












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

ArtiBest[®] Intra-articular Injection

GRAPHICAL SYMBOLS

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

Description

ArtiBest[®] Intra-articular Injection (ArtiBest[®]) is a sterile, non-pyrogenic, synovia viscosupplementation aid prepared of non-animal sodium hyaluronate (sodium salt of hyaluronic acid). Hyaluronic acid is a natural polysaccharide which occurs as an important structural element in the skin, connective tissues and synovial fluid. ArtiBest[®] has been designed to extend the implantation duration by crosslinking technology. ArtiBest[®] contains 20 mg/mL sodium hyaluronate. ArtiBest[®] is supplied in a glass syringe and is sterilized by steam.

Indication

ArtiBest[®] is indicated for use as an intra-articular injection for the treatment of knee osteoarthritis.

Mode of action

The hyaluronic acid in the synovial fluid acts both as a lubricant and a shock absorber. Injections of hyaluronic acid into the joint will restore the decreased viscosity and elasticity of synovial fluid affected by osteoarthritis and then relieves the pain and improves the mobility of the joint.

Contraindication

ArtiBest[®] should not be injected:

- Patients with infections or skin diseases in the area of the injection site.
- Patients with known hypersensitivity to hyaluronate preparation.
- At present, there are no other known contraindications to the use of ArtiBest[®] when used as recommended as an intra-articular injection.

Precautions

- Do not use ArtiBest[®] 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 ArtiBest[®].
- Strict aseptic administration technique must be followed.
- ArtiBest[®] 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 ArtiBest[®] in the patients with severe allergy diseases.
- ArtiBest[®] 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 ArtiBest[®]. The physician might treat with appropriate medication.
- Remove joint effusion, if present, before injecting ArtiBest[®]. Inject ArtiBest[®] into the joint through a 20-gauge needle. Do not use the same needle for removing joint effusion and for injecting ArtiBest[®]. 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 safety and efficacy of repeat treatment cycles of ArtiBest[®] have not been established.
- The safety and efficacy of the use of ArtiBest[®] in locations other than the knee and for conditions other than osteoarthritis have not been established.
- The safety and efficacy of use of ArtiBest[®] concomitantly with other intra-articular injections has not been established.
- The safety and efficacy of ArtiBest[®] has not been tested in pregnancy, nursing or children.
- Procedures to maintain the sterility of the injection site and use of proper

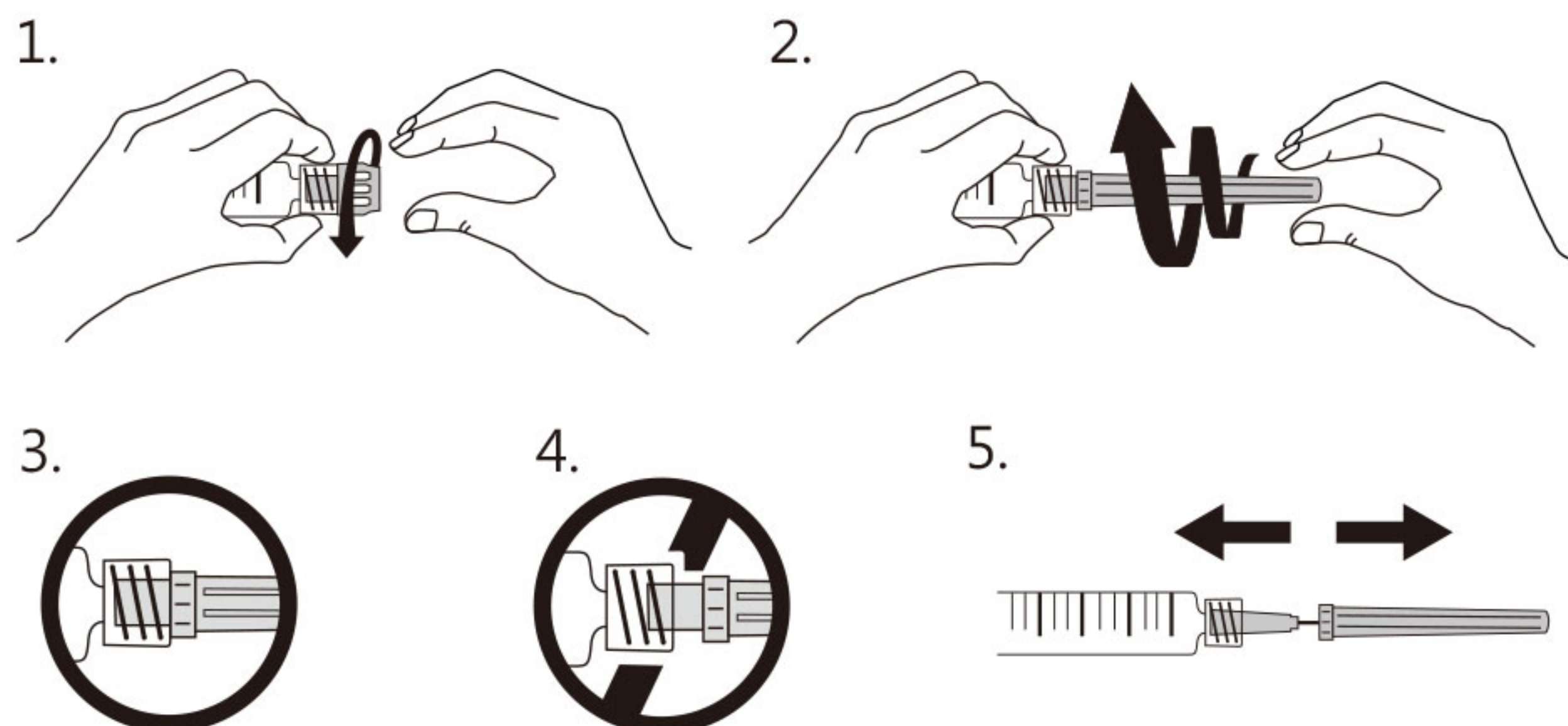
technique for injection must be followed.

- 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.

Assembly of needle to syringe

For safe use of ArtiBest[®] it is important that needle is properly assembled to the syringe. Please follow the steps :

1. Hold syringe and pull tip cap off the syringe as show in **Figure 1**.
2. Hold the luer-lock and firmly insert the hub of the needle into the syringe.
3. Tighten the needle by turning it firmly in a clockwise direction as show in **Figure 2**. Do not turning the luer-lock.
4. Tighten the needle until it is seated in the proper position, as show in **Figure 3**.
5. If the position of the needle cap is as show in **Figure 4**, it is not attached correctly.
6. Hold the luer-lock in one hand and the needle cap in the other. Without twisting, pull in opposite directions to remove the needle cap as show in **Figure 5**.
7. Before injecting, press the rod carefully until a small droplet is visible at the tip of the needle. If needle is blocked, please stop injection and change needle.
8. Improper assembly may result in separation of the needle and syringe during injection or leakage of ArtiBest[®] at luer-lock.



Dosage

ArtiBest[®] is a single dose preparation and should only be injected once per treatment course. The recommended dose is 3 ml (one syringe) per knee joint.

Administration

Remove any joint effusion, if present, before injecting ArtiBest[®]. ArtiBest[®] should be injected by using a suitable needle (for example 20-gauge). ArtiBest[®] should be injected by qualified physicians. All the rules regarding the asepsis and the injection technique should be followed.

How supplied

ArtiBest[®] is supplied in syringe and packed in a tyvek-sealed blister tray. The contents of the syringe are sterile.

Storage Conditions and Shelf Life

Shelf life is 3 years if stored in original unopened package at a temperature of 2 °C – 25 °C, protect against light, heat, and freezing.

Contents

Each ml contains:

Sodium Hyaluronate	20 mg
Phys. Sodium chloride solution, pH 7	q.s.

Warnings

- ArtiBest[®] is only for intra-articular use.
- Remove joint effusion, if present, before injecting ArtiBest[®].
- 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 resterilize. The syringe is intended for single use only. Discard any unused ArtiBest[®]
- Do not reuse.

MDA Reg. No: 0000

Qualtek Consulting Sdn. Bhd. (201401028226)
N-10-01, First Subang, Jalan SS15/4G, 47500 Subang Jaya, Selangor, Malaysia.
E-MAIL : qualtek@qualtechs.com

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