EN

JETKNEE™

Synovial Fluid Supplement

Contents:

ACTIVE INGREDIENT:

Sodium Hyaluronate 40 mg

EXCIPIENTS:

Sodium Chloride, Disodium Phosphate Dodecahydrate, Sodium Dihydrogen Phosphate Dihydrate, Mannitol, Sterile Water for Injection q.s. to 2.0 mL.

pH 6.8 - 7.8

DESCRIPTION:

JETKNEE Synovial Fluid Supplement is a product supplied in a glass syringe with hyaluronic acid (average molecular weight 1500000 Da). The product is a clear, viscous, sterile and nonpyrogenic solution. The hyaluronic acid is extracted from microorganism. Hyaluronic acid is a natural polysaccharide in synovial fluid which is identical in all living organisms and highly biocompatible. The product also contains mannitol, a free radical scavenger, which helps to stabilize the chains of sodium hyaluronate.

PACKAGE:

2.0 mL per syringe

INDICATION:

Pain and restricted mobility in degenerative changes of the knee joint.

USAGE:

1. The product is used 1-3 syringes per treatment, 1 syringe per week for adult into the affected joint.
2. Repeat treatment cycles may be administered as required.
3. Bring the product to room temperature before use.
4. The product is used for injecting to articular cavity of joint with a 18-25G needle.
5. In case of joint effusion, it is advisable to reduce the effusion by aspiration, rest, application of an ice pack and/or intra-articular corticosteroid injection. Treatment with the product can be started two to three days later.
6. The patient should avoid any strenuous activities or weight bearing activities within 48 hours following intra-articular injection.

THERAPEUTIC EFFICACY:

The product can counterbalance the mechanical stress transmitted from outside. It is a barrier protecting the joint. The product can protect synovial tissues and promote healing of articular cartilage. Anticipated duration of efficacy may last for several months after a treatment cycle.

CONTRAINDICATIONS:

- Do not administer to patients with known hypersensitivity to any of the constituents.
- Intra-articular injections are contraindicated in cases of past and present infections or skin diseases in the area of the injection site.

WARNINGS:

1. The product is intended for use as intra-articular implant only.
2. The product is for single use only, if re-using, it may cause infection even seriously inflammatory response.
3. Do not re-sterilize the product.
4. Do not mix with quaternary ammonium salts, e.g. benzalkonium chloride, to prevent precipitation.
5. Do not mix any pharmaceutical products, the study of interactions have not been established.
6. Do not inject the product into blood vessels to prevent vascular occlusion, embolization, ischemia or infarction.
7. As no clinical evidence is available on the use of hyaluronic acid in inflammatory joint diseases such as rheumatoid arthritis or Bechterew disease, treatment with the product is not recommended in these cases.
8. Do not inject the product into surrounding tissues to ensure product efficacy, if necessary, medical imaging approaches may improve injection accuracy.
9. Do not over tighten the needle to prevent product leakage, and avoid increasing extrusion force.
10. Do not over tighten the needle to prevent luer-lock loosed and product leakage.

USAGE FOR SPECIFIC POPULATIONS:

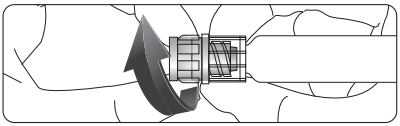
The safety of use for pregnant women, lactation, children has not been demonstrated. The physician shall pay attention to these cases.

ADVERSE EVENTS:

The potential adverse events such as pain, swelling, feeling of heat, inflammation, tachycardia, shortness of breath, hypertension, hypotension, nausea and pruritus may occur during or after the injection of the product. In very rare cases adverse events such as puffiness (face, eye or hand), joint effusion, paraesthesia, flushing, rash, dyspnea, headache, palpitation, and fatigue.

DIRECTIONS FOR USE:

(1) Hold luer-lock site and unscrew the tip cap of syringe carefully (shown as below). Do not hold syringe barrel during assembling.



(2) Keep holding luer-lock site firmly and screw the needle to the latch of syringe until fastened assembled.

NOTE!

The product is only intended to be administered by authorized personnel in accordance with local legislation. The syringe, the needle and any unused material must be discarded directly according to national regulations after the treatment session. Do not use if the pre-filled syringe or sterile pack are damaged.

STORAGE:

As indication on package, store at 2-30°C. Protect from sunlight and freezing. Do not use after the expiry date indicated on the box.

MANUFACTURE DATE AND EXPIRY DATE:

As indicated on product label and package.

SHELF LIFE: 3 years

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SYMBOLS ON PACKAGING:

	Do not re-use		Do Not Use if package is damaged
	Temperature limitation		Lot number
	Date of manufacture		Manufacturer
	Use-by date		Consult instructions for use
	Sterile. The contents of the syringe have been sterilized by using moist heat.		