



## VISCOSUPPLEMENTATION

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

## INDICATIONS

**ARTOSYAL** 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

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

**ARTOSYAL 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.

**ARTOSYAL 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.

**ARTOSYAL M** is a medical device based on hyaluronic acid sodium salt with an average molecular weight of 1,5 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.

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

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

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



TECHNICAL PRODUCT SHEET			
<b>PRODUCT DESCRIPTION</b>		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			
<b>ACTIVE INGREDIENT</b>		Sodium Hyaluronate 20 mg/ml with a molecular weight of 1,5 - 2,5 M. Daltons for <b>ARTOSYAL M</b> and 2,5 - 3,5 M. Daltons for <b>ARTOSYAL H</b> , both not crosslinked.	
<b>EXCIPIENTS</b>		Sodium monobasic phosphate, sodium dibasic phosphate, sodium chloride, water for injection.	
<b>PRIMARY PACKAGING MATERIAL</b>		Crystal syringe in blister	
		<b>VOLUME FOR M</b>	2 ml / 3 ml / 4 ml
<b>SECONDARY PACKAGING MATERIAL</b>		<b>VOLUME FOR H</b>	2 ml / 3 ml / 4 ml
		Cardboard	
<b>COLOR</b>		Transparent	<b>STERILITY</b> Sterile
<b>LAW AND DIRECTIVES APPLIED</b>		Medical Device Class III designed as Directive 92/43/CEE, manufactured in accordance with ISO 13485 requirements and regulation (EU) 2017/745.	
<b>PRODUCT PURPOSE</b>		<b>ARTOSYAL</b> 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.	
<b>HOW TO USE</b>		PROTOCOL AND DOSAGE	
		At the discretion of the doctor	Depending molecular weight and volume, 2-3 treatments a year. Renew every year.
		APPLICATION APPROACH	
		To inject in joint	
<b>FIELD OF APPLICATION</b>		Recommended for use in traumatology (Osteoarthritis)	
<b>CE MARKING</b>		<b>CE 0373</b>	
<b>PRODUCTION</b>		3 months	
<b>TRANSPORT CAUTIONS</b>		Controlled temperature	
<b>STORAGE CAUTIONS</b>		Keep in a dry place, avoid moisture, keep away from sunlight and fluorescent light, store between +2° and +25° C.	
<b>MINIMUM ORDER QUANTITY (MOQ)</b>		2520 units	
<b>EXPIRATION</b>		36 months, after manufacture date	
<b>TRADEMARK</b>		<b>ARTOSYAL</b>	
<b>MANUFACTURER</b>		THE WAVE INNOVATION GROUP SRL, ITALIA	

Contact person:  
FRANSIN KELEN TERRANI  
COMMERCIAL MANAGER  
Cell. +39 392 542 2339  
administration@thewaveinnovation.com

**THE WAVE INNOVATION GROUP S.r.l.**  
Via Mons. Luigi Bellotti, 16  
37139 Verona, Italy  
www.thewaveinnovation.com  
info@thewaveinnovation.com

