Hymovis

HYADD 4 for intra-articular injection
Prefilled syringe

Product description

I-HYMOVIS is a sterile, non pyrogenic, hydrogel manufactured with Hyadd4 (hexadecylamide of highly purified natural sodium hyaluronate obtained by bacterial fermentation) in isotonic buffered solution.
Thanks to the high viscosity and elasticity given by the hexadecylamide of sodium hyaluronate, HYMOVIS improves the lubricating and shock absorbing function of synovial fluid, protecting cartilage and soft tissues against mechanical injuries. These properties, together with the prolonged residence time in the articular joints, enable I-HYMOVIS to relieve pain and to improve joint function with a short treatment regimen.

Composition

Principal component: Hyadd4 (sodium hyaluronate hexadecylamide), 24mg/3ml.
Other components: Sodium chloride, disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, water for injection.

Indications

I-HYMOVIS is indicated for the treatment of pain in osteoarthritic joints and in the conservative treatment of the meniscal lesion of the knee and for the improvement of joint mobility through the enhancement of synovial fluid viscoelasticity.

Administration

I-HYMOVIS is intended for intra-articular injection only.
Product administration should be performed exclusively by physicians.
The sterility also on the outer surface of the syringe makes the use of the product suitable for the operating room.
Given its viscosity, inject slowly I-HYMOVIS in the affected joint using a suitable sterile needle (18 or 20 gauge)
All the rules regarding aseptic administration technique must be strictly followed.
Treatment should be avoided if the joint shows evidence of acute inflammation.
Remove any joint effusion, if present, before injecting I-HYMOVIS.

Dosage

A treatment cycle in osteoarthritic joints consists of two injections administered at one week interval.
A treatment cycle in joints with meniscal lesion consists of two injections administered at two week interval.

Contraindications

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

Warnings and Precautions

Treatment should be avoided if the joint shows evidence of acute inflammation.
The safety and efficacy of I-HYMOVIS in children and pregnant women have not been established.
The safety and efficacy of the use of I-HYMOVIS concomitantly with other intra-articular treatments have not been established.
The syringe is intended for single use; inject the contents in one joint only.
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.
Do not use HYMOVIS after the expiry date printed on the package. The expiry date refers to the product stored properly in its original package.
Do not use HYMOVIS if the package is opened or damaged.
Keep out of reach of children.

Undesirable effects

Local undesirable effects such as pain, swelling/effusion, warmth and redness may occur at the injection site. Such symptoms are usually mild and transient.
More marked inflammatory reactions have been reported with sodium hyaluronate-based products for intra-articular use.
As for any intra-articular treatment, septic arthritis may occur on rare occasions if general precautions for aseptic injection are not observed.

Interactions

Do not concomitantly use disinfectants containing quaternary ammonium salts, because sodium hyaluronate hexadecylamide may precipitate in their presence.
Avoid the contemporary administration of HYMOVIS with other intra-articular products in order to prevent any possible interaction.

Storage

Store below 25°C. Do not freeze.

How supplied

- Box containing 1 luer lock pre-filled syringe
- Box containing 2 luer lock pre-filled syringes

Each syringe has a backstop and is sealed in a blister sterilised by ethylene oxide.
The contents of each syringe, 3 ml hydrogel, are sterilized using steam. Instructions for use are included in the box.

Manufacturer:

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Date of the latest revision of the instructions for use: July 2017

Consult instructions for use
Batch code
Use by
Do not reuse
Sterilised using steam
Sterilised using ethylene oxide
Temperature limitation
Do not use if package is damaged
Manufacturer