- Treatment of degenerative and post-traumatic articular affections
- Substitution of synovial fluid
- Joint protection
- Improvement of joint function
- Reduction of joint pain
- Promotion of endogenous hyaluronic acid biosynthesis

Medical device III CE 0426

PJ PHARMA

Quality Assurance ISO 9001 - ISO 13485

MADE IN ITALY

ARTICULAR AFFECTION

DESCRIPTION

Artox 2% (40 mg) is a synovial fluid substitute based on Hyaluronic Acid (HA) which, thanks to its viscoelastic and lubricant properties, promotes the restoration of rheological conditions of the joints, altered in degenerative or post-traumatic conditions.

ARTOX 2%:

- It releases the synovial fluid and improves the visco-elasticity
- It guarantees a relief of the painful symptomatology
- It praises anti-inflammatory and analgesic properties
- It enhances the endogenous hyaluronic acid synthesis

DOSAGE

It is recommended an initial 3-week cycle (one injection per week) followed by maintenance session/s.

THERAPEUTIC INDICATIONS

- Degenerative articular affection
  - *Knee osteoarthritis*
  - *Gonarthrosis*
- Post-traumatic articular affection
  - *Sports injuries*
  - *Accidental falls and trauma*

PRESENTATION

Artox 2% is supplied in two different packages, containing:
- 1 pre-filled syringe
- 3 pre-filled syringes

Every syringe contains 2 ml of non-pyrogenic gel.

INGREDIENTS

Sodium hyaluronate (20 mg/ml), sodium chloride, sodium dihydrogen phosphate dihydrate, dibasic sodium phosphate dodecahydrate, WFI grade water.

REGULATORY STATUS

- Class III
- Free sale certificate
- CE certificate
- Certificate of origin
- ISO 13485 certificate
- US FDA registration

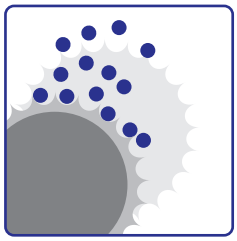
PLUS

No animal origin of hyaluronic acid
BIOTECHNOLOGICAL SYNTHESIS

PREFILLED SYRINGES
- *Pre-measured doses*
- *High level of accuracy*
- *Reduced dosing and medication errors*
- *Reduced risk of microbial contamination*

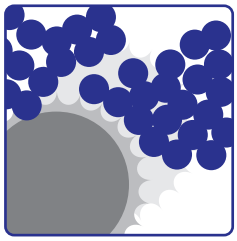
LINEAR HYALURONIC ACID
Less pain during the injection

HYALURONIC ACID MOLECULAR WEIGHT RANGE 1000 – 1500KDA



Hyaluronic acid WM < 500 kDa
Lower affinity to the hyaluronic acid receptors. No stimulation of hyaluronic acid endogenous biosynthesis is observed.

ARTOX
Best affinity to the hyaluronic acid receptors and best stimulation of hyaluronic acid biosynthesis.



Hyaluronic acid WM > 4000 kDa
The steric hindrance of the molecules limits their access to hyaluronic acid receptors. No stimulation of endogenous biosynthesis of hyaluronic acid is observed.

2% *The concentration of HA molecules in Artox 2% offers more protection to synovial fluid and allows increased viscoelastic properties to the joint cartilage in times of increased stress.*

CLINICAL TEST

- **RISK ANALYSIS - according to UNI CEI EN ISO 14971**
- **CYTOTOXICITY for DIRECT CONTACT - according to UNI EN ISO 10993-1:2004**
- **MAXIMIZATION OF DELAYED HYPERSENSITIVITY (Allergic sensitization) - according to UNI EN ISO 10993-1:2004**
- **INTRACUTANEOUS REACTIVITY - according to UNI EN ISO 10993-1:2004**
- **SALMONELLA TYPHIMURIUM REVERSION TEST (Ames test) - according to UNI EN ISO 10993-1:2004**
- **CLINICAL EVALUATION – according to MEDDEV 2.7.1**
- **STABILITY - according to ICH Guidelines**

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