Super

REGENYAL

idea

CROSS-LINKED
HYALURONIC ACID

REGENYAL
LABORATORIES

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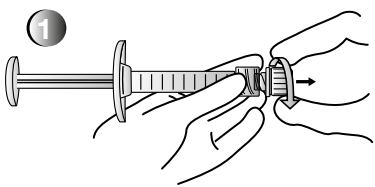

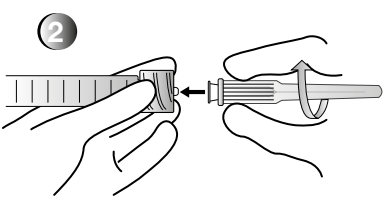

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The product is solely intended to be used by medical personnel. Do not use for applications other than indicated in this package leaflet.

DESCRIPTION

Regenyal Super Idea is a resorbable medical device (sterile, apyrogenic and physiological gel) to be used as filler for the correction of deep skin sagging on the face and to restore volume. The main component is cross-linked hyaluronic acid of non-animal origin, produced by bacterial fermentation.

COMPOSITION

Cross-linked hyaluronic acid .....25 mg/g
Phosphate buffered saline, water for injectable solutions ..... q.s. 1 g

PACKAGE 1x1ml

- package leaflet
- sealed blister containing 1 single-dose/single-use pre-filled sterile syringe
- adhesive tabs to be applied to the patient card for product traceability.
- 1 needle and 1 cannula

PACKAGE 3x1ml

- package leaflet
- 3 sealed blisters eachcontaining1 single-dose/single-use pre-filled sterile syringe
- adhesive tabs to be applied to the patient card for product traceability.
- 3 needles and 3cannulas

METHOD OF ACTION

Regenyal Super Idea is injected into the subcutaneous tissue for the supplementation of the extracellular matrix and to increase tissue volume, or for the treatment of cutaneous depressions due to wrinkles, scarring and hypo-volumes.

INTENDED USE

Regenyal Super Idea is a medical device produced in compliance with Directive 93/42/EEC MDD, intended for the treatment of imperfections in the following areas of the face:

- nasolabial folds
- acne or post-trauma scarring
- areas of the face requiring enrichment of the facial tissue (ex. cheeks, chin, cheekbones) with a temporary increase in volume of the soft tissues. The outcomes of the procedure depend on skin type and the nature of the blemishes, with results being better the less noticeable the nature of the defect.

DIRECTIONS FOR USE

Prior to any procedure with Regenyal Super Idea, the doctor must conduct adequate anamnesis and an overall assessment of the patient's condition, to ensure the absolute absence of contraindications to the implant.

The areas to be treated must be identified and assessed based on criteria to do with lines and symmetry one must adhere to.

The procedure may be performed under local anaesthesia in order to ensure the necessary comfort to the patient.

The physician should inform the patient beforehand on the methods of the procedure, its nature, warnings, precautions and possible individual outcomes, the potential adverse responses, the expected duration of treatment and the possible need for supplementary procedures for maintenance and/or detailed definition of the result achieved.

The area of the procedure should be cleaned with antiseptic solutions before injection.

Extract the syringe from the blister, remove the top as shown in the figure and screw the needle or the cannula to the luer-lock, complete with protection.

Only remove the cover just before performing the procedure.

Regenyal Super Idea is administered with a sterile needle-cannula compliant with Luer-Lock standards with standardised fittings, included in the package.

The injection should be performed in the superficial subcutaneous; the procedure is, however, at the physician's discretion and depends on the correction to be performed and the method implemented.

At the end of the procedure it is advisable to perform a gentle massage of the treated area for the product to be optimally distributed.

DOSE AND ADMINISTRATION

The volumetric markings on the syringes have indicative purposes, and the dosage to be used for the individual case is at the doctor's discretion.
The frequency with which to repeat the procedure depends on several factors, concerning both the patient's physiology (skin type, individual metabolism, anatomy, age) and lifestyle. Another factor to be taken into account is related to the chosen implant techniques. The procedure should be repeated periodically in order to maintain the results achieved, every 8 -12 months.

PRECAUTIONS

The usual precautions in case of percutaneous procedures must be taken during the procedure.
The risks are those of common infection related to the type of treatment.
Regenyal Super Idea must not be used on patients suffering from:
- infectious or inflammatory processes close to the area of the procedure
- known hypersensitivity to Keloids
- allergy to components
- immune system disorders
- chronic pathological skin condition
- conditions affecting the clotting factors or in the case of anticoagulant therapy in progress.

Around the time of treatment, the patient should avoid taking substances (Aspirin, NSAIDs, Vit. E) that act on blood fluidity, in order to reduce to the minimum the likelihood of bruising or bleeding of the injected areas. The use of Regenyal Super Idea is strictly excluded in areas where there are mammary, tendon, bone and muscle implants.
After treatment, and until swelling and redness go away completely, the implanted areas should not be exposed to make up, excessive heat (sun, UV tanning sessions, laser), or to intense cold.
After use dispose of needles and syringes according to the indicated procedures for hospital waste.

ADVERSE REACTIONS, WARNINGS AND CONTRAINDICATIONS

As is the case for percutaneous injections, there may be phenomena of:
- inflammatory reaction (redness, oedema, etc.), sometimes associated with itching and pain to the touch;
- haematomas;
- hardening or lumps at the injection site;
- skin colouring or discolouring at the injection site;

These phenomena generally resolve in a few days. Should they persist more than a week, the patient must promptly contact his/her doctor.
Regenyal Super Idea must be used intracutaneously and must not be injected into blood vessels.
No overdosage phenomena or interaction with medicinal products are known.
Do not use during pregnancy.
Regenyal Super Idea is available in sterile single use packages.
It is forbidden to reuse the content for subsequent applications or on other patients.
The product must be used immediately after opening.
Any unused product must be disposed of.
Do not use the product if the package is damaged.
Do not mix with other injectables, nor use other implants in conjunction with Regenyal Super Idea.
Perform the treatment in a suitable facility following the appropriate techniques.
Fill in the adhesive labels included in the package, then apply one on the patient card stored at the doctor's surgery and hand the other to the patient.
Keep away from the reach of children.
In rare cases, the product may cause an allergic reaction.

STORAGE METHODS

Regenyal Super Idea must be stored between 2°C and 28°C.
Do not freeze. Do not expose to heat sources.

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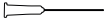
AGO/*NEEDLE* **23G x 19mm**



CANNULA/*CANNULA* **25G x 38mm**

CE 0123

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EC REP

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