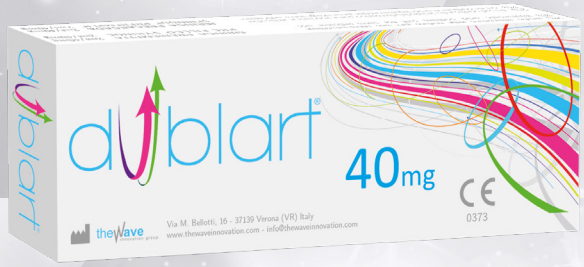
DATA SHEET



HYPERVISCOSUPPLEMENTATION

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

WORLDWIDE NEW

INDICATIONS

HYPERVISCOSUPPLEMENTATION OF DUBLART with intra-articular injections of hyaluronic acid is indicated in patients with symptomatic OA grade 4 scale KL who have not responded to first-line therapy and conservative management.

DUBLART enhances the viscoelastic properties of the synovial fluid, increases the production of endogenous HA and supports the chondrocyte and the extracellular matrix from degradation.

DESCRIPTION

DUBLART is a sterile, injectable, biodegradable and isotonic gel, for intra-articular use. It consists of two hyaluronic acids with different molecular weight (2,5 and 4 x 10^6 Dalton), produced by Streptococcus Equi bacteria, formulated at a concentration of 20 mg/ml in a physiological buffer.

DUBLART 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.

DUBLART produced with two hyaluronic acids with high/very high molecular weight 2,5 and 4 Million Daltons of natural non-animal origin, obtained from a highly controlled production process performed in state-of-the-art production plants.

DUBLART is **THE COMBINATION** of two pharmacological grade hyaluronic acids from a natural strain of Streptococcus Equi bacteria, selected for their high/very high molecular weight.

DUBLART represents a new application concept of **HYPERVISCOSUPPLEMENTATION** infiltrative therapy with a **BIPHASIC INFILTRATION TECHNIQUE** with high molecular weight linear hyaluronic acids.

theWave innovation group

dublart®

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 2,5 Million Daltons and 4 Million Daltons not crosslinked		
EXCIPIENTS	Sodium monobasic phosphate, sodium dibasic phosphate, sodium chloride, water for injection.		
PRIMARY PACKAGING MATERIAL	Crystal syringe in blister	**VOLUME**	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	**DUBLART** is indicated as a substitute for synovial fluid that, thanks to its viscoelastic and lubricating properties, reduce pain, favors the restoration of the reological condions 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	1-2 treatments per 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 +2º and +25º C.
MINIMUM ORDER QUANTITY (MOQ)	2520 units
EXPIRATION	36 months, after manufacture date
TRADEMARK	**DUBLART**
MANUFACTURER	THE WAVE INNOVATION GROUP SRL, ITALIA

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