ZOVYAL®

ZOVYAL 40 M® ZOVYAL 60 M® ZOVYAL 80 M®

2% Hyaluronic acid sodium salt for intra-articular use

INDICATIONS:
ZOVYAL M is a synovial fluid substitute which, thanks to its viscoelastic and lubricant properties, promotes the restoration of rheological conditions of the joints altered in patients with degenerative osteoarthritis. The product, improving the characteristics of the synovial fluid, exerts a protective action on the joints with a consequent improvement of the articular functionality and reduction of pain symptoms. ZOVYAL M acts only at the joint where it is injected, without exerting any systemic action.

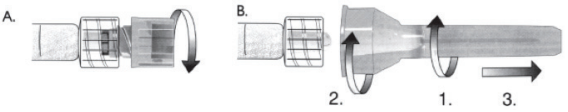
PRODUCT DESCRIPTION:
ZOVYAL M is a sterile, biodegradable, isotonic, injectable gel, for intra-articular use. ZOVYAL M consists of hyaluronic acid with a medium molecular weight (1,5-2,5 x 106 Dalton), obtained from Streptococcus equi bacteria, formulated to a concentration of 20 mg/ml in a physiologic buffer. ZOVYAL M 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 ZOVYAL M and a product leaflet. A set of two labels showing the batch number is contained in the box. One of these labels must be attached to the patient's file and the other must 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.

METHODS OF USE:
Remove any joint effusion before injecting ZOVYAL M.
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 must be treated with appropriate disinfectant. Inject ZOVYAL M adopting aseptic technique. Inject only into the intra-articular cavity. The use of ZOVYAL M is at the discretion of the doctor. ZOVYAL M must be used according to the needs of individual patients, the area and the pathology to be treated.

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 counterpressure is felt in order to ensure an airtight grip and prevent leakage of the liquid during administration.



WARNINGS - PRECAUTIONS FOR USE:
ZOVYAL M 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 must 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. 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.
CAUTION: the exterior of the syringe is not sterile.
Since ZOVYAL M has not been tested in pregnant or breastfeeding women, its use in such cases is not recommended. ZOVYAL M must not be used in patients under 18 years of age. Being ZOVYAL M 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. After use, dispose of the syringe into a suitable container according to current legislation.

SIDE EFFECTS:
There may be some temporary side reactions following injection of ZOVYAL M, 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 ZOVYAL M must be reported to a doctor. As for any intra-articular treatment, septic arthritis may rarely occur when general precautions for injections are not observed or the site of injection is not aseptic.

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

STORAGE:
Store ZOVYAL M 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 2ml (ZOVYAL 40 M), 3ml (ZOVYAL 60 M) or 4ml (ZOVYAL 80 M) of non pyrogenic gel, sterilised using moist heath.
ONLY FOR MEDICAL USE

LAST REVISED:
01/2020

SYMBOLS

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

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