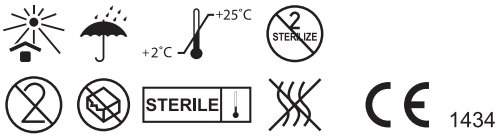
Instructions for use

Biolevox™ HA 2.2%



Sodium hyaluronate 44 mg
2 ml of intra-articular gel in a pre-filled syringe

Composition

Each 1 ml contains:	
Sodium hyaluronate	22.000 mg
Sodium chloride	8.500 mg
Disodium hydrogen phosphate	0.563 mg
Sodium dihydrogen phosphate	0.045 mg
Water for injection	q.s.

Description
Biolevox™ HA 2.2% with pH 6.8-7.4 contains high molecular weight sodium hyaluronate produced by bacterial fermentation, non-animal origin. It is sterile and non-pyrogenic. The product is for intra-articular use to improve viscosity of synovial fluid.

Indications
Pain and decreased articular mobility associated with traumatic or degenerative changes including osteoarthritis.

Contraindications
The product should not be administered to patients:
- with known hypersensitivity to any of the components of the product;
- with septic arthritis;
- with dermatosis at the injection site;
- who are using anticoagulants.

Precautions
All safety precautions during procedure should be taken to prevent occurrence of septic arthritis. The product is intended for intra-articular injection only.
Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation as hyaluronan can precipitate in their presence.
Children, pregnant or nursing women should not be treated with sodium hyaluronate as there are no clinical data available on its use in these patients.
The product should not be used if a sterile pre-filled syringe is damaged. The product must be used before the expiration date indicated on the package.
Do not re-sterilize.
It is to be used on one patient during a single appointment.
Store at temperature between +2°C and +25°C. Keep away from sunlight. Protect from moisture.
The product must be kept out of the reach of children.

Potential side effects
Biocompatibility studies have confirmed high safety of the product. Transient local reactions, such as pain, redness and swelling, may occur after intra-articular injection.
These effects can be reduced by cooling the site with cooling bags for 5 to 10 minutes after the injection.
Simultaneous oral intake of analgesics and anti-inflammatory drugs (NSAIDs) may be beneficial for pain relief.

Interactions
No incompatibility with other intra-articular injections has been reported so far.

Administration and dosage
Disinfect the skin at the site of planned injection. Take the pre-filled syringe from the packaging, remove the Luer-lock closure and screw a suitable sterile needle (21G) onto the syringe. Remove air bubbles before injection.
The therapy consists of a series of three intra-articular injections, administered at weekly intervals.
The beneficial effects of the treatment last for at least six months. Treatment cycle may be repeated, if required.

Properties and mode of action
Sodium hyaluronate is responsible for the viscosity and elasticity of the synovial fluid. Because of its lubricating and shock-absorbing properties, it enables painless, physiological joint movement. It also participates in the nutrition of the cartilage.

Supplementation of synovial fluid by intra-articular injection of sodium hyaluronate, improves the viscoelastic properties of the synovial fluid. Already after the first intra-articular injection, joint mobility is improved and pain associated with degenerative changes is relieved.

Package
A sterile pre-filled syringe, containing 2 ml of transparent gel, placed in blister and a sterile needle (21G).

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To be used exclusively by a medical doctor.
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