XUVAN-XL

Sodium Hyaluronate Sterile Injection 8 mg/ml

COMPOSITION :

Each ml contains:

Sodium Hyaluronate	BP	8 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate Dihydrate	USP	0.16 mg
Monosodium Phosphate Monohydrate	USP	0.04 mg
Water for Injection	USP	q.s.

Contains no preservatives.

DESCRIPTION :

Xuvan-XL is a sterile, clear, viscoelastic preparation containing non-pyrogenic, high molecular weight (average 6 million Dalton), non-inflammatory fraction of cross linked water insoluble sodium hyaluronate and water soluble sodium hyaluronate polymers. This polymer consists of repeating disaccharide units of N-acetyl-glucosamine and sodium glucuronate linked by β 1-3 and β 1-4 glycosidic bonds. The hydration fluid is isotonic sodium chloride solution (pH 7.2).

CHARACTERISTICS

Sodium hyaluronate is the physiological substance that is widely distributed in the extracellular matrix of connective tissues in both animals and man. For example, it is present in the vitreous and aqueous humor of the eye, the synovial fluid, the skin and the umbilical cord. Sodium hyaluronate derived from various human or animal tissues does not differ chemically.

INDICATIONS

Xuvan-XL is indicated for the treatment of pain in osteoarthritis of the knee, in patients who have failed to respond adequately to conservative non-pharmacologic therapy, and to simple analgesics, e.g., paracetamol.

DOSAGE AND ADMINISTRATION

- A single injection of Xuvan-XL is administered by intra-articular route.
- Strict aseptic administration technique must be followed. Inject subcutaneous lidocaine or similar local anesthetic prior to injection of Xuvan-XL.
- Aspirate joint effusion before injection of Xuvan-XL. Do not use the same syringe for removing joint effusion and for injection of Xuvan-XL.
- Take care to remove the tip cap of the syringe and needle aseptically. Inject Xuvan-XL into the joint through a 19 gauge needle.
- The syringe is intended for single use. The contents of the syringe must be used immediately once the container is opened. Before injection, the air bubble is removed from the injection.
- Inject the full 6 ml in one knee only. If treatment is bilateral, a separate syringe should be used for each knee.

CONTRAINDICATIONS

Xuvan-XL is contraindicated in patients with known history of hypersensitivity (allergy) to sodium hyaluronate (hyaluronan) preparations.

Xuvan-XL is contraindicated in patients with knee joint infections or skin diseases in the area of injection site.

WARNINGS

- Do not concomitantly use disinfectants containing quaternary ammonium compounds for skin preparations because sodium hyaluronate is precipitated in their presence.
- Do not inject Xuvan-XL extra-articularly or into the synovial tissues and articular capsules. This will generally result in local and systemic adverse events.
- Intravascular injections of Xuvan-XL may lead to systemic adverse events.

PRECAUTIONS

GENERAL

- The effectiveness and safety of the use of Xuvan-XL in joints other than knee have not been established.
- The safety and effectiveness of the use of Xuvan-XL concomitantly with other intra-articular injectables have not been established.
- Strict aseptic administration technique must be followed.
- The safety and effectiveness of the use of Xuvan-XL in severely inflamed knee joints have not been established.
- The pre-filled syringe is intended for single use. Use the contents of the syringe immediately after its packaging is opened. Discard any unused Xuvan-XL.
- Opened or damaged packages of Xuvan-XL should not be used. Always store in the original packaging (protected from light) at 30°C. DO NOT FREEZE.
- Aspirate synovial effusion, if present, before each Xuvan-XL injection.

- Xuvan-XL should be used with caution when there is evidence of lymphatic or venous stasis in that leg.
- Xuvan-XL should be used with caution in diabetic patients and patients with chronic disorders.

INFORMATION FOR PATIENTS
- Transient pain, and/or swelling of the joint may occur after intra-articular injection of Xuvan-XL.
- In some cases effusion may be considerable and can cause pronounced pain. Discuss with the physician if the swelling is extensive.
- As with any invasive joint procedure, patient should avoid any strenuous activities or prolonged weight-bearing such as jogging or playing tennis following the intra-articular injection. The patient should consult the attending physician regarding the appropriate time to resume such activities.
- If the patient needs to repeat the dose, the second injection of Xuvan-XL should be administered at least after 6 months.

USE IN SPECIFIC POPULATIONS
Pregnant women, Nursing mothers and Pediatric age group: The safety and effectiveness of Xuvan-XL have not been established in pregnant women, lactating mothers and pediatric patients, defined as patient's ≤ 21 years of age.

ADVERSE EVENTS
The following adverse events are among those that may occur in association with intra-articular injections, including Xuvan-XL:
- Arthralgia
- Joint effusion
- Joint warmth
- Arthritis
- Gait disturbance
- Joint stiffness
- Joint swelling
- Injection site pain
- Arthropathy

Placing an ice pack on the treated joint for 5 to 10 minutes would reduce the occurrence of such side effects.

DRUG INTERACTIONS
No information available.

PRESENTATION
Xuvan-XL is a sterile, non-pyrogenic viscoelastic preparation; supplied in a 10 ml USP type I glass PFS containing 6 ml Sodium hyaluronate, with bromo butyl rubber stopper, finger grip and plunger rod. Xuvan-XL syringe is terminally sterilized, aseptically packaged and is supplied with 19 gauge sterile needle.

STORAGE
- Keep out of reach of children
- Protect from light and moisture
- Store below 30°C
- Do not freeze

MEGA We care

Manufactured for :
MEGA LIFESCIENCES (AUSTRALIA) PTY LTD
Victoria 3810, Australia.

Manufactured by:
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