1 General Information

1.1 Name or Trade Name

Belotero® Volume Lidocaine

1.2 Device Description

Belotero® Volume Lidocaine is a biodegradable implant that is intended to be used to restore facial volumes.

Belotero® Volume Lidocaine consists of sodium hyaluronate of non-animal origin, which has been cross-linked to form a sterile, colorless, transparent, thick, elastic, biodegradable gel. It also contains physiological phosphate buffer and 0.3% lidocaine hydrochloride. Lidocaine is a local anesthetic which has been added to reduce any pain or discomfort you may experience when the gel is injected.

Belotero® Volume Lidocaine is injected into the deep subcutaneous layers or above the periosteum (the layer of tissue that covers bone surfaces) in order to enhance the cheeks, temples or chin, or to treat severe nasolabial folds (NLFs, the lines that run down from the sides of the nose to the sides of the mouth).

The expected lifetime of Belotero® Volume Lidocaine depends on various factors. These include the way the injection is given, the characteristics of the implant, how your body will metabolize (process) it, whether you have any touch up treatments and the filling effect that you desire. It can last for up to 18 months after injection.

1.3 List of Ingredients

Belotero® Volume Lidocaine is composed of high molecular weight sodium hyaluronate, crosslinked using 1,4-Butanediol Diglycidyl Ether (BDDE), in a physiological phosphate buffer at a concentration of 26.0 mg/ml in the final product.

Each ml of the product contains:

Cross-linked sodium hyaluronate: 26.0 mg

Lidocaine hydrochloride: 3.0 mg

Phosphate buffer pH 7 to make up the volume to 1 ml

Belotero® Volume Lidocaine does not contain latex, any animal products or any substances obtained from human blood. It is free of pyrogens (substances produced by bacteria that can cause fever and other symptoms) and does not contain any substances that can cause cancer, mutations, affect reproduction (CMR substances) or affect the production or activity of hormones in the body.

Belotero® Volume Lidocaine contains 1,4-butanediol diglycidyl ether (BDDE) which is considered to be the safest substance to use as a cross-linker for dermal fillers. The BDDE solution used for manufacturing Belotero® Volume Lidocaine does not contain any potentially dangerous impurities.

Belotero® Volume Lidocaine contains lidocaine hydrochloride, which is the most commonly used anesthetic in dermatologic surgery. After injection, it is metabolized by the body to 2,6-Dimethylaniline (DMA).

Validated quality controls ensure that the levels of any remaining BDDE and DMA in Belotero® Volume Lidocaine do not exceed predefined limits. As a result, we can warrant that Belotero®

Volume Lidocaine has an excellent safety profile. If you have any concern or questions with regard to the BDDE and DMA residuals (e.g. in case of known allergies), please consult your healthcare professional.

2 Contraindications

Belotero® Volume Lidocaine is contra-indicated (must not be used):

- If you have known hypersensitivity (allergy) to one of the product's components, especially to sodium hyaluronate, lidocaine hydrochloride, BDDE or to amide-type local anesthetics,
- If you are pregnant or breast-feeding,
- If you are younger than 18 years,
- If you have a general infection.

- Belotero® Volume Lidocaine must not be injected into blood vessels.
- Belotero® Volume Lidocaine must not be injected into the glabellar (between the eyebrows) or nose region.
- Belotero® Volume Lidocaine must not be injected into the infra-orbital (under the eyes) hollows, eyelids and crow's feet.
- Belotero® Volume Lidocaine must not be injected into the lips.
- Belotero® Volume Lidocaine must not be injected into inflamed or infected skin.
- Belotero® Volume Lidocaine must not be injected for the correction of superficial wrinkles and fine lines (injection of the product into the areas just below the skin surface).
- Belotero® Volume Lidocaine must not be injected into an area previously treated with a permanent dermal filler.

3 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 side effects have been reported after soft tissue fillers were accidentally injected into facial blood vessels. These include temporary or permanent damage to blood vessels, impaired vision or blindness, brain damage leading to stroke, skin necrosis (death of skin cells), damage to underlying facial structures. Your healthcare professional should immediately stop the injection if you show any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. If the product is accidentally injected into a blood vessel, you will need prompt medical attention and possibly evaluation by an appropriate healthcare practitioner.

4 Precautions

- Your healthcare practitioner should discuss all potential risks of soft tissue injection with you prior to treatment and ensure that you are aware of signs and symptoms of potential complications.

- Since there are no clinical data about how well people with an active autoimmune disease or history of autoimmune disease, severe allergies or anaphylactic shock tolerate being injected with of Belotero® Soft Lidocaine, your healthcare practitioner will decide whether such injection is appropriate if any of the above apply to you. You may be asked to have a double before treatment and you will not be injected if your disease is progressing. If you do receive an injection, you will be carefully monitored afterwards.
- It is recommended not to be injected with Belotero® Volume Lidocaine if you have a history of streptococcal diseases or if you are pre-disposed to developing thick, raised scars (hypertrophic scars or keloids).
- Belotero® Volume Lidocaine injected in the NLFs or temples may cause blockage of blood vessels, vision impairment, blindness and tissue damage or death due to interruption of the blood supply.
- Belotero® Volume Lidocaine can be used in combination with other Belotero® products during the same session but in different facial areas.
- Limited clinical data are available on the injection of Belotero® Volume Lidocaine into people with dark brown to black skin (Fitzpatrick skin type V/VI).
- Belotero® Volume Lidocaine can be used in combination treatments such as with botulinum toxin and/or calcium hydroxyapatite (Radiesse®) only if injected in different facial areas. This should only be done by an experienced practitioner who has carefully considered the potential benefits. The side effects of combined treatment can be cumulative and it might be difficult to tell which product is responsible. 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 together with other aesthetic medicine techniques such as peeling, dermabrasion or any type of laser treatment. It is necessary to wait at least two weeks after the last treatment, or longer if complete healing has not occurred by then. No clinical data are available on the combined use of Belotero® Volume Lidocaine with the above-mentioned treatments.
- If you use 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), in the period from 10 days before to 3 days after the injection, you may experience increased bruising, nodules or bleeding at the injection site.
- If you have a history of herpes-related rash, injection of Belotero® Volume Lidocaine may be associated with herpes reactivation (HHV-related diseases, e.g. pityriasis rosea).
- If you have epilepsy, heart disease, severe liver or kidney disease or porphyria, your practitioner will decide whether injection of Belotero® Volume Lidocaine is appropriate for you.
- If you are an athlete, you should consider 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 or transient local or regional numbness.
- The maximum total dose of lidocaine HCl (without epinephrine) recommended in healthy adults should not exceed 300 mg (or 4.5 mg/kg) per session. Overdosage of lidocaine HCl usually affects the central nervous system or heart and circulation.

- If other products are used at the same time, your practitioner should consider the total administered dose of lidocaine and the use of other substances structurally related to amide-type local anesthetics since their toxic effects may be additive.
- Your practitioner will need to be extra careful if you have congenital methemoglobinemia, glucose-6-phosphate dehydrogenase deficiency or are under treatment with methemoglobin-inducing agents.
- There is no known interaction with other local or local-regional anesthetics.

5 Undesirable Side-effects

Your practitioner will inform you about possible side effects before treatment.

Reactions may occur at the injection site after the treatment, but they disappear spontaneously within a few days. These include swelling, nodules or lumps/bumps, bruising, induration (hardening), redness, tenderness, pain, discoloration, itching, tingling, pins and needles, numbness or reduced sensation, scabbing, needle mark, discomfort and irritation. These reactions are generally mild or moderate in intensity. Bleeding may also occur at the injection site but this usually stops 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: acne, milia (tiny white bumps), dry, rough or peeling skin, ulcer at the injection site, inflammation, shivering, fatigue, lymphatic system disorder, rash, burning sensation, injection site feeling sore or warm, fever, itching, hives, bruising, spider veins, headache, swelling, tension, changes in skin pigmentation, induration (hardening), blistering, lump, bump or nodule (which may be inflamed), tissue death, impaired blood supply to tissues, blocked blood vessels, Tyndall effect (discoloration due to the filler being injected too near the skin surface), various hypersensitivity and allergic reactions (including asthma attack, swelling or tightening of the throat, anaphylactic shock) to one of the product's components (e.g. hyaluronic acid, BDDE, lidocaine hydrochloride), oral and dental disorders, nervous system impairment, ear, nose and throat problems (e.g. stuffy or runny nose, sore throat, altered sense of taste, nosebleed, sinusitis, transient hearing loss), pain on chewing, salivary gland enlargement, muscle twitching, muscle injury/disorder, nausea, vomiting, circulatory collapse, feeling faint, peripheral venous disease, hot flush, anxiety due to needle phobia, dissatisfaction and disappointment with the results of the treatment, discharge from injection site, migration or accumulation of the product, injection site indentation, superficial vein prominence, paralysis/palsy of the face or eyes, trigeminal neuralgia (sudden, severe facial pain) or another nerve disorder.

Rare cases have been reported in medical journals of the following side effects of products based on hyaluronic acid: 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, heart attack, non-thrombotic lung embolism as well as sarcoid granuloma formation in subjects with hepatitis C and interferon treatment, brain injuries (e.g. penetration into the brain, subarachnoid hemorrhage (bleeding into the space around the brain)), squinting, eye muscle paralysis, iris adhesions, cataract, conjunctival bleeding, drooping eyelid and excessive tear production.

The risk of granuloma, ischemia or necrosis, and blocked blood vessels is higher with deep injections and high volumes.

Isolated cases of visual impairment or blindness following unintentional injection into an artery have been reported in medical journals.

The lighter your skin, the more likely you are to develop injection-related side effects. However, the darker your skin, the more likely you are to develop excessive pigmentation after inflammation and

/ or develop thick raised scars after injection. If you are Asian, you are at higher risk of tissue reactions, e.g. itching, swelling, redness, inflammation.

6 Residual Risks

The overall residual design risks, and manufacturing risks, and the benefit/risk ratio of the devices when used on patients according to the manufacturer's instructions for use are fully acceptable.

Please refer to above safety information for details on residual risks of the product. Please ensure you follow the post-procedural care advice below and directions from your healthcare professional to minimize procedural risk.

7 Reporting Information

Contact your healthcare professional if you are experiencing any side effects or are concerned about any aspect of your treatment. Please seek immediate medical attention if you experience changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure.

You should also tell your healthcare professional about any side effects which last for more than one week. Contact your health professional immediately if you experience any of the following: changes in vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness of the face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, unusual pain during or shortly after treatment, especially if you have problems breathing. The practitioner will ensure that you receive appropriate treatment if necessary.

Adverse events are unintended and sometimes harmful occurrences, associated with the use of a therapeutic good, and include incidents involving medical devices. These can be reported to Merz Australia on our website at https://merzaustralia.com.au/adverse-event-reporting/ or to the TGA at https://www.tga.gov.au.

8 Additional Information

You 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. You should also avoid putting pressure on and/or handling the treated area.

You must avoid drinking alcohol for 24 hours before and after treatment. Alcohol may cause the blood vessels to dilate and cause more bruising.

Patient counseling information

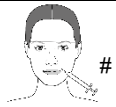
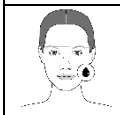
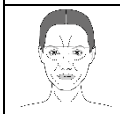
You will be instructed in appropriate post-procedural care, which may include the following, to promote normal healing and avoid complications.

- Try to rest your face for one week by limiting how much you talk, smile and laugh.

9 Implant Card Information

After injection, your physician will provide you with an implant card. This card contains all information related to your injection including product traceability information.

It is recommended to keep the implant card with you and present it to your physician in case of other appointments. Information about previous treatment must be presented to your physician before treatment.

Symbol	Title of symbol
	Patient name or ID
	Date of implantation
	Name and address of healthcare provider
	Number of injections
	Total volume injected
	Injections site(s)
	Catalogue number
	Information website for patients
	Name and address of the manufacturer
	Lot number
	Use-by-date

10 Legal Manufacturer

Manufacturer

Anteis SA

18 Chemin des Aulx

1228 Plan-les-Ouates

Switzerland

11 Australian Sponsor

Australian Sponsor Name and Address:

Merz Australia Pty Ltd

Suite 8.01A,

189 O'Riordan Street

Mascot, NSW, 2020

Australia

12 Date of Issue and Version

Version: 02

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