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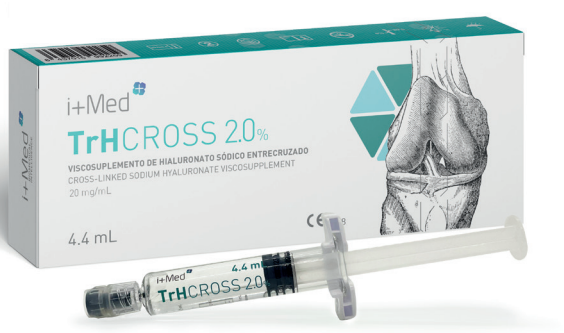
TRAUMATOLOGY



TrHCROSS

TrHCROSS is a biocompatible hydrogel of crosslinked sodium hyaluronate obtained by biofermentation and highly purified, dissolved in a physiological and isotonic buffer. The product is an injectable hydrogel, sterile and apyrogenic, with a low level of endotoxins.

	TrHCROSS 2%
pH	7.2-7.6
OSMOLALITY	200-400mOsm/kg
COMPOSITION	Crosslinked hyaluronic acid (Non-animal origin)
CROSS-LINKING AGENT	BDDE (residual BDDE <2ppm)
VOLUME	4,4 mL
VISCOSITY	120.000-170.000 cP
NaHA	2 ± 0.25 %

INTENDED USE

TrHCROSS is intended to be injected intra-articularly in the synovial space of the knee as viscosupplementation medium for synovial fluid when its viscosity has been reduced due to osteoarthritis process in patients who have not responded adequately to conservative non-pharmacological therapy and simple analgesics.

COMPOSITION

TrHCROSS contains high molecular weight crosslinked hyaluronic acid obtained by biofermentation of injectable grade and high purity, dissolved in a physiological buffer with pharmacopeia quality ingredients, and water for injection (WFI).

PROPERTIES

- Reduces the pain and increases the functionality of the affected joint.
- Provides a lubricant and shock-absortion effect on the affected joint.
- Improves the quality of life of the patient.

TECHNICAL SPECIFICATIONS

- Visual appearance: Homogeneus transparent solution
- Physiological pH
- Isotonic
- Endotoxin content ⩽0.2 EU/mL
- Sterile product
- Biocompatible product

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PACKAGING

TrHCROSS is supplied in a graduated, pre-filled and disposable Type I glass sterile syringe, containing 4.4 mL of solution, ready to use.

SHELF LIFE

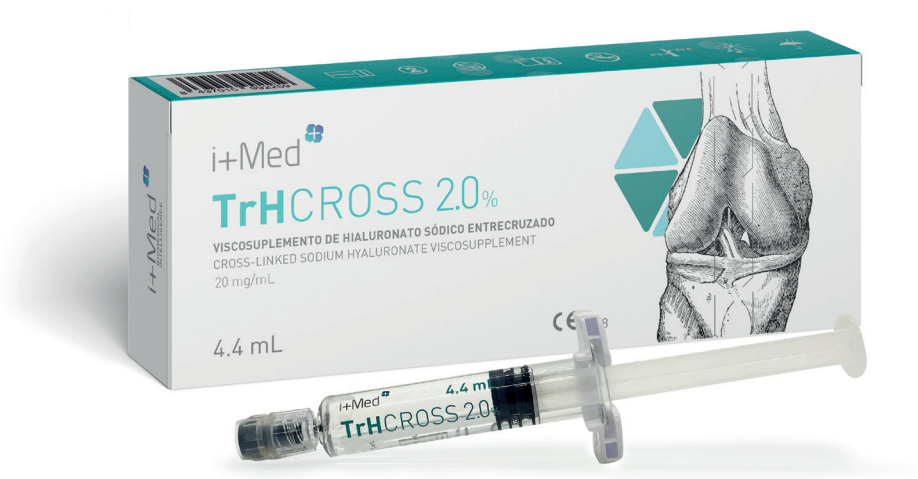
2 years.

QUALITY GUARANTEE

CE 0318

Class III medical product.

Compliance with the requeriments of the Medical Device Directive 93/42/CEE transposed into national legislation in RD 1591/2009 and UNE - EN ISO 13485:2016 “Medical Devices. Quality Management Systems”



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