HYLEXXA® Soft

Hyaluronic acid dermal filler



Hylexxa Soft is recommended for addressing minor to moderate skin depressions due to its specific formulation, which provides suitable rheology and elasticity properties. It can be used in areas around the mouth, around the eyes, frown lines, nasolabial folds, under the eyes, as well as between the eyebrows.

Product information

Instructions

Instruction:

Hylexxa® Soft is a sterile, non-pyrogenic, biocompatible, and biodegradable cross-linked hyaluronic acid gel, which is not of animal origin. The product contains Lidocaine, which helps to reduce pain during and after the injection.

Composition:

- Cross-linked Hyaluronic Acid — 22 mg/1.1 ml
- Lidocaine Hydrochloride — 3.3 mg/1.1 ml
- Phosphate Buffer pH 7 q.s. — 1.1 ml

It is presented in one single-use pre-filled syringe (PFS) sterilized by moist heat. Each package contains one instruction leaflet, one syringe, two traceability labels, and two disposable 30G1/2 needles sterilized by radiation.

Indications:

The product is an injectable implant for the filling of fine to moderate cutaneous wrinkles including:

- Perioral

- Periorbital
- Frown line
- Crow's feet
- Tear trough
- Glabella

How to Use

Mode of Administration:

Hylexxa® is a filling gel injected into the subcutaneous or deep dermis layer by authorized physicians Who have appropriate training and experience in injection techniques for volume restoration.

- Disinfect the area before injection.
- Remove the air by gently pushing down on the plunger to make a small amount of the product appear at the tip of the needle.
- Inject slowly and apply the least amount of pressure necessary.
- If the needle is blocked, do not increase the pressure on the plunger rod, instead, stop the injection and replace the needle.
- After needle insertion and before injection, it is recommended to withdraw the plunger slightly to aspirate and verify the needle is not intravascular.
- If immediate blanching occurs at any time during the injection, the injection should be stopped, and appropriate action such as massaging the area should be taken until it returns to normal color.
- The degree and duration of the correction depend on the character of the defect treated, tissue stress at the site, the depth of the implant, and the injection technique. The amount injected will depend on the areas which are to be corrected based on the experience of the medical practitioner.

Direction for assembly:

For optimal use of Hylexxa® products, it is essential that the needle is properly assembled to the syringe. See figure.

- STEP 1: Remove the tip cap: Hold the syringe, and pull the tip cap off, as shown in Figure A.
- STEP 2: Insert needle, hold the syringe body, and firmly insert the hub of the needle into the Luer-lock end of the syringe.
- STEP 3: Tighten the needle by turning it firmly in a clockwise direction (see Figure B) until it is seated in the proper position, as shown in Figure C.

NOTE: If the position of the needle cap is as shown in Figure D, it is not attached correctly. Continue to tighten until the needle is seated in the proper position.

STEP 4: Remove the needle cap, and hold the syringe body in one hand and the needle cap in the other. Pull in opposite directions to remove the needle cap without twisting, as shown in Figure E.

Post-injection care:

- Do not apply anything to the skin until the day after treatment: No cleanser, moisturizer, or makeup.
- It is strongly advised to avoid any extended exposure to sunlight.
- It is recommended to avoid UV radiation, extreme hot and cold water for two weeks following the injection treatment.

- It is recommended that the patient avoid massaging the implantation area and/or putting pressure on it for a few days following the injection treatment.
- After the injection, you can use a cold-water compress if the physician recommends it.
- Sleep in an elevated position for 24 hours after the treatment.
- Avoid heavy sports.
- To reduce inflammatory reactions, avoid injecting the vaccine one month before and after the injection.
- Avoid bathing with very hot water and sauna for a week after the injection.

Side effects:

- The patients must be informed about potential side effects associated with using this product, which may occur immediately or may be delayed.

These include, but are not limited to:

- Inflammatory reactions due to the injection
- Edema
- Swelling
- Erythema
- Hematoma
- Itching
- Redness
- Bleeding
- Urticaria
- Pain or tenderness at the injection site
- Induration or nodules at the implant point
- Cutaneous necrosis
- Dyschromia at the injection site

Patients must report inflammatory reactions which persist for more than one week, or any other side effect which develops to their physician as soon as possible.

- Any other adverse effects should be reported to the product's representative or its local distributor.

Storage condition:

It should be stored in a dry and cool place, at a temperature below 30°C, out of the refrigerator and away from frost and heat. It should also be kept out of the reach of children.

Contraindications

Contra-Indications:

It should not be used:

- In periorbital and glabellar area.
- For breast augmentation or bone, tendon, ligament, and muscular implantation.
- In intravascular injections.

Do not inject in cases of:

- Known hypersensitivity to any of the product's components and/or gram-positive bacterial proteins by Streptococcus type bacteria.
- Laser, skin peeling, and ultrasound-based treatment.
- Inflammatory or infectious cutaneous problems (acne, herpes, etc.)

The product is intended for single use only. Do not reuse it.

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