

Disclaimer:

The contents of this file are pictures of informational inserts found in the original manufacturer packaging of BELOTERO® SOFT LIDOCAINE. The content published on the inserts is NOT published or authored by Medica Depot and is NOT the property of Medica Depot. All information found on the inserts is published by the manufacturer or the corporation designated on the inserts themselves. All trademarks contained herein belong to the trademark holders and Medica Depot is not operated by, supported by or affiliated with them.



Description

BELOTERO Soft Lidocaine is a sterile, non-pyrogenic, viscoelastic, colourless, transparent gel of cross-linked sodium hyaluronate of non-animal origin, in a physiological phosphate buffer. BELOTERO Soft Lidocaine contains 0.3% of lidocaine hydrochloride.

Presentation

BELOTERO Soft Lidocaine is presented in a 1 ml sterile glass syringe for single use, sterilized by moist heat. Each box contains two sterile CE-marked hypodermic needles of 30G½ (0.3x13mm), two traceability labels and instructions for use. To ensure optimal use of the product, it is recommended to use the needles provided in the box.

Composition

Cross-linked sodium hyaluronate:	20.0 mg
Lidocaine hydrochloride:	3.0 mg
Phosphate buffer solution q.s.:	1.0 ml

The gel is latex-free, bisphenol-A-free and phthalates-free.

Indications

BELOTERO Soft Lidocaine is an injectable resorbable filler indicated to increase the volume of skin tissue. This filler enables filling fine lines (e.g. perioral and forehead lines, crow's-feet, lip commissures) and correcting scars. The presence of lidocaine aims to reduce local pain associated with the injection of the gel and to improve patient comfort.

Mode of action

BELOTERO Soft Lidocaine is a filler used for dermal tissue augmentation, thereby filling skin depressions. The tissue augmentation capacity originates from the mechanical behavior of the gel that lifts up the skin and compensates age or injury-related loss of volume. The gel is made of cross-linked sodium hyaluronate in a physiological phosphate buffer, and will over time undergo slow resorption thanks to a better resistance to degradation.

Posology and administration method

BELOTERO Soft Lidocaine is designed to be injected into the superficial to mid-dermis by a legally approved practitioner. For successful treatment it is essential that the practitioner has received prior training in the injection technique for increasing the volume of skin tissues. The treatment must be carried out under appropriate aseptic conditions. This product has been designed for use in physician's office. BELOTERO Soft Lidocaine must be injected into a healthy, non-inflamed, disinfected skin.

To ensure optimal use of BELOTERO Soft Lidocaine, it is recommended to assemble the needle according to diagrams 1-4.

Start the injection pointing the needle bevel downwards.

BELOTERO Soft Lidocaine may be injected into the superficial dermis using serial punctual injections, the linear retracing technique, anterotracing (push ahead) technique, cross-hatching technique (blanket), fan distribution technique, blanching technique, multi-puncture and micro-papular injection techniques. BELOTERO Soft Lidocaine may be used in combination with other BELOTERO fillers respecting the correct depth of injection and indication for each product.

Do not over-correct. After the injection, the practitioner can massage gently in order to distribute the product uniformly.

Depth of injection

For best performance of the product, BELOTERO Soft Lidocaine should be injected into the superficial dermis.

Contra-indications

BELOTERO Soft Lidocaine is contra-indicated in case of:

- In cases of known hypersensitivity to one of the product's components, especially sodium hyaluronate, lidocaine hydrochloride or to amide-type local anesthetics;
- In pregnant or breast-feeding women
- In young people less than 18 years old

Precautions for use

Before treatment, the patient must be informed about the device, its contra-indications and possible side effects.

- Do not inject BELOTERO Soft Lidocaine to increase the volume of the breasts.
 - Do not inject BELOTERO Soft Lidocaine in the bones, tendons and ligaments.
 - Do not inject BELOTERO Soft Lidocaine into areas presenting cutaneous problems of inflammatory or infectious type (acne, herpes, etc.). Patients suffering from rosacea should be informed that the treatment may increase the visibility of the rosacea.
- Special care applies when using BELOTERO Soft Lidocaine in order to avoid injecting the gel into blood vessels as inadvertent intravascular injection, in particular in the glabella area, could potentially lead to local vascular occlusion, ischemia and necrosis. In the absence of available clinical data on tolerance on the injection of BELOTERO Soft Lidocaine in patients with antecedents or with an active autoimmune disease or presenting history of severe multiple allergies or anaphylactic shock, the practitioner must decide whether to inject BELOTERO Soft Lidocaine on a case-by-case basis depending on the nature of the disease as well as the associated treatment. It is recommended to propose a prior double test on these patients and to not inject if the disease is active or evolving. It is also recommended to carefully monitor these patients after injection.

Patients with a history of streptococcal diseases or in patients pre-disposed to hypertrophic scars or cheloids should also discuss about these conditions with the practitioner before proceeding with the aesthetic treatment.

Patients using anti-coagulant or anti-thrombolytic substances like aspirin or non-steroidal anti-inflammatory medications may have increased reactions of hematomas or bleeding at the injection site. Special care should apply in patients suffering from severe bleeding disorders.

In cases of patients suffering of epilepsy, impaired cardiac conditions, severely impaired hepatic function or severe renal dysfunction or porphyria, the practitioner must decide whether to inject BELOTERO Soft Lidocaine on a case-by-case basis depending on the nature of the disease as well as the associated treatment.

It is recommended not to inject BELOTERO Soft Lidocaine into the periorbital region without prior specific training and a good knowledge of the anatomy of the area.

BELOTERO Soft Lidocaine must not be used in immediate association with other aesthetic medicine techniques such as peeling, dermabrasion, or any type of laser treatment, except for other products of BELOTERO range. In all cases, even if the complete healing of the last treatment occurs earlier, BELOTERO Soft Lidocaine must not be used earlier than 2 weeks after the last treatment.

No clinical data are available on the combined use of BELOTERO Soft Lidocaine with the above-mentioned treatments. No clinical data is available on the injection of BELOTERO Soft Lidocaine into an area already treated with other filling products not belonging to BELOTERO range. BELOTERO Soft Lidocaine should not be injected into an area treated with a permanent or semi-permanent implant.

It has to be considered by practitioners and athletes that lidocaine may produce positive results in anti-doping tests.

It should be noted that the presence of lidocaine may cause local redness or hyper-sensitivity.

For normal healthy adults, it is recommended that the maximum total dose of lidocaine HCl (without epinephrine) does not exceed 300 mg (or 4.5 mg/kg) per session. Overdosage of lidocaine HCl usually results in sign of the central nervous system or cardiovascular toxicity.

When using concurrently lidocaine in different application forms (e.g. topical administration), the total administered dose should be considered. The concomitant use of other local anesthetic agents or agents structurally related to amide-type local anesthetics should also be considered since the systemic toxic effects may be additive. Care should be taken for patients with congenital methemoglobinemia, with glucose-6-phosphate dehydrogenase deficiencies and patients who are receiving concomitant treatment with methemoglobin-inducing agents.

Check the integrity of the inner packaging prior to use, and the expiry date for both the syringe and the needle. Do not use these products if the expiry date has lapsed or if the packaging has been opened or damaged.

Needle has to be handled with care after removal of its protective shield.

If the needle becomes obstructed and the injection pressure becomes too high, stop the injection and change the needle.

Do not transfer BELOTERO Soft Lidocaine into another container and do not add other substances to the product unless no recommendation exists.

Only the gel is sterile, but not the outside of the syringe. The outside walls of the syringe must not be put in direct or indirect contact with the injection site or the needle.

BELOTERO Soft Lidocaine must not be used with an automated injection system not recommended by Merz. If an automatic system is used, it is recommended that

the practitioner has already read the injection system's instructions for use and been trained in using this system.

Patient label is to be attached to patient records to ensure traceability of the product.

Do not recap the needle at the end of the injection session and discard it with the syringe and with the remaining product after use. Disposal should be in accordance with the accepted medical practice and current applicable directives to ensure their correct elimination.

Do not re-sterilize and do not reuse, due to the associated risks including infection.

The patient should avoid applying makeup for at least 12 hours after treatment and avoid exposure to heat (saunas, Turkish baths, etc.), UV rays or massage and prolonged exposure to the sun for 2 weeks after the treatment.

Incompatibilities

Sodium hyaluronate precipitates in the presence of quaternary ammonium salts (such as benzalkonium chloride). It is therefore recommended that BELOTERO Soft Lidocaine does not come in contact with such substances.

There is no known interaction with other local or loco-regional anesthetics.

Side effects

Possible side effects exist and must be described to the patient by the practitioner before treatment. Very slight bleeding may occur during the injection although this 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 like redness, erythema, edema, pain, burning sensation, sensitivity, sometimes accompanied by itching or stinging in the treated area. These reactions usually 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,
- Allergy to one of the product's components, especially 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 taken into account.

It is recommended that the patient report any undesirable effects lasting more than a week to his/her practitioner. The practitioner may then prescribe the patient appropriate treatment.

Assembly of needle to syringe

For optimal use of BELOTERO Soft Lidocaine, it is important that the needle is properly connected to the syringe. Improper assembly may result in separation of the needle and syringe during injection and/or product leakage at Luer-lock level. See diagrams 1, 2, 3 and 4.

1. Firmly hold the glass cylinder of the syringe and the Luer-lock adaptor between the thumb and the index fingers.
2. With the other hand, grasp the protective cap and unscrew it.
3. Push & Twist the needle on the syringe until a resistance is felt. Do not overtight. Overtight of the needle may lead to the Luer-lock moving and dislodging from the syringe.
4. Keep holding the Luer-lock and remove the sheath from the needle.

Storage

Store between 2°C and 25°C. Protect from light and freezing. Avoid mechanical shocks.