# JALUPRO® HMW

HIGH MOLECULAR WEIGHT

**INJECTABLE FOR INTRADERMAL IMPLANT**

THE PRODUCT IS INTENDED ONLY FOR EXCLUSIVE USE OF MEDICAL PERSONNEL
Do not use for applications different from those reported in this package leaflet

## DESTINATION OF USE

JALUPRO® HMW is a medical device carried out according to Directive EEC 93/42 MDD.
It is indicated for the treatment of skin defects and depressions caused by wrinkles and scars.
It can be used concomitantly with physical or chemical treatments, such as peeling, laser-therapy and dermoabrasion.

## DESCRIPTION

JALUPRO® HMW is an injectable solution, sterile, re-adsorbable, which acts as filler, supporting the restoration of physiological conditions of elasticity and the temporary volume substitution by means of soft tissues growing.
The device acts as:
- tissutal lubricant, usable for minimising the evidence of skin furrows, acting as a filler
- as adjuvant in physical or chemical treatments, such as peeling, laser-therapy and dermoabrasion.

## COMPOSITION

WATER FOR INJECTABLE, SODIUM HYALURONATE, GLYCINE, L-PROLINE, L-LEUCINE, L-LYSINE HCL

## PACKAGING

The package contains:
- one glass syringe monodose / monouse, apyrogen, containing a sodium hyaluronate sterile gel.
- one glass bottle monodose / monouse containing a water solution of sterile aminoacids.
The package does not contain needles.

## MODE OF ACTION

It is an implantable medical device for:
- correction of imperfections and defects of skin tissues;

It is a filler for skin imperfections of mild to moderate entity, it is injected in the skin tissue to make up for the intercellular matrix and increase the volume in skins anatomically depressed, favouring the normalisation of imperfections.
The more marked defects reduce considerably its efficacy and duration.

## MODE OF USE

The package contains a pre-filled syringe (A) containing 20 mg of a sterile gel of sodium hyaluronate and a bottle (B) containing 80 mg of a sterile solution of aminoacids.
Use a sterile needle with standard attack Luer-Lock with normalised connectors.
The choice of the needle is competence of the physician performing the implant, according to the adopted technique.
Before the intradermal administration, the product should be reconstituted and the gel contained in the syringe (A) should be dissolved in the water solution (B).
Remove the syringe from the container, unscrew the syringe rubber cap to apply the needle. Take the needle with its protection, plug the needle on the device and remove the protection only before to perform the product reconstitution.
To reconstitute the product proceed as follows:
Using an aseptic technique, inject the gel contained in the syringe directly into the bottle containing the solution, using the needle. The needle used for this operation should be preferably disposed and not re-used for the injection.
After the addition of the gel, the content of the bottle should be reconstituted by shaking the bottle until an homogeneous and moderately viscous solution is obtained. Aspirate thereafter with the syringe the obtained solution, ready for use and change the needle.
The resulting solution is enough to allow an extractable volume of 2.5 ml for intradermal administration.
Inject the reconstituted solution following the modalities described at the following paragraph "Precautions for use" or according to the techniques chosen by the physician.

## PRECAUTIONS FOR USE

The product should be used only by physicians.
Before to start the implant it is necessary to sterilise the area to be treated, an anaesthetic cream can be used to apply about 30 minutes before the intervention or according to the specific indication of the chosen product. For injections in areas particularly sensitive of face or lips, a more effective anaesthetic approach may be adopted, such as a troncular injection.
After to have identified the intersection point, insert the needle along the furrow and recall gradually, realising in the meantime the gel.
After the injection of the product, perform, if necessary, a slight massage to model the treated area. The amount of material needed for the treatment changes according to the width and the depth of the area to treat.
For the correction of very limited defects, the papillar derma is typically the more indicated point where inject the material.
In case of marked defects the better result is in general obtained by injecting the solution in the central part until the deep one of the reticular derma. If necessary, this operation may be completed with a further, more superficial, injection.
To prevent any possible reddening and swelling and minimise the painfulness, it is advisable to avoid the insertion of excessive amounts of product and a slow injection is recommended.

## CONTRAINDICATIONS

Contraindicated in case of known hypersensitivity to the components.
Do not perform the implant in case of skin irritation and/or inflammatory processes in progress in the area to be treated.
Do not use in patients predisposed to coagulation disorders
No overdose effects are known.
No side effects are known.
No interactions are known with drugs and medicinal products.
Rarely local reaction may occur, caused by hypersensitisation phenomena which appear with oedema, heating sensation and/or itching; normally these reactions resolve spontaneously in a short time ( max two days ).
More rare may be the episodes of infection caused by the type of treatment, the technique and the environmental conditions.
Although no side effects are known, in case of pregnancy and lactation it is advisable to perform the application according to the physician's opinion, only after a careful anamnesis.

## WARNINGS

- The expiry is referred to the product unopened and correctly stored
- Do not use if the package is open or damaged
- Do not use after the expiry date
- Do not re-sterilise
- Do not freeze
- Do not use the content of the syringe separately from that of the bottle
- Do not use in case of known hypersensitivity to the components

## WARNINGS FOR THE PHYSICIAN

The physician should perform a careful anamnesis to ascertain the lacking of contraindications.
The physician should inform the patient, before to perform the implant, about methods of administration, warnings, precautions, possible reactions to the treatment, potential adverse reactions, effects and further interventions needed to maintain the results.

- The product is injectable by intradermic route. Do not use for different applications, do not inject in veins
- Use in aseptic environment, using the appropriate techniques
- Sterile product, do not use after the expiry date
- Do not re-sterilise
- Use just after the opening; the unused product should be disposed
- Do not mix with other implants and/or injectable products
- The product is monouse/mono-patient; to be used exclusively in a single session, the re-use of the reconstituted product (syringe A + bottle B) for other applications is forbidden
- The product is a monouse/mono-patient device, the re-use for distinct applications may be source of infections
- Apply the additional label, available into the package on the clinical folder of the patient (to be stored by the physician)
- keep out the sight and reach of children
- After the infiltration, to prevent any form of contamination, close carefully the needle with its cap and dispose as hospital waste.

## WARNINGS FOR THE PATIENT BEFORE THE IMPLANT

The performed tests demonstrated an high tolerability of the product, however rare local reactions could occur, as swelling and rash, which resolve spontaneously.
Do not expose the treated area to sources of heat till swelling reabsorption.
In case of adverse reactions following the injection, please contact your physician.
Warnings and Contraindications are reported in the relevant paragraphs.

## DOSAGE AND ADMINISTRATION

The graduation of the syringe is indicative.
The dosage is a choice of the physician performing the implant and depends on the general conditions of the patient, according to his evaluation.
Do not repeat the treatment before three days.
The implant should be performed following the rules of technique and asepsis prescribed for this mode of administration.
Repeat weekly, for four/six consecutive applications, or with different frequency according to the choice of the physician performing the implant.
The repetition of the treatment is left to the opinion of the physician.

## MODE OF DISPOSAL

Do not dispose in the environment.
The unused product should be disposed as hospital waste.

## STORAGE

JALUPRO® HMW should be stored at a temperature between 5° e 25° C.
Do not store in refrigerator. Do not freeze. Store in a cool and dry place, protect from moisture and sources of heat.

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