allevyal®

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Hyaluronic acid sodium salt for intra-articular use

PRODUCT DESCRIPTION:
ALLEVYAL® is a sterile, non-pyrogenic, biodegradable, isotonic, injectable gel, for intra-articular use. ALLEVYAL® consists of medium chain (1.0-1.5 x 10^6 Dalton) hyaluronic acid, obtained from Streptococcus equi bacteria, formulated to a concentration of 20 mg/ml in a physiologic buffer.
ALLEVYAL® is characterised by viscoelastic properties, therefore allows to facilitate the normalisation of the viscosity of the synovial fluid present in the intra-articular cavity.
Each box contains one syringe of ALLEVYAL® and a product leaflet. A set of two labels showing the batch number is contained in the box. One of these labels should be attached to the patient's file and the other should be given to the patient to ensure traceability.

COMPOSITION:
Sodium hyaluronate (20 mg/ml), sodium chloride, sodium dihydrogen phosphate dihydrate, dibasic sodium phosphate dodecahydrate, WFI grade water.

INDICATIONS:
ALLEVYAL® is a synovial fluid substitute which, thanks to its viscoelastic and lubricant properties, promotes the restoration of rheological conditions of the joints, altered in degenerative or post-traumatic conditions.
The product, improving the characteristics of the synovial fluid, exerts a protective action of the joints and helps the improvement of joint function and the reduction of pain symptoms.
ALLEVYAL® acts only at the joint where it is injected, without exerting any systemic action.

WARNINGS - PRECAUTIONS FOR USE:
ALLEVYAL® is suitable only for intra-articular injections and must only be dispensed by a doctor who has received specific training on the intra-articular injection technique.
Before use, check the integrity of the syringe and the expiration date.
Do not use needles other than those listed.
The product should not be injected in the presence of an infected or severely inflamed joint.
The infiltration must be avoided in the case of infections in place or inflammatory conditions of the skin in proximity of the injection.
As no clinical experience is available for the use of Hyaluronan in children, treatment with ALLEVYAL® is not recommended in these cases.
After the intra-articular injection, it is advisable to recommend to the patient to avoid physical activities demanding stress for the articulation and resume normal activities after a few days.
ALLEVYAL® is a disposable product; the quality and sterility are guaranteed only if the syringe is sealed. Any residue must be discarded and not reused even after new sterilisation.
Do not use the product if the package is already opened or damaged.
The assembled syringe must be discarded immediately after use, regardless of whether or not the solution has been completely administered.
After use, dispose according to applicable national practice.

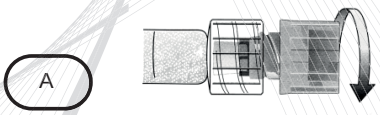
INCOMPATIBILITIES:
There are incompatibilities between sodium hyaluronate and quaternary ammonium compounds, such as solutions of benzalkonium chloride. Contact between ALLEVYAL® and these substances should be therefore avoided.

SIDE EFFECTS:
There may be some temporary side reactions following injection of ALLEVYAL®, such as pain, stiffness, warmth, redness or swelling. These secondary manifestations may be relieved by applying ice on the treated articulation. Usually, these effects disappear after a short time. If symptoms persist, consult a physician. Any other unwanted side effects associated with the injection of ALLEVYAL® should be reported to a doctor.

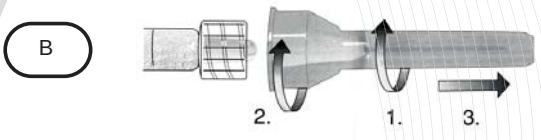
METHODS OF USE:
Remove any joint effusion before injecting ALLEVYAL®; the removal of the effusion and the injection of ALLEVYAL® the same needle must be used. Remove the protective cap of the syringe, with particular attention to avoid contact with the opening. Firmly screw the needle, of diameter between 18 and 22 g, at the collar of Luer lock, following the instruction given below. Before injection, the site should be treated with appropriate disinfectant.Inject ALLEVYAL® adopting aseptic technique. Inject only into the joint cavity.
It is recommended to perform an initial cycle of 3 to 5 weekly treatments, possibly followed by maintenance sessions, according to the medical prescription.

INSTRUCTIONS FOR ASSEMBLY OF THE SYRINGE NEEDLE:

A. Carefully unscrew the cap of the tip of the syringe, being particularly careful to avoid contact with the opening.



B. Gently grip the needle guard and mount the needle on the luer-lock mount, screwing it tight until a slight counter-pressure is felt in order to ensure an airtight grip and prevent leakage of the liquid during administration.



STORAGE:
Store ALLEVYAL® at 2–25°C (36–77°F) in a dry place in the original box. Protect from light, heat and frost. Keep out of reach of children.

CONTENTS OF THE PACK:
Pre-filled syringe containing 2 ml or 4 ml of non-pyrogenic gel, sterilised using moist heath.

LAST REVISED:
September 2017

CE 1984

SYMBOLS

Consult instructions for use
Do not re-sterilise
STERILE Sterilised using steam
Keep dry
Keep away from sunlight
Store between +2°C and +25°C
Do not use if package is damaged
Do not reuse
Manufacturer
LOT Batch number
Use by

aerazen laboratories

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