HyalOne

Hyaluronic acid sodium salt solution for intra-articular injection
Pre-filled syringe 60 mg/4 ml

Product description

HYALONE is a sterile, non pyrogenic, viscoelastic solution manufactured with hyaluronic acid sodium salt, obtained by bacterial fermentation from a fraction of high molecular weight. Hyaluronic acid, a polysaccharide of the glycosaminoglycan family, is naturally present in many human tissues such as cartilage and synovial fluid; it is continuously secreted into the joint space and represents a major component of the synovial fluid, to which it provides its characteristic viscosity and elasticity. Such properties are fundamental for the lubricating and shock absorbing functions exherted by the fluid in normal joints to protect cartilage and soft tissues against mechanical injuries.

In traumatic and degenerative joint disorders, an insufficient amount of hyaluronic acid and a loss of viscosity occur in synovial fluid, resulting in an impairment of joint function and in a painful symptomatology. Extensive data in the literature indicate that intra-articular administration of hyaluronic acid is capable to restore the visco-elastic properties of the synovial fluid, with alleviation of pain and improvement of joint mobility.

Composition

Principal component: Hyaluronic acid sodium salt 1.5%.

Other components: Sodium chloride, Disodium hydrogen phosphate dodecahydrate, Sodium dihydrogen phosphate dihydrate, Water for injection.

Indications

HYALONE is a temporary synovial fluid replacement for patients affected by degenerative or mechanical arthropathy of the hip and knee, that causes an alteration of the functional performances of the synovial liquid, without active synovitis.

Dosage and Administration

Product administration shall be performed exclusively by qualified physicians.

All the rules regarding the asepsis and the injection technique shall be followed.

Remove any joint effusion, if present, before the administration.

Further treatments after the first application may be needed to maintain the benefit of the treatment over time, depending from the individual patient needs.

Inject HYALONE using a suitable sterile needle (for example 18 or 20 G).

When HYALONE is used in the hip, it is recommended to perform the injection under ultra-sound guidance. This is not necessary when HYALONE is used in the knee.

The sterility also on the outer surface of the syringe makes the use of the product suitable for the operating room.

Contraindications

Do not administer to patients with ascertained individual hypersensitivity to the product components and in cases of infections or skin diseases in the area of the injection site.

There is no evidence of contraindications to repeat the treatment.

Warnings and Precautions

Although pre-clinical studies performed in experimental animals indicate that the product has no potential reproductive and developmental toxicity, HYALONE has not been tested in pregnant women.

Do not use in case of package damage.

Do not use the product after the expiry date reported on the package.

The expiry date refers to the product kept in its original package at a temperature not exceeding 25°C.

The product is for single use, that means it is intended to be used once only for a single patient. The assembled syringe must be discarded immediately after use, regardless of whether or not the solution has been completely administered.

If this product is reprocessed and/or reused, Fidia Farmaceutici cannot guarantee performance, functionality, material structure, or cleanliness or sterility of the product. Reuse could lead to illness, infection and/or serious injury to the patient or user.

After use, dispose according to applicable national practice.

Keep out of reach of children.

Undesirable effects

Local pain, swelling, heat and redness may occur sporadically at the injection site. Such symptoms are generally mild and transient.

More marked inflammatory reactions, sometimes with sodium pyrophosphate crystals, have been occasionally reported in association with intra-articular injections of hyaluronate.

As for any intra-articular treatment, septic arthritis may rarely occur when general precautions for injections are not observed or the site of injection is not aseptic.

Interactions

Do not use concomitantly with disinfectants containing quaternary ammonium salts, because hyaluronic acid can precipitate in their presence.

In order to prevent any possible interactions, avoid the contemporary administration of HYALONE with other intra-articular products.

Storage

Store at a temperature not exceeding 25°C.

How supplied

Each syringe is sealed in a blister sterilised by ethylene oxide and contains 60 mg hyaluronic acid sodium salt in 4 ml solution sterilised using steam.

Manufacturer

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