BIOPORT

BIOPORT® TRICOMBO

Is bio-matrix in the form of a sterile, viscoelastic solution consisting of two highly purified cross-linked biopolymers, sodium hyaluronate and chondroitin sodium sulfate, and N-acetylglucosamine (NAG), a natural amino sugar. It contains sodium hyaluronate derived from bacterial fermentation of a Streptococcus strain and chondroitin sodium sulfate produced from bovine cartilage, and NAG sourced from chitin, a naturally long-chain polymer of N-acetylglucosamine.
BIOPORT® TRICOMBO is a sterile viscoelastic solution processed using an aseptic processing technique and supplied in a disposable glass syringe delivering 2.25 mL of solution.

KEY INDENTIFICATION

Ingredient	**Composition mg / prefilled syringe**
Sodium hyaluronate	36.000
Chondroitin sulfate sodium	67.500
N-acetylglucosamine	67.500
Sodium dihydrogen phosphate monohydrate	1.163
Disodium phosphate dodecahydrate	11.340
Sodium chloride	9.675
Sodium hydroxide/ 1M Hydrochloric acid *	Up to 7.4 ± 0.2
Water for injections	add to 2.25 ml
Nitrogen**	-

*As solution 1M
**Not found in finished product – it is used as an Insertisation agent

CE 0050

PROPERTIES

Average molecular weight	3MDa
Elasticity mode G' in rest 0,5 Hz / running 2.5 Hz.	250 Pa / 490 Pa
Viscosity mode G" at rest/running	190 Pa / 275 Pa

ADMINISTRATION

The administration of BIOPORT® TRICOMBO is reserved for medical practitioners trained in joint injection techniques. It is recommended to administer two treatment cycle per year, every 6 months, according to doctor's recommendation.

SHELF LIFE AND STORAGE

Store at temperatures of 15- 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 2.25ml solution for injection of Sodium Hyaluronate 36mg/2.25ml and Chondroitin sodium sulfate 67.5mg/2.25ml and N-acetylglucosamine 67.5mg/2.25ml is packed in Becton Dickenson colorless syringe Type I glass, equipped with rubber syringe plunger, plunger rod and backstop. Pre-filled syringe is labeled and packed 1 syringe with 2.25 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 252.1173) 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, Retkeilijänkatu 5, 00980 Helsinki, Finland

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