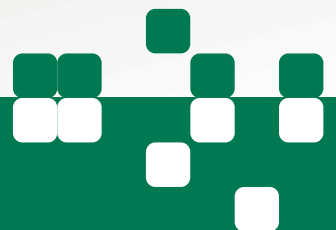


Arthro-Patch

MODERN SOLUTION FOR VISCOSUPPLEMENTATION



ARTRO-PATCH is a biologically inert gel based on stabilized hyaluronic acid, designed for intra-articular administration to restore the visco-elastic properties of synovial fluid in traumatic and degenerative lesions of the synovial joints, manifested by pain syndrome and/or reduced mobility.

Arthro-Patch was developed in the form of a gel for optimal efficacy and safety during a course of treatment comprising of a single intra-articular injection.

Hyaluronic acid is a natural polysaccharide present in many organs and tissues of the human body. In synovial joints its function is to provide lubrication of joint surfaces and shock absorption.

Stabilized form of hyaluronic acid («cross-linked») allows it to remain intact in a synovial joint for a longer period of time (due to the slower bioenzyme degradation) and has a longer therapeutic effect.

The special technology of «soft crosslinking» of hyaluronic acid allows to achieve the crosslinking coefficient of 0.18%, which minimizes the adverse effects of additional chemical compounds used to stabilize hyaluronic acid.

The absence of components of animal origin in the composition of Arthro-Patch allows minimizing the risks of allergic reactions and adverse side effects.

The volume of gel Arthro-Patch is 3.0 ml, which is sufficient for a full replacement of the entire volume of synovial fluid of the knee joint.



COMPOSITION: pre-filled syringe containing 90 mg (30 mg/ml – 3.0 ml) of stabilized hyaluronic acid gel.

1. Altman R, Moskowitz R, Intraarticular sodium hyaluronate (Hyalgan) in the treatment of patients with osteoarthritis of the knee: a randomized clinical trial. Hyalgan Study Group, The Journal of rheumatology, 1998;25(11):2203.
2. Watterson JR, Esdaile JM., Viscosupplementation: therapeutic mechanisms and clinical potential in osteoarthritis of the knee, Journal of the American Academy of Orthopaedic Surgeons, 2000;8(5):277.

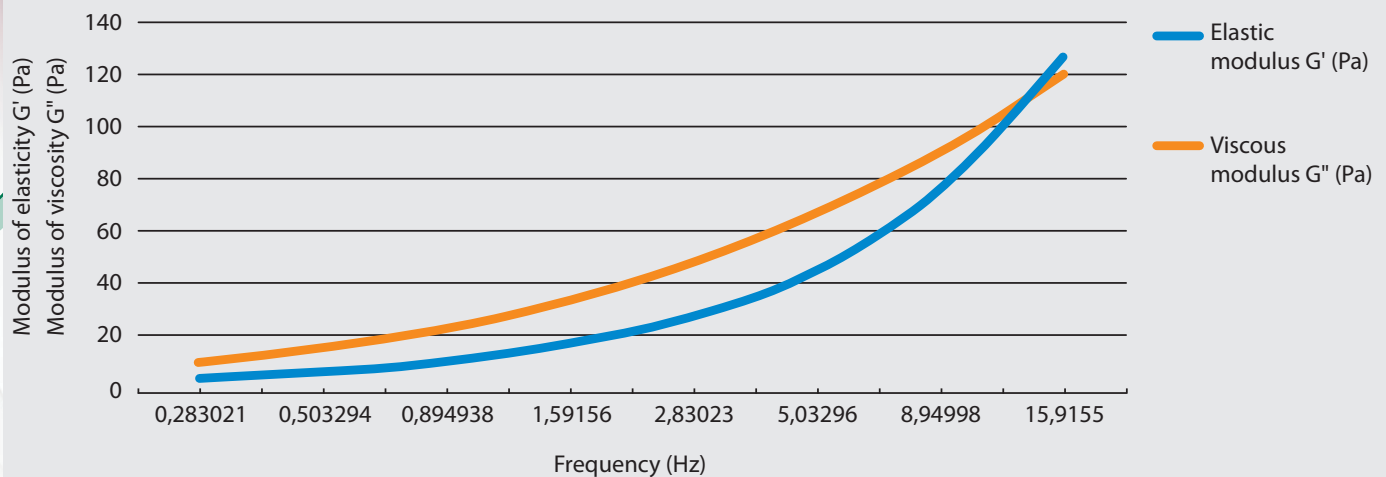
Visco-elastic properties of Arthro-Patch are as close as possible to the properties of synovial fluid of a healthy person.

Table 1.

Properties of synovial fluid of a healthy person and synovial fluid in osteoarthritis.^{1,2,3,4}

	Molecular weight of HA (MDa)	Concentration of HA (mg/ml)	Visco-elastic properties		Zero shear viscosity (Pa.s)
			Elastic modulus (G') (Pa) at 2.5 Hz	Viscous modulus (G'') (Pa) at 2.5 Hz	
Synovial fluid of a healthy person	6,3 – 7,6	2,5 - 4	23	7	6 - 175
Synovial fluid of the patient with osteoarthritis	1,6 – 3,48	1 - 2	7	5	001 – 1

Visco-elastic properties of Arthro-Patch 30 mg/ml



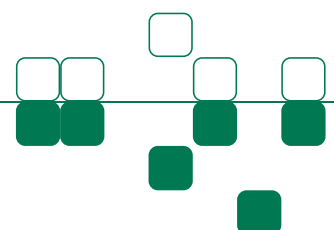
- Osmolarity – 270-330 mOsm/kg.
- Molecular weight of hyaluronic acid before stabilisation – 2.3 million Da.
- pH 7,2-7,4
- Zero shear viscosity (Pa.s) – 8.27

Arthro-Patch allows to:

- Reduce the severity of osteoarthritis symptoms and reduce the dose of NSAIDs;
- Reduce the rate of osteoarthritis progression;
- Improve patient's quality of life;
- Maximally postpone the need for surgery (endoprosthesis);



3. Fam H, Bryant J, Kontopoulou M., Rheological properties of synovial fluids, Biorheology, 2007;44(2):59-74.
 4. Balazs EA, Denlinger JL., Viscosupplementation: A new concept in the treatment of osteoarthritis, The Journal of rheumatology Supplement, 1993;39:3.



INSTRUCTIONS

for the use of the medical product
Injection implant on the basis of stabilized hyaluronic acid
ARTRO-PATCH

COMPOSITION

*Injection implant on the basis of stabilized hyaluronic acid,
30 mg/ml – 3 ml.*

3 ml volume contains:

Sodium hyaluronate.....90.0 mg;

Phosphate buffer pH 7.2 – 7.4.....to 3.0 ml.

PACKAGE CONTENT

Each package contains a Luer-Lock syringe with pre-filled injection implant based on stabilized hyaluronic acid *Arthro-Patch*. Each package contains two 21 G 1½" needles for the syringe. The implant volume in the syringe and the concentration are indicated on the carton.

DESCRIPTION

Arthro-Patch is a colorless transparent viscous gel of stabilized hyaluronic acid of non-animal origin, sterile, apyrogenic, with physiological pH level.

Mechanism of action

Hyaluronic acid is a natural polysaccharide (glycosaminoglycan), which is an important structural element of the connective tissue of the skin and synovial fluid.

Arthro-Patch is a biocompatible prolonged action injection implant with visco-elastic properties, acts as a shock absorber, stabilized gel, which restores joint mobility.

INDICATIONS

Temporary replacement of synovial fluid upon its deficiency in the knee joint or other synovial joints due to injuries or degenerative diseases such as osteoarthritis.

Contraindications

- Hypersensitivity to hyaluronic acid
- Skin injuries and infections in the area of medical product application
- Infectious lesions of the joints, rheumatoid arthritis in the active stage, ankylosing spondylitis
- Coagulopathy
- Pregnancy and lactation
- Children under the age of 18 years.

SAFETY MEASURES

- Use only for intra-articular administration.
- A week before the procedure patients should not take large doses of vitamin E, aspirin, antipyretics and anticoagulants.
- It should be used with caution in patients with venous or lymphatic stasis in the limbs.
- Extreme caution should be taken during administration of the medical product in the area of anatomical projection of nerves and their plexuses. Violation of the implant injection technique in these areas may lead to traumatic damage to the peripheral nerves, increased pain, impaired sensitivity and development of paralysis in the corresponding areas of innervation.
- Avoid injection of the medical product into tenosynovial muscle membranes, located near the injection site, which may lead to the increase of the pain syndrome, movement disorders in the affected joint and adjacent joints.

- It should be used with caution in patients with a history of chondrocalcinosis, since the injection may lead to disease exacerbation.
- It is recommended to limit physical activity within 48 hours after the injection.
- It is recommended not to expose the injection site to intense heat or cooling during the first 48 hours after the injection.

INCOMPATIBILITY

Injection implants *Arthro-Patch* shouldn't be used together with quaternary ammonium salts (benzalkonium chloride).

DOSAGE AND ADMINISTRATION

- This medical product is intended only for intra-articular injections and should be administered exclusively by medical specialists with appropriate experience and medical education, as well as knowledge of the technique of performing intra-articular injections. It is recommended to inject the implant using the needles contained in the package.
- Before the procedure, the doctor is obliged to acquaint the patient with the instructions for use and inform him/her about the predicted result of therapy and the potential risks associated with the medical product use.
- Before the implant injection in the presence of effusion in the joint, it should be aspirated and appropriate therapeutic measures should be taken.
- Intra-articular injections should be performed in aseptic conditions. Before the administration, the area of the implant injection should be thoroughly disinfected.
- If necessary, local and regional anesthesia can be used. In this case, you should follow the instructions for use of these medications.
- Remove the syringe with the implant ready for injection from the sterile package, carefully unscrew the rubber cap from the syringe and attach the needle tightly. Remove the protective cap from the needle.
- The contents of the syringe should be used immediately after opening the package.
- In case of impaired needle injectability and difficulty of the implant injection, terminate the procedure and replace the needle.
- If possible, it is recommended to carry out intra-articular injection under the control of ultrasound.
- *Arthro-Patch* is injected into the affected joint. The course of therapy consists of a single administration. If necessary, a second course may be assigned in 6 months.
- The concentration and volume of the medical product is selected by the doctor individually, taking into account the clinical situation of the patient and the size of the joint.

SHELF LIFE: 2 years.

STORAGE CONDITIONS

Store in a dry place, protected from direct sunlight, out of reach of children at temperatures from +2 °C to +30 °C.

Store in a sealed original package.

Do not freeze.

Before administration, read the instructions for *Arthro-Patch* use.

