ERELLE REVITAL

Filler for tissue augmentation based on Carboxymethyl Cellulose and Lidocaine

Manufacturer: **Bioitech S.r.l.** - Via Chiana, 87 - 00198 Roma

INSTRUCTIONS FOR USE

Composition

Slightly cross-linked carboxymethyl cellulose, lidocaine 0,3%,Buffered isotonic saline solution pH 7.

Description and presentation

Erelle™ is a sterile intradermal injection system, based on sodium carboxymethyl cellulose, a biosynthetic substance that is neither animal nor human in origin.

Erelle™ adopts a crosslinking process to improve its stay in the human body.

Erelle™ Revital is sold in disposable 5 ml vials. Each pack contains 3 vials, 6 disposable sterile needles 30 G.” for the injection of the product, a package insert and 3 traceability Labels containing the lot number of the device.

Indications

Erelle™ is a product intended exclusively for medical personnel trained in infiltration of materials for dermatological, reconstructive and aesthetic use (filling).

Erelle™ is fully biodegradable and slowly resorbable. A few sessions at regular intervals helps to maintain the result of the correction.

Erelle™ Revital with 30 G ½” needle, is suitable for:

restoring the water balance of the skin, the correction of very superficial wrinkles and treatment of acne sequelae.

Contraindications

Erelle™ cannot be used:

• for the treatment of periocular wrinkles

• for intravascular injection

• in association with peeling, laser, dermabrasion

• inpatients with tested hypersensitivity to product components

• in pregnant and nursing women

• on persons under the age of 18

• in patients with a proven tendency to develop hypertrophic scars

• on burnt skin or the skin of patients undergoing radiotherapy treated with acetylsalicylic acid and anticoagulants

• in the presence of inflammation or infection of thearea to be treated.

Side effects

The doctor must inform the patient about any undesirable side effects related to the implanting of Erelle™. Side effects may occur immediately after injection or after acertain period of time. Temporary erythemas in the infiltrated area, which resolve within 36 hours, are possible with useof the product.

Other side effects may include:

• inflammatory reactions and edemas, which may be associated with itching

• pain immediately after implanting

• hardening or nodules in the injection site

• coloration of the skin in the injection site

• low effectiveness of the treatment

• insufficient filling effect.

Furthermore, resorbable fillers have been associated on rare occasions with secondary phenomena such as: necrosis of the glabellar region, abscesses, fistulas and granulomas of the treated area.

The persistence of inflammatory reactions for more than 7 days or the occurrence of side effects other than those described should be promptly communicated to the physician,who will immediately report them to the distributor or manufacturer.

Precautions

Erelle™ is only suitable for intradermal and subcutaneous injections. Do not inject into an area that has already been injected with a non-resorbable filler or that has recently been treated.

The use of cosmetics containing alcoholic solutions is not recommended in the hours following the infiltration of Erelle™.

Exposure to sunlight, UV rays, intense cold and the use of saunas or steam baths should be avoided for 48h.

Prevent the contents of the vial from coming into contact with solutions based on Quaternary Ammonium.

The presence of a small amount of air in the vial is normal, and should not be considered as a sign of alteration in the product.

Throw away the device and the remains of the product after use.

Dosage and administration

The doctor’s mastering of injection techniques is essential for successful treatment. The patient must be informed about possible adverse effects that might arise and contraindications of the treatment.

The injection site must be thoroughly disinfected before treatment.

The product should be injected slowly with the needle supplied.

The amount of Erelle™ to be injected and the injection mode depend on the type of wrinkle to be treated.

It is advisable to massage the treated area after injection to spread the product more evenly within the tissues.

Overcorrection of the areas to be treated is not recommended.

Use of Erelle™ device:

• Open the package containing a Vial

• Remove the cap on the Vial

• Open the package containing a 30 G needle.

• Take the product with a 5 ml luer-lock syringe and a 23 G - 22 G needle(not included in the package)

• Remove the 23 G - 22G needle from the syringe

• Screw the needle clockwise on the luer-lock connector of the syringe containing the product

• Remove the needle cap

• Push the syringe plunger to remove air until the increase in resistance to pressure is felt

• Apply the product by multiple injections after having thoroughly disinfected the area to be treated.

Warnings and storage conditions

• **This product is for the exclusive use of trained medical personnel**

• Follow the instructions for use

• Check the integrity of the package and the vial before use

• Check the expiration date on the package

• Do not use the product after the expiration date

• Do not resterilize

• Use the contents of the vial and the needle on a single patient

• Do not reuse

• Used needles should be discarded in special containers

• Keep away from high and low temperatures

• Avoid sun exposure

• Avoid knocks

• Store between 8°C and 25°C.

Package: 3 disposable 5 ml vials, 6 disposable 30 G” sterile needles.