AU

Lidocaine

e.p.t.q.

S 100
S 300
S 500

epitique

IMPLANT, HYALURONIC ACID GEL WITH LIDOCAINE

[COMPOSITION]

Cross-linked sodium hyaluronate	24mg/ml
Lidocaine hydrochloride	3mg/ml
Phosphate buffered saline	q.s.

[DESCRIPTION]

e.p.t.q. Lidocaine is a sterile, non-pyrogenic, viscoelastic, colourless, transparent gel composed of cross-linked sodium hyaluronate gel of non-animal origin with 0.3% lidocaine hydrochloride in a physiologic phosphate buffer.

[INDICATIONS]

e.p.t.q. Lidocaine is intended to be used for the correction of nasolabial folds. The product is for cosmetic use only. The addition of lidocaine provides a pain-relieving effect during treatment. .

[CONTRAINDICATIONS]

- e.p.t.q. Lidocaine is contraindicated:
  - in patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies,
  - in patients with history of facial keloid formation or hypertrophic scar,
  - in patients with known hypersensitivity to one of the product's components, especially to sodium hyaluronate, local anesthetics of the amid type, such as lidocaine,
  - in patients presenting with porphyria,
  - in pregnant or breastfeeding women,
  - in young patients under 18 years old,
  - in patients with active (or a history of) autoimmune disease.
- e.p.t.q. Lidocaine contains trace amounts of gram positive bacterial proteins and is contraindicated for patients with a history of allergies to such material.

[WARNINGS]

- Do not use where there is active disease, such as inflammation, infection or tumours, in or near the intended treatment site.
- Do not inject into the periorbital region (eyelids, under-eye dark circles, crow's feet) or glabella region as there is risk of ocular ischaemic events leading to loss of vision.
- Do not inject intravascularly. Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction.
- Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures.
- Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure.
- Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.
- Do not use in patients with:
  – a history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement),
  – bleeding disorders or in patients who are taking thrombolytics or anticoagulants. or inhibitors of platelet aggregation in the preceding 2weeks,
  – receiving medical treatment that reduces or inhibits liver metabolism (cimetidine, beta blockers).
- Do not inject this product into an area where an implant other than hyaluronic acid has been placed.
- Do not resterilize.
- Do not mix with other products.

[PRECAUTIONS]

General considerations relevant to injectable medical devices

- As with all transcutaneous procedures, product implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection, such as, plastic surgeons and dermatologists.
- Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.
- Knowledge of the anatomy of treatment site and special caution are required in order to avoid perforation or compression of vessels, nerves and other vulnerable structures.
- Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent crossinfections are to be observed.
- Special caution should be exercised when treating areas with limited collateral circulation, due to increased risk of ischemia.
- Special caution should be exercised in treating facial areas with limited soft tissue support or soft tissue cover, such as the periorbital area, to avoid formation of palpable lumps.
- Patients with pre-existing pigmented dark lower eye lid circles, thin skin and pre-existing tendency toward oedema formation are not suitable candidates for treatment of the lower periorbital region.
- Patients using immunosuppressants are not suitable candidates for treatment.
- Special caution should be exercised in treating patients with a tendency to form hypertrophic scars or any other healing disorders.
- Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.
- Patients who are using substances that affect platelet function, such as aspirin and nonsteroidal anti-inflammatory drugs or high dose vitamin C may, as with any injection, experience increased bruising or bleeding at injection sites.
- Patients with unattainable expectations are not suitable candidates for treatment.
- Check the integrity of the inner packaging and the expiry date for both syringe and the needle prior to use. Do not use beyond the expiry date or if package is opened or damaged.
- In case of re–use, this can cause to depress performance of the product and may lead to severe cross–infection.
- After use, syringes, remaining product and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, state and federal requirements.

Specific considerations relevant to the use of this product

- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine is used concurrently . High doses of lidocaine can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction. The recommended maximum adult dose of lidocaine for dermatology local anesthesia is 3.0 mg/kg (max : 200mg).
- Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide–type local anaesthetics e.g., certain antiarrhythmics, since the systemic toxic effects can be additive.
- Lidocaine should be used cautiously in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.
- Practitioners and athletes should consider that lidocaine may produce positive results to anti-doping tests.
- It should be noted that the presence of lidocaine may cause local redness or hypersensitivity.
- 0.3% lidocaine injection has no reported effect on driving and operating machinery.
- If the product is injected too superficially this may result in visible lumps and/or bluish discoloration.
- The patient should avoid applying makeup for at least 12 hours after treatment and to avoid prolonged exposure to sunlight, UV, as well as extreme cold and heat for two weeks after the injection. Patients should also avoid putting pressure on and/or handling the treated area.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is performed after treatment with this product there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if the product is administered before the skin has healed completely after such a procedure.
- The product is a clear, colorless gel without particulates. In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe and notify the manufacturer.
- Glass is subject to breakage under a variety of unavoidable conditions. Care should be taken with the handling of the glass syringe and with disposing of broken glass to avoid laceration or other injury.

[INCOMPATIBILITY]

Sodium hyaluronate precipitates in the presence of quaternary ammonium salts, such as benzalkonium chloride. It is therefore recommended that the product does not come into contact with such substances. There is no known interaction with other local or loco-regional anesthetics.

[ADVERSE EVENTS]

Patients must be informed of the potential risks and adverse events related to the injection procedure and to the use of this product.
A slight bleeding may occur during the injection, and it disappears spontaneously as soon as the injection is finished. In occasional cases one or more of the following may occur either immediately or as a delayed reaction (list not exhaustive):

- Reactions usually associated with injections such as redness, erythema, oedema or pain sometimes accompanied by itching in the treated area. These reactions may last for a week.
- Hematomas in the treated area,
- Swelling in the treated area,
- Indurations or nodules in the treated area,
- Coloration or discoloration in the treated area,
- Poor effect or weak filling effect,
- Allergy to one of the product's components, especially to sodium hyaluronate. and lidocaine hydrochloride.
- Cases of necrosis, abscesses and granulomas after sodium hyaluronate injections have been reported in the literature. These rare potential risks must nevertheless be considered. Patients should be instructed to report any side effects which last for more than one week to his/her practitioner. The practitioner may then prescribe the patient appropriate treatment. Any other undesirable side effects associated with injection of the product must be reported to the distributor and/or to the manufacturer.

[TREATMENT PROCEDURE]

Before the treatment, patients should be informed of the indications of the product as well as its contraindications and potential adverse events. For successful treatment it is essential that the practitioner has received a specific training on the injection techniques for soft tissue augmentation. A good knowledge of the anatomy and physiology of the site to be treated is required. The treatment must be carried out under appropriate aseptic conditions. The product must be injected into a healthy, non-inflamed and previously rigorously disinfected skin. It is recommended to use one of the supplied needles, as a smaller needle diameter should require a greater force to inject the implant. Aspiration before injection should be performed to prevent a vascular injection.
If the needle becomes obstructed and the injection pressure becomes too high, stop the injection and change the needle.
The product should be injected slowly. The quantity of gel to be injected depends on the area to be treated and the correction to be achieved. Do not over-correct. If blanching is observed, i.e. the skin turns a white color, the injection should be stopped immediately and the area massaged until it returns to a normal color. Gently massage the treated area after the injection to distribute the product uniformly.

[ASSEMBLY OF NEEDLE TO SYRINGE]

For safe use of the product, it is important that the needle is properly assembled to the syringe. Improper assembly may result in separation of the needle and syringe during injection. See diagram 1, 2 and 3.
1. Firmly hold the white colored ribbed part of the Luer-lock adaptor of the syringe between the Thumb and the index fingers. Break the protective cap at 90° and remove it with the other hand.
2. Keep holding the luer-lock, firmly push and screw the needle on the syringe clockwise until a resistance is felt. Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level.
3. Next, remove the protective cap from the needle by holding the luer-lock in one hand, the protective cap in the other, and pulling the two hands in opposite directions.

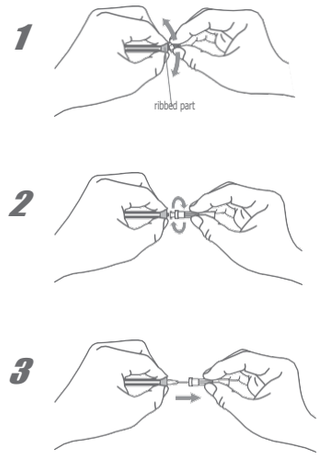
[SHELF LIFE AND STORAGE]

Expiry date is indicated on each package.
Shelf-life is 24months from the date of manufacture.
Store between 2°C-25°C, and protect from direct sunlight and freezing.

[SYMBOLS USED ON LABELING]

- Date of manufacture
- Manufacturer
- Use by date
- Batch code
- European Community Authorized Representative
- Do not re-use
- Do not use if package is damaged
- Caution, consult accompanying documents
- Temperature limitation
- Fragile, handle with care
- Keep away from rain
- Keep away from sunlight
- Sterilized using steam (Syringe)
- Needle
- Do not resterilize
- Sterilized using ethylene oxide (Needle)
- Consult instructions for use

[DIAGRAM]



Manufacturer of Needles

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1639 needles

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