med supply
SOLUTIONS

BELOTERO® LIPS SHAPE with Lidocaine Product Specifications

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13. Instructions how to use the patient implant card
An implant card is provided with Belotero Lips Shape. This implant card must be completed by the physician according to the below instructions and provided to the patient after injection.

Number	Symbols	Details
1		Please enter patient's name.
2		Please enter the date of implantation.
3 - 4		Please enter the name and address of the healthcare professional.
5		Please enter the number of injections.
6		Please enter the total volume injected.
7		Please enter the injection site(s)
8	Product label	Please stick here one of the product traceability label, you can keep the second one for your records.

<u>Important information to be provided to the patient</u>
Instruct the patient to keep the patient implant card with her/him and to present it to her/his healthcare professional in case of other appointments. Information about previous treatment must be presented to her/his healthcare professional before treatment!

 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 Lips Shape:

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

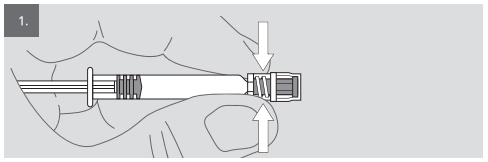
Date of the instructions for use: 2021-11-05

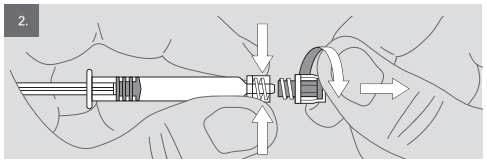
MN 170000199, AU

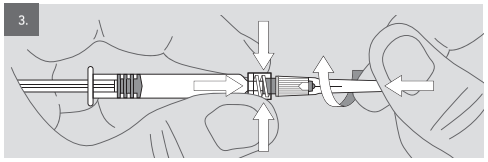
BELOTERO®

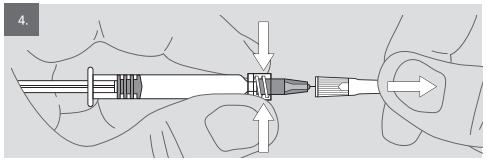
MERZ AESTHETICS®

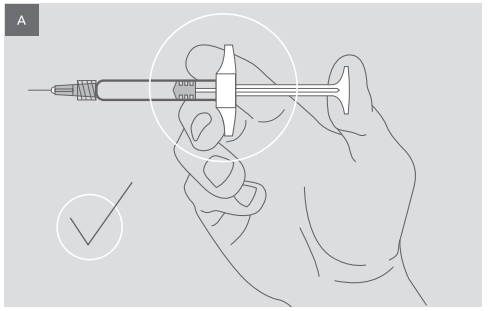
LIPS SHAPE

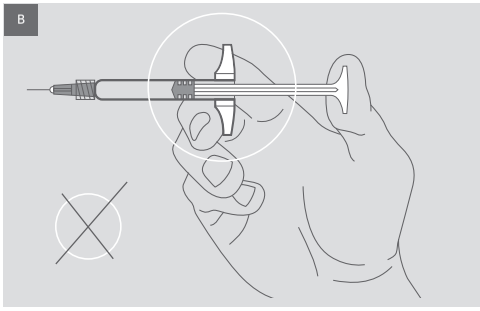












Backstop in the right position during injection

GB INSTRUCTIONS FOR USE FOR BELOTERO® LIPS SHAPE

1. Description
Belotero Lips Shape is a sterile, non-pyrogenic, viscoelastic, colourless, transparent cross-linked sodium hyaluronate gel of non-animal origin in a physiological phosphate buffer. Belotero Lips Shape contains 0.3% of lidocaine hydrochloride.

2. Presentation
Belotero Lips Shape 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.

3. Composition

Cross-linked sodium hyaluronate:	25.5 mg/ml
Lidocaine hydrochloride:	3.0 mg/ml
Phosphate buffer pH 7 q.s.:	0.6ml

Sodium hyaluronate is produced by fermentation of Streptococcus equi.

4. Indications

4.1 Intended use
Belotero Lips Shape is an injectable biodegradable implant intended for lip enhancement.
The presence of lidocaine aims to reduce local pain associated with the injection of the gel and to improve patient comfort.

4.2 Indications
Belotero Lips Shape is indicated for submucosal or subcutaneous injection into the lips.
Belotero Lips Shape is indicated for injection into the deep dermis for treatment of perioral lines and severe oral commissures.

5. Posology and administration method
Belotero Lips Shape is designed to be injected into the deep dermis and the mucous membrane of the lips by authorized practitioners who have the appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection in order to minimize the risk of potential complications. Submucosal or subcutaneous injection is recommended for lip enhancement.
Inject Belotero Lips Shape slowly and not too fast to apply the least amount of pressure necessary, according to the appropriate injection technique using the provided needles. General recommended injection techniques are for example: linear or serial threading, fanning, cross-hatching or serial puncture. The quantity of product to be injected depends on the area to be corrected.
The risk of an intravascular injection can be reduced by different strategies, including aspiration prior to injection, utilizing lower volumes and serial injections in high-risk areas, treating one side at a time, pinching/tenting the skin to provide more space superficial to the branches of the main arteries, and manual occlusion of the origin of the supratrochlear vessels with the non-dominant finger. Blunt cannulas may reduce, but not eliminate the risk.

Belotero Lips Shape must be injected under appropriate aseptic conditions into a healthy, non-inflamed. Before injection, thoroughly disinfect the area to be treated.
To ensure optimal use of Belotero Lips Shape, it is recommended to assemble the needle according to the diagrams below. Improper assembly may lead to a separation of the needle and syringe and / or leakage of the gel at the Luer lock connection during injection.
If the needle becomes obstructed and the injection pressure becomes too high, stop the injection and change the needle.
The use of the enclosed 27G½ needle is recommended, as a smaller needle diameter would require a greater force to inject the implant.
The quantity of gel to be injected depends on the area to be treated and the correction to be achieved. Do not overcorrect.
The graduations on the syringe label are only intended for orientation for the user.
Gently massage the treated area after the injection to distribute the product uniformly.
Before treatment, the patient's suitability for the treatment and the patient's need for pain relief (topical anesthetics, ice packs, distraction techniques, local anesthetic injections, or nerve blocks depending on the injection site and size of needle used), should be assessed.

6. Contra-indications

Belotero Lips Shape is contra-indicated:
- In case of known hypersensitivity to one of the product's components, especially to sodium hyaluronate, lidocaine hydrochloride, BDDE and to amide-type local anesthetics,
- In pregnant or breast-feeding women,
- In young patients under 18 years old,
- In patients presenting a general infection.
- In patients presenting an active auto-immune disease.

Do not inject Belotero Lips Shape into blood vessels.
Do not inject Belotero Lips Shape into areas presenting cutaneous inflammation or infection due to e.g. immunological, allergic, bacterial, fungal or viral causes.
Do not inject Belotero Lips Shape into an area previously treated with a permanent dermal filler.
Do not inject Belotero Lips Shape in the glabellar or nose region.

7. Precautions for use

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.
In the absence of available clinical data on tolerance and efficacy of the injection of Belotero Lips Shape 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 Lips Shape 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 Lips Shape in patients with a history of streptococcal diseases or in patients pre-disposed to hypertrophic scars or keloids.
Belotero Lips Shape injected in the temples area may be associated with an increased risk for intravascular complications and the consequences of local vascular occlusion, embolization, vision impairment, blindness, ischemia, necrosis or infarction.
Belotero Lips Shape can be used in combination with other Belotero products during the same session but in different facial areas. Instructions for use of each product should be followed.
No clinical data is available on the injection of Belotero Lips Shape into patient with a Fitzpatrick skin type V/VI.
Belotero Lips Shape can be used in combination treatments such as with botulinum toxin and/or calcium hydroxylapatite (Radiesse®) only if injected in different facial areas. Practitioners should be experienced and patients appropriately selected as benefits but also adverse events can be cumulative and causality of adverse events could become difficult to determine. Instructions for use, depth of injection and appropriate recommendation of each product should be followed. No clinical data are available on the injection of Belotero Lips Shape into an area already treated with other aesthetic products or procedures.
Belotero Lips Shape 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 Lips Shape must not be used earlier than 2 weeks after the last treatment. No clinical data is available on the combined use of Belotero Lips Shape with the above-mentioned treatments.
Patients using anti-coagulation, anti-platelet, or thrombolytic medications (e.g. warfarin), anti-inflammatory drugs (oral/ injectable corticosteroids or non-steroidal anti-inflammatory drugs (NSAIDs; e.g. aspirin, ibuprofen)), or other substances known to increase coagulation time (vitamins or herbal supplements, e.g. Vitamin E, garlic, Ginkgo biloba and St. John's Wort), from 10 days pre- to 3 days post-injection may have increased reactions of hematomas, nodules or bleeding at the injection site.
Injection of Belotero Lips Shape into patients with a history of previous herpetic eruption may be associated with reactivation of the herpes (HHV related diseases, e.g. pityriasis rosea).
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 Lips Shape 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 or transient loco-regional numbness.
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 signs 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.
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 inner packaging has been opened or damaged.
Do not transfer Belotero Lips Shape into another container and do not add other substances to the product.
Only the gel is sterile, but not the outside of the syringe. Discard the syringe and the remaining product and the needles in the appropriate container 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 and should avoid strenuous physical activity following treatment.
The patient must avoid drinking alcohol for 24 hours before and after treatment. Alcohol may cause the blood vessels to dilate and cause more bruising.
There is no known interaction with other local or loco-regional anesthetics.

8. Warnings

Sodium hyaluronate precipitates in the presence of quaternary ammonium salts (such as benzalkonium chloride). It is therefore recommended that Belotero Lips Shape does not come into contact with such substances.
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 vascular complication, vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures. Practitioners should 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.

9. Side effects and adverse events

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

Injection site reactions may occur following injection into the skin but disappear spontaneously within a few days. This includes swelling, nodule or lump/bump, bruising, hematoma, ecchymosis, induration, erythema/redness, tenderness, pain, discoloration and pruritus/ itching, tingling, paraesthesia, numbness, hypoesthesia, scabbing, needle mark and discomfort or irritation. These injection site reactions are generally of mild or moderate intensity. A transient bleeding may also occur at the injection site and usually stops spontaneously as soon as the injection is finished.
- Adverse events:

In occasional cases, one or more of the following may occur either immediately or as a delayed reaction: acne cystic, milia, skin dryness (rough facial skin, exfoliation), injection site erosion, inflammation, shivering, fatigue, lymphatic system disorder, rash, burning sensation, injection site sore/ warmth/fever, pruritus/ itching, urticaria, hematoma, telangiectasia, ecchymosis, edema (including lymph edema), headache/cephalgia, tumefaction, tension, swelling (including persistent swelling), hyper- or hypo-pigmentation, angioedema, induration, blister vesicle, papule, lump/ bump (visible and/or palpable material) or nodule (including inflammatory nodules), mass, granuloma (including inflammatory signs and foreign body reactions), necrosis, ischemia, vascular occlusion, embolization, infarction, Tyndall effect (including translucent chords), hypersensitivity, allergic reactions (including asthma attack, Quincke's edema, anaphylactic shock or throat tightening) to one of the product's components (e.g. hyaluronic acid, lidocaine hydrochloride, BDDE), oral and dental disorders, nervous system impairment, impairment of the otorhinolaryngological system (e.g. nasal congestion, oropharyngeal pain, dysgeusia, rhinorrhea, epistaxis, sinusitis, transient hearing loss, mastication pain, parotid gland enlargement, muscle twitching, muscle injury, nausea, vomiting, circulatory collapse, presyncope, peripheral venous disease, hot flush, anxiety caused by trypanophobia, patient dissatisfaction and disappointment (due to lack of or reduced performance, decreased firmness/response, undesirable aesthetic effect, injection site discharge, device migration, product distribution issue (e.g. product accumulation), injection site indentation, superficial vein prominence, overcorrection or cranial nerve disorder (e.g. cranial nerve paralysis, facial paralysis, trigeminal neuralgia).
Literature reported rare cases of the following adverse events with hyaluronic acid products such as infection (e.g. erysipelas, phlegmon, cellulitis, including open or draining wounds and (dental) abscess, impetigo, pustules), chronic infection (including biofilm formation), scarring, persistent skin discoloration, sensory dysfunction, non-thrombotic lung embolism as well as sarcoid granuloma formation in subjects with hepatitis C and interferon treatment, cerebral injuries (e.g. intracranial penetration, subarachnoid hemorrhage), strabismus, ophthalmoplegia, iris adhesions, cataract, conjunctival hemorrhage, eyelid ptosis and lacrimation.
The risk of granuloma, ischemia, necrosis and vascular occlusion is higher with deep injections and high volumes.
Isolated cases of visual impairment or blindness following unintentional intra-arterial injection have been reported in literature.
Patients should be instructed to report any side effects which last for more than one week and any adverse event as soon as it occurs to his/ her practitioner, especially if patient has changes in his/ her vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in his/ her face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment. The practitioner may then refer the patient to the appropriate treatment.
Patients with lighter skin types are more likely to develop injection-related adverse events. However, patients with skin of color are more likely to develop post-inflammatory hyperpigmentation and / or hypertrophic scar/keloid formation following injection procedures. Patients with specific ethnic characteristics, e.g. Asian population, should be informed of a higher risk of tissue reactions, e.g. itching, swelling, erythema, inflammation.

10. Assembly of needle to syringe

For optimal use of Belotero Lips Shape, 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 dislodging from the syringe.
(4) Keep holding the Luer-lock and remove the sheath from the needle.

11. Storage

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

12. References

Updated documentation may be available from ANTEIS SA, Switzerland.