ENGLISH

ARTHRUM H 2%

PRODUCT INFORMATION

DESCRIPTION

ARTHRUM H 2% is a sterile viscoelastic, non-pyrogenic and physiological solution of non-cross-linked non-animal origin hyaluronic acid.
This solution comes in a pre-filled disposable syringe.
Each box contains one syringe of ARTHRUM H 2% and a 21G (0.8 x 50 mm) sterile disposable needle for injecting (intra-articular injection) the product, instructions and a set of labels for traceability.

COMPOSITION

ARTHRUM H 2%	2 ml
Sodium hyaluronate (NaHA) Sodium chloride (NaCl) Borate buffer Ph 7.2 q.s. (Sodium Borate, Boric Acid, Water for Injection)	40 mg 18 mg qs 2 ml

STERILISATION

The syringes of ARTHRUM H 2% are steam sterilised.
The 21G needles are sterilised by ethylene oxide.

INDICATIONS

ARTHRUM H 2% is indicated for relieving pain and restoring the mobility of the joint by replacing and supplementing the viscoelasticity of the synovial fluid of the osteoarthritic joint.
ARTHRUM H 2% produces its therapeutic effect by visco-supplementation, a process that improves the physiological and rheological properties of the synovial fluid of the osteoarthritic knee.
ARTHRUM H 2% is indicated in treating the symptoms of osteoarthritis using intra-articular injections.
ARTHRUM H 2% must be administered intra-articularly by a doctor to relieve the pain associated with osteoarthritis of the knee.

CONTRAINDICATIONS

ARTHRUM H 2% should not be used for:
- Patients who are hypersensitive to hyaluronic acid.
- Patients with autoimmune diseases, sarcoidosis, multiple severe allergies or cardiovascular diseases treated with anticoagulants.
- Patients taking immunosuppressants or interferon.
- Women who are pregnant or breast-feeding.
- Children.

ARTHRUM H 2% should not be used in conditions of inflammation of the joint (RHEUMATOID ARTHRITIS).
ARTHRUM H 2 % should not be injected at the same time as an injectable corticosteroid.

PRECAUTIONS FOR USE

ARTHRUM H 2% is only indicated for the intra-articular injections.
Do not inject intravascularly.
Do not inject outside the joint cavity or in the synovial tissue or capsule.

INCOMPATIBILITIES

Hyaluronic acid (sodium hyaluronate) solution is incompatible with quaternary ammonium salts such as benzalkonium chloride. ARTHRUM H 2% should never come into contact with this type of product or surgical equipment that has been cleaned with this type of product.

ADVERSE REACTIONS

Patients must be informed by the practitioner about information regarding the potential of immediate or delayed adverse reactions associated with the injection of this product before the procedure.
The different potential adverse reactions are:
- The immediate side effects of the injection:
  Pain, redness and swelling at the injection site
- Inflammatory side effects:
  Pseudogout attack
  Chondrocalcinosis
  Pseudoseptic arthritis
- Other side effects
  Low efficacy or little effect of the treatment of osteoarthritis with a very advanced radiologic grade.

New and/or persistent side effects should be reported by the patient to the practitioner as soon as possible to remedy the problem using appropriate treatment.
Other unwanted side effects related to the injection must be reported to the distributor and/or manufacturer.

INSTRUCTIONS - DOSAGE

ARTHRUM H 2% is to be injected by the intra-articular route by an approved specialist practitioner in accordance with applicable local rules.
The practitioner's technical skills are vital for successful treatment. The device must therefore be used by practitioners who have received specific training in injection techniques.
The device must be used in the original packaging provided.
No guarantee will be provided should this product be modified or used in any way that is not in accordance with the conditions of use given in these instructions, which may affect its sterility, safety or efficacy.
Practitioners must inform patients about the indications, contraindications, incompatibilities and potential adverse reactions related to the device before starting treatment.

Procedure for use:
- Before the injection, the area to be treated must be carefully disinfected
- Ensure that the sterility protector is intact.
- Take the syringe and remove the protective cover.
- Holding the main part of the syringe, insert the needle into the Luer lock system.
- Gently turn the needle clockwise to attach the needle in the Luer lock system.
- Check to see that the needle is attached.
- Remove the needle cap.
- Inject slowly.

Ignoring these instructions can result in the needle becoming detached and/or a leak in the Luer lock.
The regimen for ARTHRUM H 2% is 3 intra-articular injections at one-week intervals.

WARNING

- Check the expiry date on the labelling.
- Do not reuse. Sterility cannot be guaranteed when reused.
- Do not re-sterilize.
- It is advised to use the needle provided. Practitioners using other needles or cannulas do so under their own responsibility.
- Used needles and syringes must be disposed of in appropriate containers. Refer to the existing guidelines for disposal.

STORAGE CONDITIONS

- Store between +2°C and +30°C.
- Keep away from light and frost.

ARTHRUM H 2% is a CE 0459 medical device - Made in France by LCA S.A.

Year of authorisation to affix CE marking: 1998.
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For professional use only.

CE 0459 STERILE 2 STERILIZE 30°C 2°C

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