



VISCOSUPPLEMENTATION

HYALURONIC ACID SODIUM SALT 2,0% FOR INTRA-ARTICULAR INJECTION

INDICATIONS

PROYAL is a substitute for synovial fluid which, thanks to its viscoelastic and lubricating properties, helps restore the rheological conditions of the joints, altered in case of degenerative or post-traumatic pathologies.

The product, improving the characteristics of the synovial fluid protecting joints and promotes the improvement of articular functionality and the reduction of the painful symptomatology.

DESCRIPTION

PROYAL is a biodegradable, isotonic and injectable sterile gel, for intra-articular use.

PROYAL M consists of medium molecular weight hyaluronic acid ($1,5 - 2,5 \times 10^6$ Dalton), produced by the *Streptococcus Equi* bacteria, formulated at a concentration of 20 mg/ml in physiological buffer.

PROYAL H consists of high molecular weight hyaluronic acid ($2,5 - 3,5 \times 10^6$ Dalton), produced by the *Streptococcus Equi* bacteria, formulated at a concentration of 20 mg/ml in physiological buffer.

PROYAL M is a medical device based on hyaluronic acid sodium salt with an average molecular weight of 1,7 Million Daltons. It is characterized by viscoelastic properties, therefore it allows to favor the normalization of the viscosity of the synovial fluid present in the intra-articular cavity.

PROYAL H is a medical device based on hyaluronic acid sodium salt with an average molecular weight of 3,2 Million Daltons which allows perfect diffusion within the joint, this means that no painful swellings are created in the inoculum.

PROYAL is obtained by fermentation and this guarantees absolute purity, thus reducing to a minimum the risks of allergens and inflammatory reactions.

PROYAL also has a very high persistence and duration of action on the site.



TECHNICAL PRODUCT SHEET				
PRODUCT DESCRIPTION		Sterile injectable medical device for intra-articular use, which function is integrating hyaluronic acid in synovial fluid. Pre-filled syringe containing 2ml/40mg 3ml/60mg 4ml/80mg of non-pyrogenic gel, sterilized using moist heat.		
TECHNICAL CHARACTERISTICS OF THE PRODUCT				
ACTIVE INGREDIENT		Sodium Hyaluronate 20 mg/ml with a molecular weight of 1,5 - 2,5 M. Daltons for PROYAL M and 2,5 - 3,5 M. Daltons for PROYAL H , both not crosslinked.		
EXCIPIENTS		Sodium monobasic phosphate, sodium dibasic phosphate, sodium chloride, water for injection.		
PRIMARY PACKAGING MATERIAL		Crystal syringe in blister	VOLUME FOR M	2 ml / 3 ml / 4 ml
			VOLUME FOR H	2 ml / 3 ml / 4 ml
SECONDARY PACKAGING MATERIAL		Cardboard		
COLOR		Transparent	STERILITY	Sterile
LAW AND DIRECTIVES APPLIED		Medical Device Class III designed as Directive 92/43/CEE, manufactured in accordance with ISO 13485 requirements and regulation (EU) 2017/745.		
PRODUCT PURPOSE		PROYAL is indicated as a substitute for synovial fluid that, thanks to its viscoelastic and lubricating properties, favors the restoration of the rheological conditions of the joints altered in case of degenerative or post-traumatic conditions.		
HOW TO USE	PROTOCOL AND DOSAGE		APPLICATION APPROACH	
	At the discretion of the doctor	Depending molecular weight and volume, 2-3 treatments a year. Renew every year.	To inject in joint	
FIELD OF APPLICATION		Recommended for use in traumatology (Osteoarthritis)		
CE MARKING		CE 0373		
PRODUCTION		3 months		
TRANSPORT CAUTIONS		Controlled temperature		
STORAGE CAUTIONS		Keep in a dry place, avoid moisture, keep away from sunlight and fluorescent light, store between +2° and +25° C.		
MINIMUM ORDER QUANTITY (MOQ)		2520 units		
EXPIRATION		36 months, after manufacture date		
TRADEMARK		PROYAL		
MANUFACTURER		THE WAVE INNOVATION GROUP SRL, ITALIA		

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