

BIOPORT



BIOPORT® CROSSLINK

Is a sterile, viscoelastic solution containing two highly purified cross-linked biological polymers, sodium hyaluronate and chondroitin sodium sulfate. It consists of sodium hyaluronate derived from bacterial fermentation of a Streptococcus strain and chondroitin sodium sulfate produced from bovine cartilage. BIOPORT® CROSSLINK is a sterile viscoelastic solution processed using an aseptic processing technique and supplied in a disposable glass syringe delivering 3 mL of solution.

KEY IDENTIFICATION

Ingredient	Composition mg / prefilled syringe
Sodium hyaluronate	60,00
Chondroitin sodium sulfate	90,00
Sodium chloride	10,50
Sodium Dihydrogen Phosphate Monohydrate	1,35
Disodium phosphate dodecahydrate	15,15
1M Sodium hydroxide / 1M Hydrochloric acid *	Ad to pH = 7,4 ± 0,2
Water for injections	ad to 3,00 ml

CE 0050

PROPERTIES

Average molecular weight	3MDa
Elasticity mode G' in rest 0,5 Hz / running 2,5 Hz.	242 Pa / 468 Pa
Viscosity mode G'' at rest/running	180 Pa / 220 Pa

ADMINISTRATION

The administration of BIOPORT® CROSSLINK is reserved for medical practitioners trained in joint injection techniques, administered as a single injection per treatment.

SHELF LIFE AND STORAGE

Store at temperatures below 25°C, in the original package, in order to protect from light. Do not freeze. Shelf life is 36 months after manufacture date.

PRESENTATION

Minimum 3ml solution for injection of Sodium Hyaluronate 60mg/3ml and Chondroitin sodium sulfate 90mg/3ml is packed in Becton Dickinson colorless syringe Type I glass, equipped with rubber syringe plunger, plunger rod and backstop. Pre-filled syringe is labeled and packed 1 syringe with 3 ml solution for injection and instructions for use in a box printed carton box.

REGULATORY

- Medical Device Class III designed as Directive 92/43/CEE
- CE Certificate (No 252.979) issued by a Notified Body identification number 0050
- Manufactured in accordance with ISO 13485 requirements.
- Manufacturer: S.C. ROMPHARM COMPANY S.R.L. 1A Eroilor Street, Otopeni, Ilfov, 075100, Romania
- Distributor: NIKOVARI BIO TECH OY, Retkeilijätkäkatu 5, 00980 Helsinki, Finland
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