STYLAGE® EN
S Lidocaïne

COMPOSITION

• Cross-linked (BDDE) hyaluronic acid	16 mg
• Lidocaine hydrochloride	3 mg
• Phosphate buffer and mannitol (35 g/L) - pH 7.2 q.s	1 g
• 0.8 ml pre-filled syringe	

DESCRIPTION

Stylage® S Lidocaïne is a cross-linked hyaluronic acid gel of non-animal origin, incorporating an antioxidant (mannitol). It is sterile and non-pyrogenic, with physiological pH and osmolarity.
The gel is packaged in a 0.8 ml pre-filled syringe and sterilised using autoclave. **Stylage® S Lidocaïne** is for single-use. Each box contains two 0.8 ml pre-filled syringes, four single-use sterile needles, one instruction leaflet and labels with the batch number - one of which must be given to the patient while the other is attached to the doctor's patient file.

INDICATIONS

Stylage® S Lidocaïne is a hyaluronic acid injectable gel designed to fill skin depressions on the face (i.e. treatment of nasolabial folds) by injection into the dermis.
Lidocaine hydrochloride is intended to reduce the pain associated with the injection.

MODE OF ACTION

Stylage® S Lidocaïne must be injected into the area to be treated, where it will generate volume by filling the injected area. **Stylage® S Lidocaïne** will then be resorbed slowly over time. The duration of the product depends on the patient's skin type and the depth of injection. Thus, based on the characteristics of the area treated, the patient, and the depth of the injection, one to two injection sessions are necessary for optimal treatment of the aesthetic defect. Through regular touch-up sessions, it will be possible to make the desired correction more durable.

CONTRAINDICATIONS

Stylage® S Lidocaïne must not be used:
- In combination with a peeling, laser treatment, or dermabrasion. The practitioner shall decide upon the necessary waiting period after these treatments before the injection;
- In patients with a tendency to develop hypertrophic scars;
- In patients with known hypersensitivity to one of the ingredients or amide-type local anaesthetics;
- In women who are pregnant or breastfeeding or in children;
- In areas, or near areas, with inflammatory or infectious skin problems (acne, herpes, etc.);
- In patients with porphyria.

PRECAUTIONS FOR USE

- It is strongly recommended to obtain the patient's informed consent prior to treatment.
- If the patient has a history of herpes, there is a risk that needle punctures may trigger a new episode of herpes.
- For patients with a history of, or who are currently suffering from an autoimmune disease, the practitioner must decide on the indication on a case-by-case basis, based on the nature of the illness and the associated treatments. The practitioner must also ensure special monitoring of these patients, which includes offering a double test before injection, and he/she must not perform the injection if the illness is progressive.
- Patients with a history of streptococcal disease, such as recurrent sore throat or acute rheumatic fever, must undergo a double test before any injection. The injection is not recommended in cases of acute rheumatic fever with cardiac localisation.
- Combining **Stylage® S Lidocaïne** with certain medications that reduce or inhibit hepatic metabolism is not recommended.
- In case of haemostatic disorder or anticoagulant treatment, the risk of haematoma is increased.
- The intake of aspirin, NSAIDs, platelet aggregation inhibitors, anticoagulants, or vitamin C during the week preceding the injection should be avoided.
- **Stylage® S Lidocaïne** must not be injected into the blood vessels. Any accidental intravascular injection may cause vascular occlusion, which can lead to rare but serious complications such as vision disorders, blindness, necrosis of the skin and/or underlying tissues, depending on the area injected.
- **Stylage® S Lidocaïne** must not be injected into the nerves. Any accidental nerve damage may cause transient paresthesia.
- It is not advised to inject implants from the **Stylage®** product line into an area that has already been corrected using implants from a product line other than **Stylage®** as no clinical data is available.
- It is advised not to mix it with another product.
- Only the needles provided with **Stylage® S Lidocaïne** should be used for the injection, as the combination of these two devices has been validated.
- Inject slowly to avoid overcorrections.
- In case of increased pain during injection, stop the procedure and withdraw the needle.
- Do not use if the packaging has been damaged (syringe, blister pack, lid).
- Inject immediately after opening.
- Discard the syringe and the residual product when the injection is complete, and dispose of the needles in an appropriate container, in accordance with the current national regulations.
- The **Stylage® S Lidocaïne** implant is for single-use. Do not reuse.
  An implant must be used only for one single patient to prevent any risk of cross-contamination.
- After opening, the product can never be re-sterilised, even if the implant has not been injected.
- **Stylage® S Lidocaïne** contains an active ingredient, lidocaine hydrochloride, which can induce a positive result in tests performed in anti-doping controls.

DOSAGE - METHOD OF ADMINISTRATION

- The treatment should be carried out by a legally qualified practitioner, trained in implant injection techniques and with good knowledge of the anatomy of the face and the injection planes. The practitioner should also consider the presence of lidocaine hydrochloride in **Stylage® S Lidocaïne**. The practitioner chooses the product to inject based on the anatomy of the area and the desired effect.
- **Stylage® S Lidocaïne** is recommended for injection into the superficial to middle dermis of the face.
- Before carrying out the treatment, it is essential:
  - to thoroughly confirm the patient's medical history with her/him;
  - to explain the indications and expected results of **Stylage® S Lidocaïne** to the patient;
  - to explain the contraindications, precautions for use, and potential adverse effects related to the treatment with the patient as well as the "advice to patients".
- Before injection:
  - disinfect the area to be treated with an appropriate antiseptic solution;
  - verify the integrity of the needles;
  - verify that the gel is not cloudy.
- In the event of refrigerated storage, bring the product to room temperature before injection.
- Screw the needle firmly onto the Luer Lock hub of the syringe.
- Observe the aseptic and handling rules related to this type of intervention.
- Methods of injection:
  - Slowly inject into the recommended area, using the sterile needle provided. It is recommended to use the technique of linear threading injection, multipoint injection, or a combination of both techniques. If an injection is too deep, the effectiveness of the correction will be reduced. If an injection is too superficial, discolouration of the skin or slight indurations may appear or the correction may be irregular.
- The amount to be injected depends on the skin defect to be corrected. Only the practitioner can define the dose to be injected for obtaining an optimal correction.
- Do not overcorrect. In the event of overcorrection, small indurations or irregular correction may appear.
- It is advised not to inject more than 20 ml of cross-linked hyaluronic acid per person per year.
- If the needle is blocked, do not increase the pressure required for injection. Replace the needle.
- After the injection, do not apply a cold pack; massage the treated area well in order to optimise the uniformity of the correction.

ADVICE TO PATIENTS

- Recommend using a sunscreen with a high protection factor during the two weeks following treatment.
- Advise the patient not to wear make-up during the 12 hours following the injection and avoid exposing the treated area to intense heat (UV, sauna, steam room) or extreme cold, at least until any potential post-injection swelling or redness disappear.
- The practitioner should tell the patient that he/she must keep him informed of any "abnormal" developments in the treated area (see adverse effects).

ADVERSE EFFECTS

The practitioner must inform the patient of any potential immediate or delayed adverse effects that may occur following injection of **Stylage® S Lidocaïne**, in particular (this list is not exhaustive):
- Inflammatory reactions such as redness, oedema, or erythema, potentially associated with itching and/or pain at the injection site, which usually resolve in less than a week.
- Haematomas.
- Induration or nodules, colouration or discolouration in the injected area.
- Poor efficacy or a weak filling effect.
- Local mobility of the implant.
- Rare cases of necrosis, abscesses, granulomas and hypersensitivity have been reported in literature following injections of hyaluronic acid. The patient must be informed about this.
- In patients who have a severe predisposition to allergies, dermatological disease, haemostasis disorder, or inflammatory disease, or in the event the precautions for use have not been observed, the incidence of adverse effects may increase.
- The patient must inform the practitioner of any adverse effects mentioned above that lasts for more than one week, or the appearance of any other adverse effect. The practitioner must report it to the reseller or manufacturer as soon as possible and should carry out an appropriate care.

STORAGE - EXPIRY DATE

- **Stylage® S Lidocaïne** must be used before the expiration date indicated on the packaging and on the syringe.
- **Stylage® S Lidocaïne** must be stored in its original packaging, at a temperature between 2°C and 25°C [36°F and 77°F], away from frost and light.
- If storage conditions are not observed, the product's performance can be compromised.

1. Remove the end cap of the syringe carefully.

2. Hold the ring at the end of the syringe and firmly insert the hub of the needle into the Luer-lock end of the syringe, by screwing until you feel some **strong counter pressure**.

3. Remove the needle cap.

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Caution: Consult the instruction leaflet.	Expiry date. Use before the date shown.	Batch code.	Do not reuse.	Sterilised using steam or dry heat. Syringe contents have been sterilised using moist heat.	Sterilised using irradiation. Needles/cannulas have been sterilised using irradiation.	Sterilised using ethylene oxide. Needles/cannulas have been sterilised using ethylene oxide.			
Sterile fluid pathway. Syringe contents have been sterilised using moist heat.	Temperature limits. Store between 2°C and 25°C (35.6° F and 77° F).	Keep away from sunlight.	Fragile, handle with care.	Do not use if package is damaged.	Manufacturer.	RFID-based remote authentication system for VIVACY products (Radio Frequency Identification).	The CE marking was obtained in compliance with Directive 93/42/EEC relating to medical devices. Stylage® S Lidocaine obtained CE marking in 2009. 0344 corresponds to the number of the Notified Body.	Patented cross-linking technology.	Injection system with a bi-material technology and patented ergonomics.

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