
AA-20	2.0mL 1.0% Sodium Hyaluronate
AA-25	2.5mL 1.0% Sodium Hyaluronate
AA-27	2.7mL 1.0% Sodium Hyaluronate
AA-30	3.0mL 1.0% Sodium Hyaluronate
AA-35	3.5mL 1.0% Sodium Hyaluronate

Warning

- ArtiAid® is only for intra-articular use.
- Remove joint effusion, if present, before injecting ArtiAid®.
- Do not concomitantly use disinfectants containing quaternary ammonium salts because hyaluronate can be precipitated in their presence.
- The content of the syringe is manufactured using asptic filling techniques. Do not resterilize. The syringe is intended for single use only, if reuse will cause cross infection. Do not reuse. Discard any unused ArtiAid®.