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GB INSTRUCTIONS FOR USE FOR BELOTERO® INTENSE LIDOCAINE

Description
BELOTERO Intense 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 Intense Lidocaine contains 0.3 % of lidocaine hydrochloride.

Presentation
BELOTERO Intense 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 27G½ (0.4 x 13 mm) and two traceability labels as well as 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:	25.5 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 Intense Lidocaine is an injectable resorbable filler indicated to restore or increase the volume of skin tissue. This implant enables filling of folds and deep wrinkles as well as significant volume enhancement of the desired areas (e.g. reliefs and contours of the face, lip volume). 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 Intense 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
This device is designed to be injected into the deep dermis by a legally approved practitioner. For successful treatment it is essential that the practitioner has received prior training in the injection technique for soft tissue augmentation. The treatment must be carried out under appropriate aseptic conditions. This product has been designed for use in physician's office.
BELOTERO Intense Lidocaine must be injected into a healthy, non-inflamed, disinfected skin. To ensure optimal use of BELOTERO Intense Lidocaine it is recommended to assemble the needle according to the diagrams 1-4. Start the injection pointing the needle bevel downwards.
The use of the included 27G½ needles is required, because a lower diameter would require greater force when injecting the implant.
BELOTERO Intense Lidocaine may be injected into the deep dermis using serial punctual injections, the linear retrotracing technique, anterotracing (push ahead) technique, cross-hatching technique (blanket) and the fan distribution technique. BELOTERO Intense Lidocaine may be used in combination with other BELOTERO fillers respecting the correct depth of injection and indication for each product.
If the needle becomes obstructed and the injection pressure becomes too high, stop the injection and change the needle. BELOTERO Intense Lidocaine should be injected slowly. The quantity to inject depends on the correction to be achieved.
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 Intense Lidocaine should be injected into the deep dermis.

Contra-indications
BELOTERO Intense Lidocaine is contra-indicated in case of:
- known hypersensitivity to one of the product's components, especially sodium hyaluronate, lidocaine hydrochloride and 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.
Special care applies when using BELOTERO Intense Lidocaine in order to avoid injecting the gel into blood vessels as inadvertent intravascular injection, in particular in the glabellar area, could potentially lead to local vascular occlusion, ischemia and necrosis. Therefore BELOTERO Intense Lidocaine is not recommended in this area.
Furthermore:
- Do not inject BELOTERO Intense Lidocaine to increase the volume of the breasts.
- Do not inject BELOTERO Intense Lidocaine in the bones, tendons and ligaments.

Do not inject BELOTERO Intense Lidocaine into areas presenting cutaneous problems of inflammatory or infectious type (acne, herpes, etc.). In the absence of available clinical data on tolerance on the injection of BELOTERO Intense 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 Intense 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.
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 Intense Lidocaine on a case-by-case basis depending of the nature of the disease as well as the associated treatment.
It is recommended not to inject BELOTERO Intense Lidocaine into the periorbital region without prior specific training and a good knowledge of the anatomy of the area.
BELOTERO Intense Lidocaine must not be used in immediate association with other aesthetic medicine techniques such as peeling, dermabrasion, or any type of laser treatment. In all cases, even if the complete healing of the last treatment occurs earlier, BELOTERO Intense Lidocaine must not be used earlier than 2 weeks after the last treatment.
No clinical data are available on the combined use of BELOTERO Intense Lidocaine with the above-mentioned treatments. No clinical data is available on the injection of BELOTERO Intense Lidocaine into an area already treated with other filling products not belonging to BELOTERO range. BELOTERO Intense 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 hypersensitivity.
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 defiencies 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 or the cannula.
Do not transfer BELOTERO Intense Lidocaine into another container and do not add other substances to the product.
Only the gel is sterile, but not the outside of the syringe.
BELOTERO Intense 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 Intense 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. 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 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 Intense 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.