




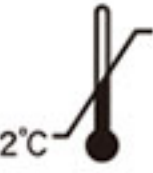







Read this package insert completely before use and comply with the instructions for use.

ArtiAid® Plus Intra-articular Injection

GRAPHICAL SYMBOLS

	Single use only		Catalog Number
	Read instructions before use		Lot Number
	Sterilized using aseptic processing techniques		Store between 2-25°C
	Do not re-sterilize		Keep away from sunlight
	Use by expiry date		Do not use if package is damaged
	Manufacturer		

Description

ArtiAid® Plus is a sterile, non-pyrogenic, synovial viscosupplementation aid prepared of the non-inflammatory, viscous, aqueous solution of a defined molecular weight (more than 1,500 KDa) 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 15 mg/ml (1.5%) 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® Plus when used as recommended as an intra-articular injection.
- Do not administer less or more than 3 injections of ArtiAid® Plus per treatment.
- Do not administer ArtiAid® Plus in locations other than the knee and for conditions other than osteoarthritis.
- Do not administer ArtiAid® Plus concomitantly with other intra-articular injection.
- Do not administer ArtiAid® Plus in pregnancy, nursing or children.

Precautions

- Do not use ArtiAid® Plus 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® Plus.
- Strict aseptic administration technique must be followed.
- ArtiAid® Plus 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 (such as foreign body induced inflammatory) that can be occurred with the injection of any biological materials. Be careful of use of ArtiAid® Plus in the patients with severe allergy diseases.
- ArtiAid® Plus 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® Plus. The physician might treat with appropriate medication.
- Remove joint effusion, if present, before injecting ArtiAid® Plus. Inject ArtiAid® Plus into the joint through a 20-gauge needle. Do not use the same syringe for removing joint effusion and for injecting ArtiAid® Plus. 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.
- 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.
- Do not administer ArtiAid® Plus if it is not stored at the recommended condition.

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.

Administration

Inject ArtiAid® Plus, using a suitable needle (for example 20G), in the affected joint at weekly interval for 3 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® Plus. For patients who respond to treatment, the effect of treatment lasts for at least 6 months.

Storage Conditions and Shelf Life

Shelf life is 2 years if stored in original unopened package at the correct temperature. Protect against light, heat and frost. Optimal storage condition is below 25°C and do not freeze.

How Supplied

ArtiAid® Plus is manufactured using aseptic filling techniques. ArtiAid® Plus is a sterile, non-pyrogenic solution of sodium hyaluronate in physiological buffered saline solution, supplied in a disposable syringe.

Each syringe contains (AAP-20):

Sodium hyaluronate	30.0 mg
Sodium chloride	15.6 mg
Dibasic sodium phosphate (heptahydrate)	0.8 mg
Sodium dihydrogen phosphate (dihydrate)	0.028 mg
Sterile water for injection	q.s.

Catalogue No.	Product spectrum
---------------	------------------

AAP-20	2.0 mL 1.5%	Sodium Hyaluronate
AAP-25	2.5 mL 1.5%	Sodium Hyaluronate
AAP-30	3.0 mL 1.5%	Sodium Hyaluronate
AAP-35	3.5 mL 1.5%	Sodium Hyaluronate
AAP-40	4.0 mL 1.5%	Sodium Hyaluronate

ArtiAid® Plus is available in packages of either one syringe or ten syringes per carton.

Warning

- ArtiAid® Plus is only for intra-articular use.
- Remove joint effusion, if present, before injecting ArtiAid® Plus.
- 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 aseptic filling techniques. Do not re-sterilize. The syringe is intended for single use only. Discard any unused ArtiAid® Plus. Do not reuse. If re-use, will cause cross infection.

MBI MAXIGEN BIOTECH INC.

MAXIGEN BIOTECH INC.
No.88, Keji 1st Rd., Guishan District, Taoyuan City 33383, Taiwan
TEL : +886-3-3287-222 FAX : +886-3-3287-333
www.mbi.com.tw E-MAIL : service@mbi.com.tw