



INNOVATIVE H.A. CARTILAGE REPAIR

INJECTION THERAPY FOR THE REPAIR OF ARTICULAR CARTILAGE

WORLDWIDE NEW

INTRODUCTION

Osteoarthritis (OA) is a degenerative disease that affects different tissues of the surrounding joints such as articular cartilage, subchondral bone, synovial membrane, and ligaments. No therapy is currently available to completely prevent the progression of the disease due to poor understanding of the pathology mechanisms. Articular cartilage is the main tissue afflicted by OA, and chondrocytes are cellular components of the tissue that actively participate in the degeneration process. Multiple factors influence the development and progression of OA including inflammation during disease progression and by the biomechanical alterations of cartilage due to wear and trauma. During the progression of OA, extracellular matrix (ECM) cartilage is actively remodelled by chondrocytes in inflammatory conditions.

This alteration of ECM, in turn, changes the biomechanical environment of chondrocytes, which further push the progression of the disease in the presence of inflammation. Changes in the composition and ECM structure also prevent the participation of mesenchymal stem cells in the cartilage repair process by inhibiting their chondrogenic differentiation.

SINODRIAL

The Wave innovation group has been making injectable medical devices for the treatment of osteoarthritis diseases for years, devices such as **SINODRIAL** which not only slow down the degradation of articular cartilage, but thanks to the high molecular weight of hyaluronic acid with amino acid and precursors, contribute to regenerate cartilage. **SINODRIAL**'s mission is to stimulate chondrocytes to produce elastic and reticular fibers of which cartilage is composed with.

SINODRIAL is an injectable class III Medical Device.

CONCLUSION

SINODRIAL demonstrates its clinical activity by activating the metabolic and reparative processes of articular cartilage. The high molecular weight of hyaluronic acid hydrogel with precursors and amino acids stimulate chondro regeneration with cell surface receptors, increase the production of type II collagen and minor collagens, and positively influence the ability of chondrocytes for the correct maintaining of the extracellular matrix of cartilage.



TECHNICAL PRODUCT SHEET			
PRODUCT DESCRIPTION		Sterile injectable medical device for intra-articular use, is a synovial fluid replacer, helps restore the rheological conditions of altered joints. 2 pre-filled syringe, each containing 2ml/50mg of non-pyrogenic gel, sterilized using moist heat.	
TECHNICAL CHARACTERISTICS OF THE PRODUCT			
ACTIVE INGREDIENT		Sodium Hyaluronate 25 mg/ml with a molecular weight of 3 Million Daltons not crosslinked, with hidroxyproline, proline, glycine and lysine,...	
EXCIPIENTS		Sodium monobasic phosphate, sodium dibasic phosphate, sodium chloride, water for injection.	
PRIMARY PACKAGING MATERIAL		Crystal syringe in blister	VOLUME 2 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		SINODRIAL is a Bio-regenerant based on collagen precursors, which facilitates chondrocytes to produce quickly tropocollagen that polymerizes in the extracellular matrix of the cartilage forming real collagen. It is indicated for the treatment of reconstructing of the cartilage and its annexes.	
HOW TO USE	PROTOCOL AND DOSAGE		APPLICATION APPROACH
	At the discretion of the doctor	2/4 treatments per year (1 syringe every 2 weeks). 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		SINODRIAL	
MANUFACTURER		THE WAVE INNOVATION GROUP SRL, ITALIA	

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