**Aufbewahrungshinweis**
Nicht einfrieren und nicht extremer Hitze aussetzen.
**CRESPINE®GEL** soll bei Raumtemperatur (18 °C – 25 °C) gelagert werden.

**Hersteller**
BioPolymer GmbH & Co. KG
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Germany
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Stand der Information: 10.2009

# CRESPINE gel

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## Injectable implant for the treatment of osteoarthritis

**Hyaluronic Acid Implant of High Purity – One single injection**

## Instructions for use

**Description**
**CRESPINE®GEL** is an absorbable intra-articular implant of high purity. It is a medical device, manufactured from a hyaluronic acid of non-animal origin.
**CRESPINE®GEL** is a sterile, apyrogenic, visco-elastic, water-insoluble, biologically compatible (non-immunising, non-inflammatory, non-toxic) gel implant, manufactured from a cross-linked hyaluronic acid that is obtained by fermentation.
Hyaluronic acid is a naturally occurring polysaccharide in the dermal matrix of human skin and a component of synovial fluid. Hyaluronic acid is chemically, physically and biologically identical in the tissues of all higher organisms.

**Composition**
**1 ml CRESPINE®GEL contains:**

| | |
|---|---|
| Cross-linked hyaluronic acid sodium salt | 14 mg |
| Sodium chlorid | 6,9 mg |
| Water for injection ad | 1 ml |

**Mode of action**
**CRESPINE®GEL** is injected into joints as a supplement to the altered synovial fluid, for the reduction of the pain symptoms and improved functioning of the joints.
**CRESPINE®GEL** is not a medicine in the sense of the law on medical devices.

**Indication and application**
**CRESPINE®GEL** is indicated for the correction of joints with degenerated cartilage surfaces and pathologically altered synovial fluid. After the injection, there is improvement of the pain symptoms and of the hyaluronic acid layer on the surface of the joint cartilage.
**Treatment areas:**
Gonarthrosis/osteoarthrosis of the knee joint and the hip joint

**Contraindications**
**CRESPINE®GEL** may not be used in the event of:
- autoimmune illnesses
- incompatibility with gram-positive bacteria
- active inflammation or infection processes
- anticoagulant therapies
- known allergy to hyaluronic acid

**ADVICE**
**CRESPINE®GEL** is only intended for intra-articular injection and must not be injected into blood vessels. This could lead to an occlusion of the vessels and an embolism.
No clinical data is available concerning use with pregnant or breastfeeding women and with young people under 18.
**CRESPINE®GEL** is packed sterile for one-off use. It must not be re-sterilised. If the packaging is opened/defective, it must not be used.
**CRESPINE®GEL** is supplied in a sterile syringe and is ready for use. It must not be mixed with other injected agents.

**Precautions**
As with all injection treatments of the joints, the general, valid contraindications for intra-articular injection are also to be observed in treatment with **CRESPINE®GEL**.
As with all implants, **CRESPINE®GEL** must not be used on patients with existing infections and inflammation processes in the vicinity of the implantation site.
The patients should not take any aspirin, steroids or high doses of vitamin E before the treatment, as these substances can lead to bleeding and proneness to inflammation at the place of the injection.
The syringes and needles used count as contaminated and must therefore be destroyed in accordance with the recognised rules of medical practice.

**Adverse effects**
**Caused by the injection:**
As with any other injection, patients may suffer from the following symptoms:
- temporary erythema
- slight swelling
- pain
- itching
- discolouration
- hardening

Typically these reactions spontaneously disappear within 2 to 5 days following the injection.
**Caused by the product:**
Hypersensitivity to the hyaluronic acid after the injection is reported in fewer than 1 % of treatments in 3.000 treatments. This hypersensitivity manifests itself in a swelling and hardening at the implantation site. These reactions can occur immediately after the injection or 2–4 weeks later. The clinical data shows that these reactions are mild or moderate and last 2 weeks at most. These reactions can be caused by the residue of endotoxins in the hyaluronic acid solution (0.025 I.U./mg). This is the highest purity that hyaluronic acid products can have.
Treatment with the product should thus be ruled out for patients with multiple allergies.

**Application instructions**
A full anamnesis must be produced before treatment, in order to rule out any contraindications.
The treating doctor must explain all the precautionary measures and possible side-effects to the patients before the treatment.
The area to be treated must be carefully prepared with an antiseptic. The syringe is removed from the blister pack, the cap is taken off the syringe and a needle is attached. **CRESPINE®GEL** is injected by means of a sterile needle. The implantation, and thereby the selection of the needles, is carried out intra-articularly in the articular space.
**ADVICE**
The injection technique is of decisive importance for the end result. **CRESPINE®GEL** must only be used by authorised medical personnel in agreement with the regional legal regulations. It is possible to treat several joints at the same time.
**IMPORTANT ADVICE**
The graduation on the syringe is an orientation aid for the user and refers to the final volumes. It does not perform a measuring function, but instead only states the quantities used, relating to the nominal volumes of 2 ml.

**Nature and contents of container**
**CRESPINE®GEL** is supplied sterile in a 2 ml syringe with integrated Luer Lock adapter in a blister, for one-off use. Instructions for use and labels with the batch number and date of use are packed together with the blister in a cardboard box.
A label is given to the patient with these, in order to guarantee that the product can be traced.

**ADVICE**
In the event that the packaging or the blister are damaged, the product must not be used. Do not re-sterilise **CRESPINE®GEL**.

**Precautions for storage**
Do not freeze or expose to extreme heat.
**CRESPINE®GEL** should be stored at room temperature (18 °C – 25 °C).

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