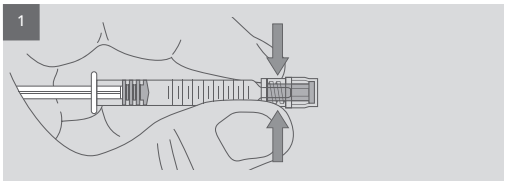
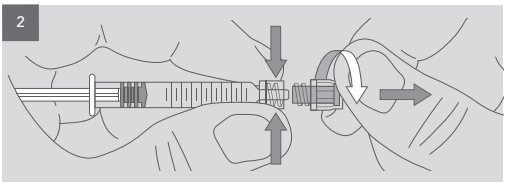
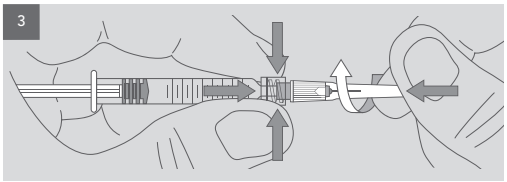
BELOTERO®

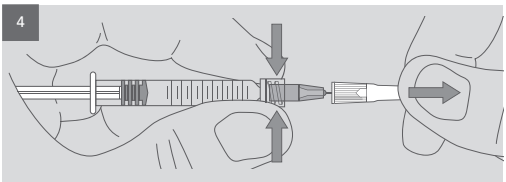
MERZ AESTHETICS

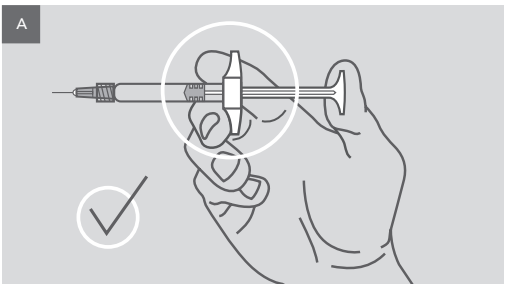
INTENSE LIDOCAINE

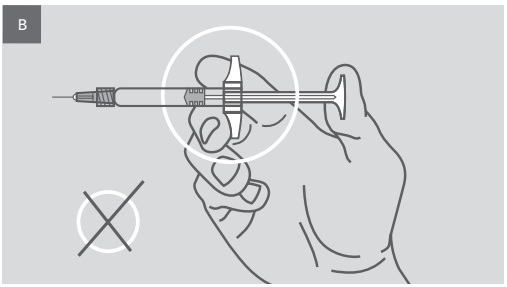












Backstop in the right position during injection

GB INSTRUCTIONS FOR USE FOR BELOTERO® INTENSE LIDOCAINE

Description
BELOTERO Intense Lidocaine is a sterile, non-pyrogenic, viscoelastic, colourless, transparent cross-linked sodium hyaluronate gel 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 single use pre-filled sterile glass syringe sterilized by moist heat. Each box contains one instruction leaflet, one syringe, two traceability labels and two sterile CE-marked needles for single use only. The dimensions of needles are stated on the external box.

Composition

Cross-linked sodium hyaluronate:	25.5 mg/ml
Lidocaine hydrochloride:	3.0 mg/ml
Phosphate buffer pH 7 q.s.:	gel volume

Sodium hyaluronate is produced by fermentation of Streptococcus equi.
The volume of the gel in each syringe is stated on the external box.

Indications
BELOTERO Intense Lidocaine is an injectable resorbable implant indicated to fill deep wrinkles and folds, as well as to restore and enhance soft tissue volume (e.g. contours of the face, lip volume etc.). It is also suitable for correction of facial atrophic scars.
The presence of lidocaine aims to reduce local pain associated with the injection of the gel and to improve patient comfort.

Posology and administration method
BELOTERO Intense Lidocaine is designed to be injected into the deep dermis by a legally approved practitioner.
BELOTERO Intense Lidocaine can be used for all skin types.
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.
BELOTERO Intense Lidocaine must be injected into a healthy, non-inflamed and previously rigorously disinfected skin.
It is recommended to use one of the supplied needles.
To ensure optimal use of BELOTERO Intense Lidocaine, it is recommended to assemble the needle according to the diagrams above.
The use of the enclosed 27G½ needle is recommended, as a smaller needle diameter would require a greater force to inject the implant.
BELOTERO Intense Lidocaine can be used in combination with other BELOTERO products during the same session. Instructions for use of each product should be followed.
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 of gel to be injected depends on the area to be treated and the correction to be achieved. Do not over-correct.
Gently massage the treated area after the injection to distribute the product uniformly.

Contra-indications
BELOTERO Intense Lidocaine is contra-indicated:
- In case of known hypersensitivity to one of the product's components, especially to sodium hyaluronate, lidocaine hydrochloride and amide-type local anesthetics,
- In pregnant or breast-feeding women,
- In young patients under 18 years old,
- In patients presenting a general infection.

Do not inject BELOTERO Intense Lidocaine into blood vessels.
Do not inject BELOTERO Intense Lidocaine into areas presenting cutaneous problems of an inflammatory or infectious type (acne, herpes…).
Do not inject BELOTERO Intense Lidocaine into an area previously treated with a permanent dermal filler.
Do not inject BELOTERO Intense Lidocaine in the glabellar region.

Precautions for use
Before treatment the patient must be informed about the device, its contra-indications and possible side effects.
In the absence of available clinical data on tolerance and efficacy of the injection of BELOTERO Intense Lidocaine in patients with antecedents or with an active autoimmune disease or in patients presenting a 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 to these patients and to not inject if the disease is evolving. It is also recommended to carefully monitor these patients after injection.
It is recommended not to inject BELOTERO Intense Lidocaine in patients with a history of streptococcal diseases or in patients pre-disposed to hypertrophic scars or cheloids.
BELOTERO Intense Lidocaine can be injected in the periorbital region only by trained experienced practitioners with a deep knowledge of the anatomy. Injection of dermal fillers into this area may be associated with an increased frequency and severity of side effects.

BELOTERO Intense Lidocaine can be injected in the nose only by trained experienced practitioners with a deep knowledge of the anatomy. Injection of dermal fillers into this area may lead to local vascular complications such as ischemia or necrosis.
BELOTERO Intense Lidocaine must not be used in association with other aesthetic medicine techniques such as peeling, dermabrasion, or any type of laser treatment before complete healing of the last treatment. In any case, even if the healing occurs earlier, BELOTERO Intense Lidocaine must not be used earlier than 2 weeks after the last treatment. No clinical data is 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 another filling product.
Check the integrity of the inner packaging and the expiry date for both the syringe and the needle prior to use. Do not use these products if the expiry date has lapsed or if the packaging has been opened or damaged.
Patients using antithrombotic substances such as aspirin or non-steroidal anti-inflammatory medications may have increased reactions of hematomas, nodules or bleeding at the injection site.
In cases of patients suffering from 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.
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.
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 (topical administration…), the total administered dose of lidocaine 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.
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/ANTEIS. If an automatic system is used, it is recommended that the practitioner has previously read its instructions for use and is trained on the use of the system.
Discard the syringe and the remaining product after use.
Do not re-sterilize and do not reuse due to the associated risks including infection.
The patient must avoid applying makeup for at least 12 hours after treatment as well as avoid saunas, Turkish baths and prolonged exposure to the sun or UV rays for 2 weeks after the treatment. Patients should also avoid putting pressure on and/or handling the treated area.

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 into contact with such substances.
There is no known interaction with other local or loco-regional anesthetics.

Side effects

Patients must be informed by the practitioner about possible side effects before treatment. 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,
- 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.

Assembly of needle to syringe

For optimal use of BELOTERO Intense Lidocaine it is important that the needle is properly connected to the syringe. 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. Grasp the protective cap with the other hand and unscrew it.
3. **Push & Twist** the needle on the syringe **until a resistance is felt.** Do not over-tight. Over-tightening of the needle may lead to the Luer-lock moving and dis-lodging 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.

References

Updated documentation may be available from ANTEIS SA, Switzerland.


Caution


Consult instructions for use


Do not use if package is damaged


Single use product. Do not re-use.


Open the blister by pulling the Tyvek lid following the arrow

Sterile. Sterilized by moist heat. Only the gel is sterile, but not the outside of the syringe.

Sterile. Sterilized by irradiation. Only the needle itself is sterile, but not the outside of the needle packaging.

Temperature limit of storage: 2 °C – 25 °C

Batch code


Use-by date


CE mark in accordance with Directive 93/42/EEC relating to medical devices. This mark is followed by the notified body number.


Date of manufacture


Manufacturer

Manufacturer of the needles:

TSK Laboratory, Japan,
2-1-5 Hirayanagi-cho, Tochigi-Shi,
Tochigi-Ken, 328-0012 Japan;

The needles are CE marked CE 0123

Manufacturer of BELOTERO Intense Lidocaine:

ANTEIS SA
18 Chemin des Aulx
CH-1228 Plan-les-Ouates
Geneva, Switzerland

Australian Sponsor Name and Address:

Merz Australia Pty Ltd
Level 3, 244 Coward Street
Mascot, NSW, 2020
Australia

Date of the instructions for use: 2015-04-13

MN 64034, AU