med supply
SOLUTIONS

BELOTERO® VOLUME with Lidocaine Product Specifications

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13. Instructions how to use the patient implant card
An implant card is provided with Belotero Volume Lidocaine. 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. This symbol on the box means only the needle / cannula itself is sterile, but not the outside of the needle / cannula packaging.

Sterile. Sterilized by ethylene oxide. This symbol on the box means only the needle / cannula itself is sterile, but not the outside of the needle / cannula 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 / cannulae is mentioned on the labels of the needles / cannulae and could be:

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

The needles are CE marked CE 0123

Sterimedix Ltd
Thornhill Road
North Moons Moat
Redditch, Worcestershire
B98 9ND
United Kingdom

The cannulae / needles are CE marked CE 0123

Manufacturer of Belotero Volume 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

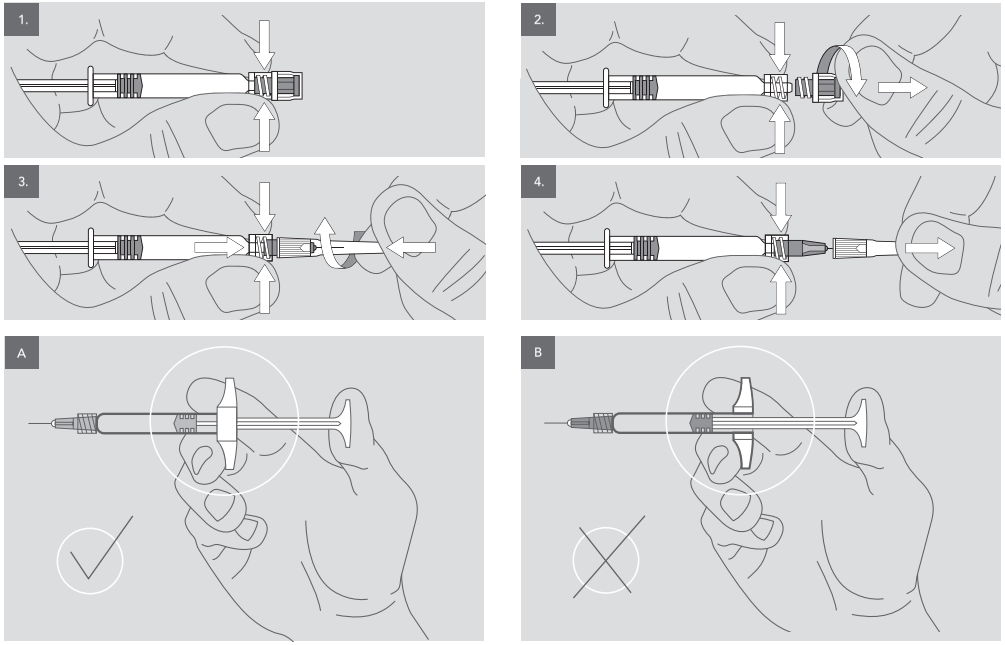
Date of the instructions for use: 2021-11-05

MN 170000196, AU

BELOTERO®

MERZ AESTHETICS®

VOLUME LIDOCAINE



Backstop in the right position during injection

GB INSTRUCTIONS FOR USE FOR BELOTERO® VOLUME LIDOCAINE

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

2. Presentation
Belotero Volume Lidocaine is presented in a single use prefilled glass syringe, sterilized by moist heat. Each box contains one instruction leaflet, two syringe(s), two traceability labels per syringe and sterile CE-marked needles/cannulae for single use only. The number of syringes, the dimensions and the number of needles/cannulae are stated on the external box.

3. Composition

Cross-linked sodium hyaluronate:	26.0 mg/ml
Lidocaine hydrochloride:	3.0 mg/ml
Phosphate buffer pH 7 q.s.:	1 ml

Sodium hyaluronate is produced by fermentation of Streptococcus equi.

4. Intended use/Indications

4.1. Intended use
Belotero Volume Lidocaine is an injectable biodegradable implant intended for restoration of facial volumes.
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 Volume Lidocaine is indicated for injection into the the deep subcutaneous layers or above the periosteum for enhancement of the cheeks, the temples, the chin, or to treat severe nasolabial folds (NLFs).

5. Posology and administration method
Belotero Volume Lidocaine is designed to be injected into the deep subcutaneous layers or above the periosteum 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 risks of potential complications.
Inject Belotero Volume Lidocaine slowly and not too fast to apply the least amount of pressure necessary, according to the appropriate injection technique using the provided needles/cannulae.
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 Volume Lidocaine must be injected under appropriate aseptic conditions into a healthy, non-inflamed skin. Before injection, thoroughly disinfect the area to be treated.
It is recommended to use one of the supplied needles/cannulae.
To ensure optimal use of Belotero Volume Lidocaine it is recommended to assemble the needle according to the dia-

grams below. Improper assembly may lead to a separation of the needle/cannula and syringe and/or leakage of the gel at the Luer lock connection during injection.
If the needle becomes obstructed and the injection pressure is too high, stop the injection and change the needle or the cannula.
The quantity of the gel to be injected depends on the area to be treated and the correction to be achieved. Do not over-correct.
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 Volume Lidocaine is contra-indicated:
- In case of known hypersensitivity to one of the product's components, especially to sodium hyaluronate, lidocaine hydrochloride, BDDE or to amide-type local anesthetics,
- In pregnant and breast-feeding women,
- In young patients under 18 years old,
- In patients presenting a general infection.

Do not inject Belotero Volume Lidocaine into blood vessels.
Do not inject Belotero Volume Lidocaine into the glabellar or nose region.
Do not inject Belotero Volume Lidocaine into the infra-orbital hollows, eyelids and crow's feet.
Do not inject Belotero Volume Lidocaine into the lips.
Do not inject Belotero Volume Lidocaine into areas presenting cutaneous problems of an inflammatory or infectious type (acne, herpes…).
Do not inject Belotero Volume Lidocaine for correction of superficial wrinkles and fine lines (injection of the product into the superficial dermis).
Do not inject Belotero Volume Lidocaine into an area previously treated with a permanent dermal filler.

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 Volume Lidocaine in patients with antecedents or with an active auto-immune disease or in patients presenting a history of severe multiple allergies or anaphylactic shock, the practitioner must decide whether to inject Belotero Volume 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 not to inject if the disease is evolving. It is also recommended to carefully monitor these patients after injection.
It is recommended not to inject Belotero Volume Lidocaine in patients with a history of streptococcal diseases and in patients pre-disposed to hypertrophic scars or keloids.
Belotero Volume Lidocaine injected in the NLFs or temples area may lead to local vascular occlusion, embolization, vision impairment, blindness, ischemia, necrosis or infarction.
Belotero Volume Lidocaine 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.
Limited clinical data are available on the injection of Belotero Volume Lidocaine into patient with a Fitzpatrick skin type V/VI.
Belotero Volume Lidocaine 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 Volume Lidocaine into an area already treated with other filling aesthetic products or procedures.
Belotero Volume 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 Volume Lidocaine must not be used earlier than 2 weeks after the last treatment. No clinical data is available on the combined use of Belotero Volume Lidocaine 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 Volume Lidocaine 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 Volume 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 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 packaging has been opened or damaged.
Do not transfer Belotero Volume 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.
Discard the syringe and the remaining product and the needles/cannulae in the appropriate container after use.
Do not re-sterilize and do not re-use 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.
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 Volume Lidocaine 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, pruritus/itching, tingling, paresthesia, numbness, hypoesthesia, scabbing, needle marks 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, muscle twitching, muscle injury/disorder, 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, 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 or 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 Volume 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 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.