DATA SHEET

thewave innovation group

PROYAL®

VISCOSUPPLEMENTATION

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

INDICATIONS

Under specific pathological conditions, the production of hyaluronic acid tends to decrease, thus favouring the appearance of related phenomena, for example, the onset of joint problems, as happens with the osteoarthritis process.

During osteoarthritis, the joint loses its physiological visco-elastic properties as the hyaluronic acid contained in the synovial fluid is reduced both in terms of concentration and molecular weight. As a result, the synovial fluid loses its protective role against mechanical stress.

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.

PROYAL (class III medical device) by improving the characteristics of the synovial fluid, protects the joints and promotes the improvement of joint function and the reduction of painful symptoms.

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 x 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 x 10^6 Dalton), produced by the Streptococcus Equi bacteria, formulated at a concentration of 20 mg/ml in physiological buffer.

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.

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PROYAL M PROYAL H

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**		**APLICATION APROACH**
	At the discretion of the doctor	From 1-4 treatments per 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 +2º and +25º 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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