

## Instructions for use

# BioleVox™

## HA tendon

**Sodium hyaluronate 32 mg**  
**2 ml of 1.6% gel in a pre-filled syringe**

### Composition

Each 1 ml contains:

Sodium hyaluronate	16.000 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 tendon with pH 6.8-7.4 contains high molecular weight sodium hyaluronate produced by bacterial fermentation. It is sterile and non-pyrogenic. Medical device is intended for injection around the tendon or into the tendon sheath.

### Indications

Pain and limitation of mobility in tendon diseases caused by injuries (e.g. strained tendon) or overload changes (e.g. tennis elbow, rotator cuff tendinopathy).

### Contraindications

Medical device should not be used in patients:

- with known hypersensitivity to any of the components of the product;
- with septic tendonitis;
- with dermatosis at the injection site;
- taking anticoagulants.

### Precautions

All safety precautions during procedure should be taken to prevent occurrence of septic tendonitis.

Medical device is intended only for injection around the tendon or into the tendon sheath.

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 this medical device as there are no clinical data available on its use in these patients.

Medical device should not be used if a sterile pre-filled syringe is damaged.

Medical device must be used before the expiration date indicated on the package.

Do not re-sterilize.

Medical device is to be used on one patient during a single procedure.

Store at temperature between +2°C and +25°C.

Keep away from sunlight.

Protect from moisture.

Medical device must be kept out of the reach of children.

### Potential side effects

Biocompatibility studies have confirmed high safety of the medical device. Transient local reactions, such as pain, redness and swelling, may occur after injection. These effects can be reduced by cooling the site of injection for

5 to 10 minutes after the injection.

The simultaneous use of oral analgesics and anti-inflammatory agents may be beneficial for pain relief.

### Interactions

No data.

### Administration and dosage

Disinfect the skin at the site of planned injection. Take the pre-filled syringe from the blister, unscrew the Luer-lock closure and screw a suitable sterile needle (25G) onto the syringe. Remove air bubbles before injection.



















The therapy consists of a series of two injections, administered at weekly intervals. The beneficial effects of the treatment last for at least 6 months. Treatment cycle may be repeated, if required.

### Properties and mode of action

Sodium hyaluronate contained in BioleVox™ HA tendon increases the level of sodium hyaluronate naturally occurring in the soft tissues surrounding the tendons, enabling strengthening and moisturizing the affected area, thus creating an excellent environment for regeneration. Because of its action, it relieves pain and limitation of mobility caused by injuries or overloads of tendons.

### Packaging

Pre-filled syringe containing 2 ml of transparent gel, placed in a blister, instructions for use, sterile needle (25G).

Symbol	Definition				
	Manufacturer		Keep dry		Caution
	Keep away from sunlight		CE marking of conformity		Consult instructions for use
	Do not use if package is damaged and consult instructions for use		Sterilized using steam or dry heat		Unique device identifier
	Temperature limit		Non-pyrogenic		Distributor
	Do not re-sterilize		Lot number		Reference number
	Medical device		Expiry date		Do not re-use

To be used exclusively by a medical doctor.

Date of issue: 05/2024

### Manufacturer:

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Rev. 01/2024

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