Hymovis®

HYADD® 4

High Molecular Weight Viscoelastic Hyaluronan
For intra-articular injection

DIRECTIONS FOR USE

Hymovis® is intended to be injected into the knee joint and is administered as a two intra-articular injection regimen. Standard intra-articular injection site preparation and strict aseptic administration technique must be followed.

1. Using an **18 – 20** gauge needle, it is recommended to remove synovial fluid or effusion before injecting HYMOVIS®. Do not use the same syringe for removing synovial fluid and for injecting Hymovis®; however, the same **18 – 20** gauge needle can be used.

2. While firmly holding the luer hub, remove the protective rubber cap on the tip of the syringe (Fig. 1) by twisting the tip cap (Fig. 2) before pulling it off (Fig. 3), as this will minimize product leakage.

3. To ensure a tight seal and prevent leakage during administration, secure the **18 – 20** gauge needle (Fig. 4) tightly while firmly holding the luer hub (Fig. 5).
Take care not to rotate the hub during needle attachment which can lead to loosening of the hub (Fig. 5). Do not overtighten or apply excessive leverage when attaching the needle or removing the needle guard (Fig. 6), as this may break the syringe tip.

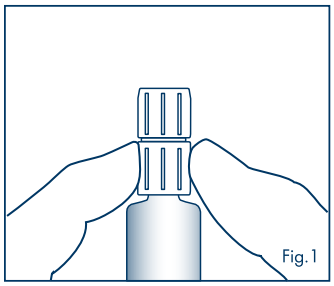
Fig.1

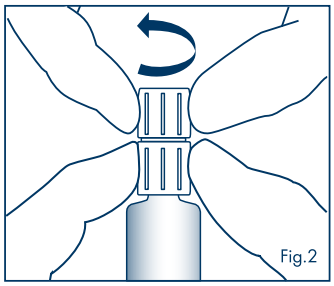
Fig.2

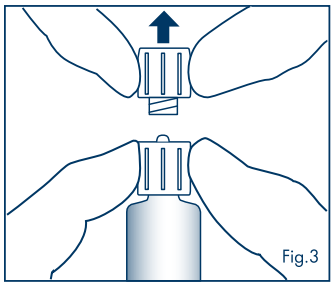
Fig.3

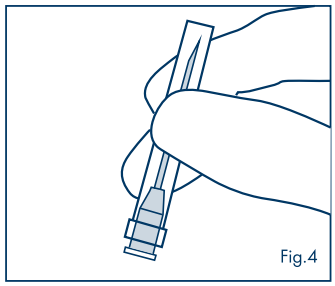
Fig.4

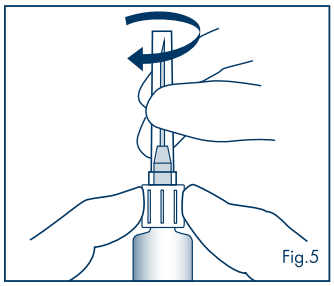
Fig.5

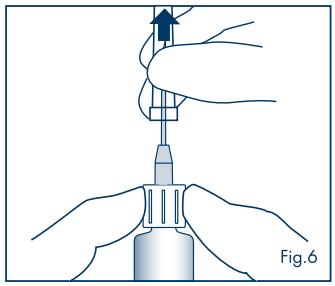
Fig.6

4. Inject the full 3 mL in one knee only (do not overfill the joint). If treatment is bilateral, a separate syringe should be used for each knee.

5. Administer the second injection of HYMOVIS® in the same joint in a week after the first injection following the same guidelines.

If you have any questions, want medical information, have a product quality issue or need to report a patient adverse event, please call 1-866-HYMOVIS (1-866-496-0847).

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Pharma USA Inc.

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INFORMATION FOR PRESCRIBERS

Hymovis® High Molecular Weight Viscoelastic Hyaluronan

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

DESCRIPTION

Hymovis® is a sterile, non-pyrogenic, viscoelastic hydrogel contained in a single-use syringe. Hymovis® is based on an ultra-pure hyaluronan engineered using a proprietary process to increase viscosity, elasticity and residence time without chemical crosslinking. This results in a natural hyaluronan similar to the hyaluronan found in the synovial fluid present in the human joint. The hyaluronan in Hymovis® is derived from bacterial fermentation.

INDICATIONS

Hymovis® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics (e.g., acetaminophen).

IMPORTANT SAFETY INFORMATION

Hymovis® is contraindicated in patients with known hypersensitivity (allergy) to hyaluronate preparations or gram-positive bacterial proteins. Do not administer Hymovis to patients with infections or skin diseases in the area of the injection site or joint.

The safety and effectiveness of the use of Hymovis have not been tested in pregnant women, nursing mothers, or children. The safety and effectiveness of the use of Hymovis in joints other than the knee or for concomitant use with other intra-articular (IA) injections have not been established. The effectiveness of repeat treatment cycles of Hymovis has not been established. Arthralgia, transient pain, or swelling may occur after the IA injection. The incidence of arthralgia in the clinical study for Hymovis was equivalent to the control group. No serious adverse events or pseudoseptic reactions were reported. Transient increases in inflammation following any IA hyaluronan injection have been reported in some patients with inflammatory joint conditions.

Strict aseptic technique should be used by licensed medical professionals trained to deliver agents into the knee joint. Joint effusion should be removed prior to injection of Hymovis®. Do not use disinfectants containing quaternary ammonium salts for skin preparation as hyaluronan can precipitate in their presence.

Patients should avoid strenuous or prolonged (eg, more than one hour) physical activities within 48 hours following the IA injection.

See package insert for full prescribing information including indications, contraindications, warnings, precautions, and adverse events.

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