DATA SHEET

FLUICONDRIAL®

VISCOSUPPLEMENTATION

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

INDICATIONS

FLUICONDRIAL 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

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

FLUICONDRIAL 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.

FLUICONDRIAL 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.

FLUICONDRIAL M is a medical device based on hyaluronic acid sodium salt with an average molecular weight of 1,6 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.

FLUICONDRIAL H is a medical device based on hyaluronic acid sodium salt with an average molecular weight of 3,1 Million Daltons which allows perfect diffusion within the joint, this means that no painful swellings are created in the inoculum.

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

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

FLUICONDRIAL® M FLUICONDRIAL® 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 **FLUICONDRIAL M** and 2,5 - 3,5 M. Daltons for **FLUICONDRIAL 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	**FLUICONDRIAL** 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	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 +2º and +25º C.
MINIMUM ORDER QUANTITY (MOQ)	2520 units
EXPIRATION	36 months, after manufacture date
TRADEMARK	**FLUICONDRIAL**
MANUFACTURER	THE WAVE INNOVATION GROUP SRL, ITALIA

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