

- 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

**GERMANMED**®

## ARTICULARAFFECTION

### **DESCRIPTION**

JUNCTUREX 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.

#### **JUNCTUREX 2%**

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



It is recommended an initial **3-weeks** 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**

JUNCTUREX 2% is supplied in one package containing:

- 1 pre-filled syringe

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

## No animal origin of hyaluronic acid BIOTECHNOLOGICAL SYNTHESIS

# X

**PLUS** 

#### **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

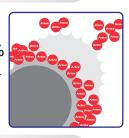


#### Hyaluronic acid WM < 500 kDa

Lower affinity to the hyaluronic acid receptors. No stimulation of hyaluronic acid endogenous biosynthesis is observed.

#### **JUNCTUREX 2%**

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 **JUNCTUREX 2%** offers more protection to synovial fluid and allows increased viscoelastic propreties 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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Medical device III CE<sub>0426</sub>