

**INDICATIONS:**

Proyal is a medical device that provides benefits related to pain and joint function of the knee, slows the progression of osteoarthritic pathology, improving quantitatively and qualitatively the articular cartilage. It has an excellent safety profile, and is suitable for cases of osteoarthritis and after an arthroscopic procedure. Its chemical-physical properties are determined by its molecular weight of hyaluronic acid interconnection to form a medium and high viscosity solution that acts both as a lubricant and as a shock absorber. Proyal acts only at the level of the joint in which it is injected, without exercising any systemic action.

**DESCRIPTION:**

PROYAL M/H are sterile injectable, biodegradable and isotonic gels, for intra-articular use. PROYAL M consists in a hyaluronic acid with a medium molecular weight (> 1650 kDa), while PROYAL H has a high molecular weight (> 3000 kDa), both produced by Streptococcus Equi bacteria, formulated at a concentration of 20 mg / ml in a physiological buffer. PROYAL M/H are characterized by viscoelastic properties, therefore they favor the normalization of the viscosity of the synovial fluid present in the intra-articular cavity. Each pack contains a sterile vial-syringe in a PROYAL M/H blister and a leaflet.

**COMPOSITION:**

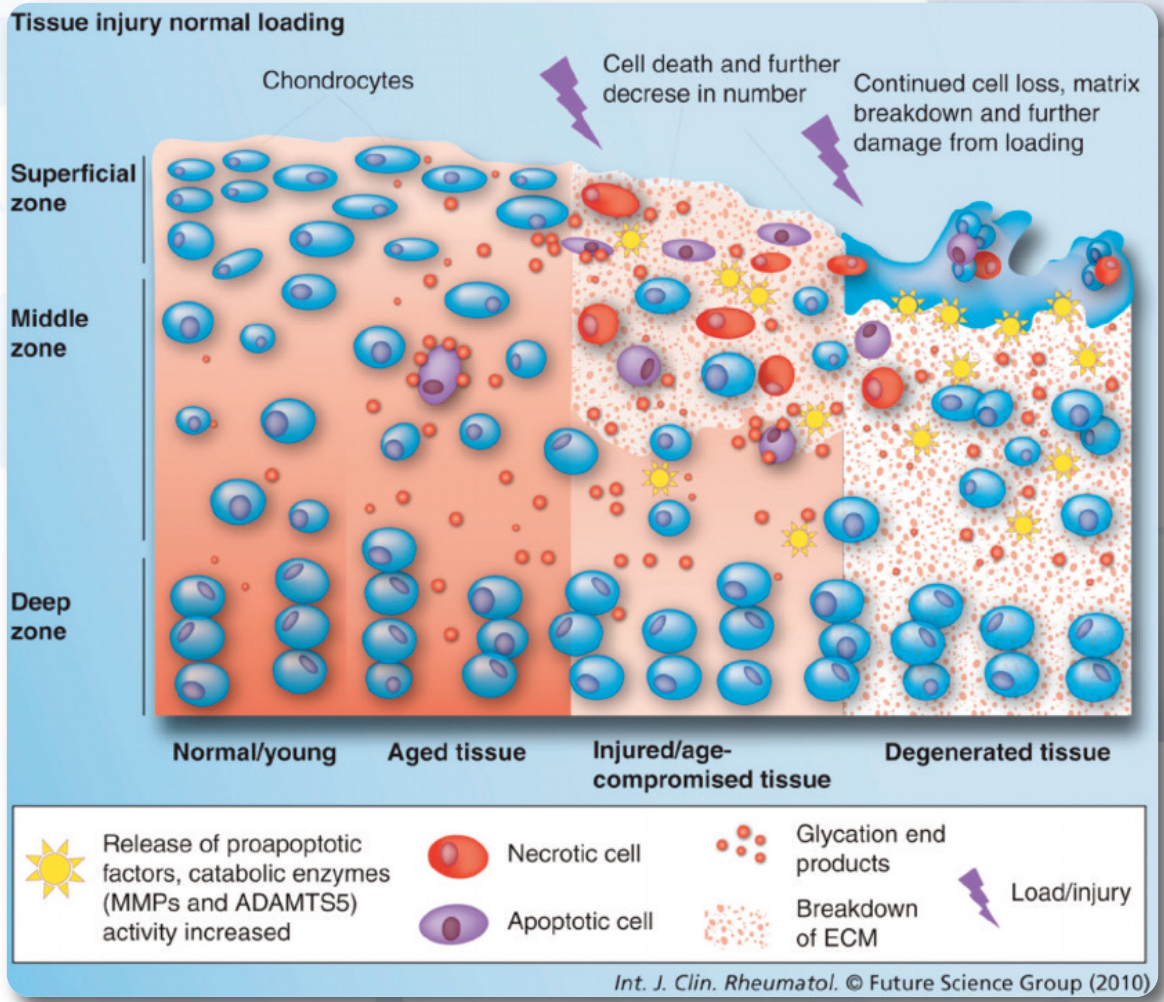
Sodium hyaluronate (20 mg / ml), monobasic sodium phosphate dihydrate, sodium phosphate diphosphate dodecahydrate, water p.p.i.  
One syringe contains 2 ml of apyrogenic solution, sterilized with moist heat.

**METHOD OF USE:**

PROYAL must be injected using sterile 20/22 G needles by specialized medical personnel, carefully observing all the rules regarding asepsis and injection techniques. PROYAL is a single-use medical device, therefore to be used only once on a single patient.

**PROYAL M** - 1650 kDa average molecular weight  
**PROYAL H** - 3100 kDa average molecular weight

The viscoelastic properties of Proyal lubricate the synovium and confer considerable shock absorption, while its macromolecular and hydrophilic dimensions allow to retain liquids in the joint cavity during movement.



As OA progresses, the natural concentration and distribution of HA into the joint moves to lower ranges of molecular weight, leading to a degradation of the mechanical / viscoelastic properties of endogenous synovial fluid. It has also been shown that the lower ranges of molecular weight distributions are strongly related to pain. The administration of HA aims to restore the decline of the HA concentration and the distribution of the average molecular weight within the OA knee.



**CONSERVATIVE THERAPY**

Hyaluronic acid with medium and high molecular weight



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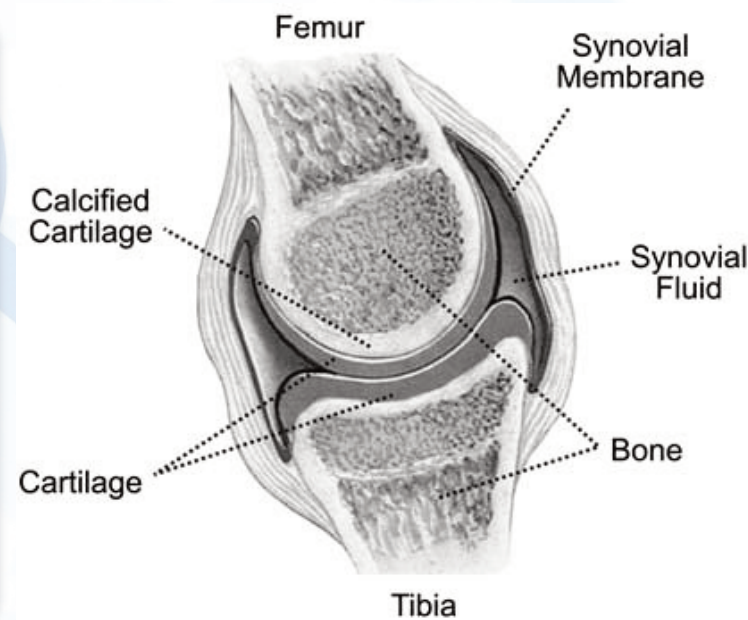
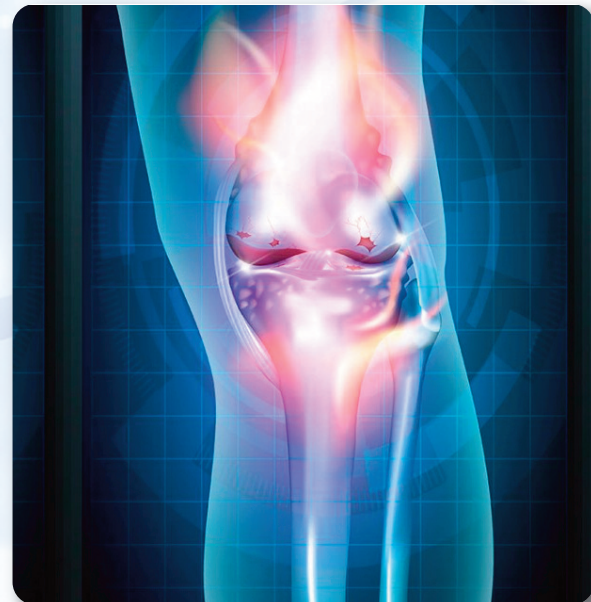


## VISCOINDUCTION BIOLOGICAL ACTION

- Inhibits chondrodegeneration;
- Hinders the apoptosis of the chondrocytes;
- Reduces inflammatory processes;
- Activates a greater production of hyaluronic acid by the synoviocytes;
- Decreases nerve impulses and sensitivity of tendon nociceptive extremities;
- Stabilizes the cartilage matrix;
- Stimulates chondrocyte proliferation;
- Increases the production of collagen and aggrecan type 2 by chondrocytes;
- Breaks down the degradation of type 2 collagen;
- Improves the metabolism and activity of synovial fibroblasts.



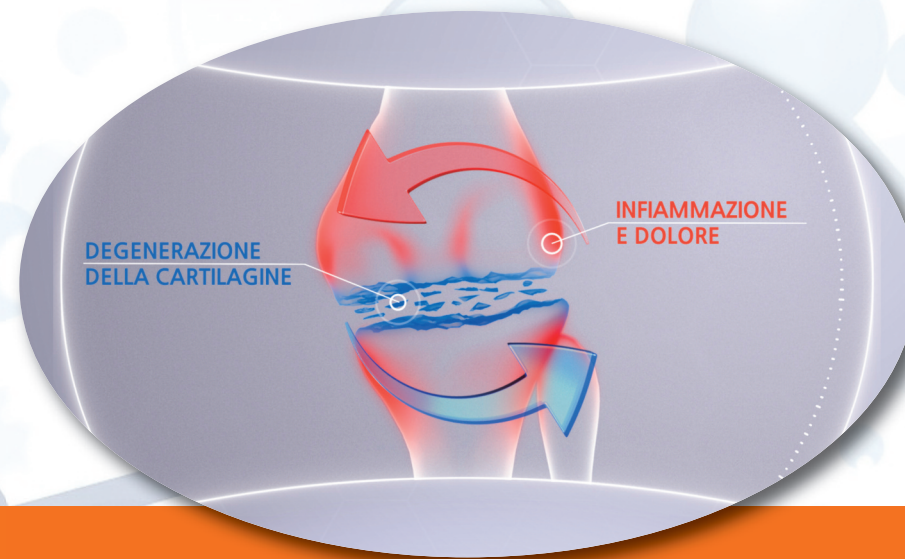
## THERAPEUTIC EFFECTS



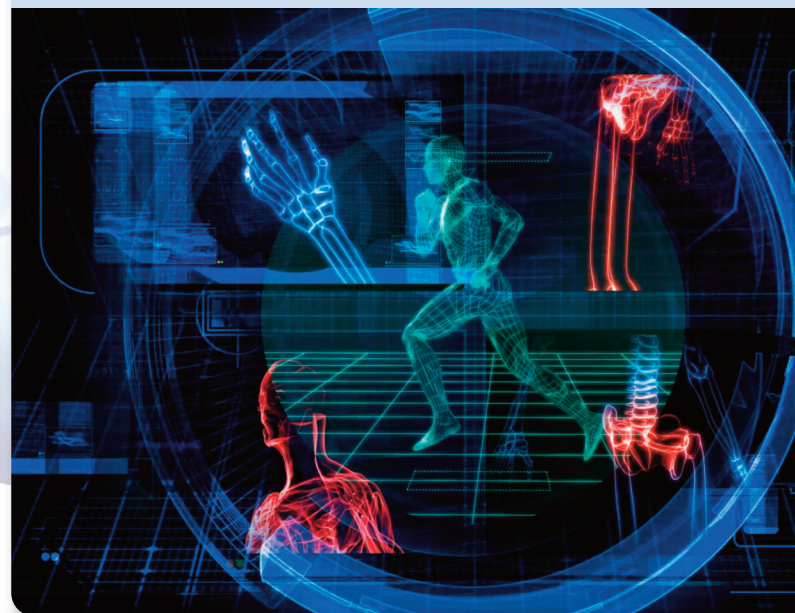
PROYAL has a dual function within the synovial joint: a mechanical action of lubrication and shock absorber of joint mechanical stress (viscosupplementation) and a strictly biological activity on articular structures (viscoinduction).

## CONSERVATIVE THERAPY

Knee osteoarthritis (OA) is one of the main causes of disability among the adult population. The use of intra-articular infiltrations of hyaluronic acid during osteoarthritic pathology is aimed at pain reduction and functional improvement of joint function.



## GOALS OF CARE:

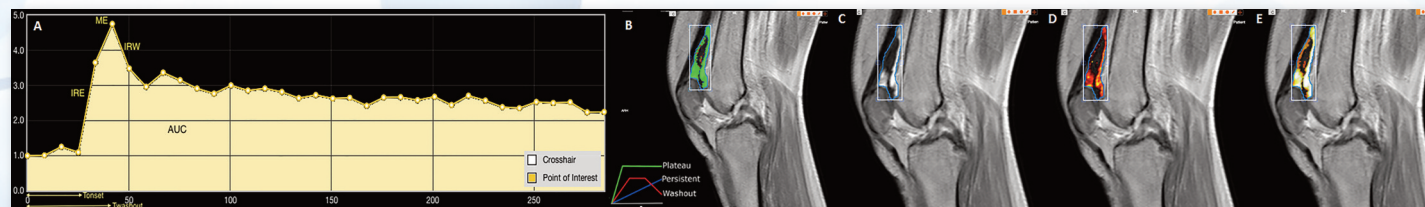


RESTORES THE RHEOLOGICAL CONDITIONS: ELASTICITY AND VISCOSITY OF THE SIOVIAL LIQUID

SLOWS DOWN CARTILAGE DEGENERATION'S

CHECKS THE PAINFUL SYMPTOMATOLOGY

AGREES PREVENTIVELY ON THE OSTEOARTROTIC PATHOLOGY



## VISCOSUPPLEMENTATION MECHANICAL ACTION

The viscosupplementation with Proyal H consists in the injection of exogenous high molecular weight hyaluronic acid into the diarthrotic joints.

- Restores the rheological properties of the synovial fluid;
- Produces mechanical, analgesic, anti-inflammatory and chondroprotective effects;
- Provides benefits regarding pain and function;
- Improve quantitatively and qualitatively the articular cartilage;
- Increases significantly the viscoelastic properties of the knee;
- Stimulates a greater production of hyaluronic acid by the sinoviocytes;
- Gives a great analgesic effect.



## THERAPEUTIC EFFECTS



Proyal M/H - 2 ml 40 mg  
Proyal M/H - 4 ml 80 mg

## DOSAGE

**Proyal M** 2 ml 1 infiltration every 8/10 days for 4 applications unless otherwise advised by the doctor or according to the patient's clinical condition

**Proyal H** 2 ml 1 infiltration every 10/15 days for 3 applications unless otherwise advised by the doctor or as necessary.