

This leaflet will answer some questions you may have and help you decide whether injection with BELOTERO Volume Lidocaine is right for you. This information does not replace the discussion with your healthcare professional.

1 Device Description

BELOTERO Volume Lidocaine is a product type known as a “dermal filler”. It is an injectable, biodegradable implant intended for restoration of facial volumes.

It contains a substance called sodium hyaluronate, formulated to be a colorless, transparent, thick, elastic gel.

It also contains a small amount of a numbing agent called lidocaine, which may help to reduce any discomfort or pain at the injection site.

BELOTERO Volume Lidocaine is classified as a device but is not indicated for the formal treatment of any specific disease or medical condition. It is intended for aesthetic purposes only. It does not contain any substances obtained from animals, human blood nor any substances that are known to be harmful to health.

List of Constituents / Composition

The key ingredients in the final product of BELOTERO Volume Lidocaine are listed below:

Composition per ml

Sodium hyaluronate: 26mg/ml

Lidocaine hydrochloride: 3.0 mg/ml

Physiological phosphate buffer pH 7 to make the volume up to 1 ml

Note: Sodium hyaluronate is crosslinked using 1,4-Butanediol Diglycidyl Ether (BDDE)

2 Intended User

BELOTERO Volume Lidocaine is designed to be injected only by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

3 Indications

BELOTERO Volume Lidocaine is indicated for injection into the deep layers of the skin to enhance the cheeks, the temples, the chin or to treat severe nasolabial folds (lines which run downwards from the corners of the nose).

4 Performance Characteristics

Injection with BELOTERO Volume Lidocaine is not intended to treat a disease or medical condition. This product is only for elective aesthetic purpose to improve a person's appearance. Following the injection of BELOTERO Volume Lidocaine, the expected benefit for the person is an aesthetic improvement due to facial volumes becoming restored or facial wrinkles becoming filled out.

The Belotero range of dermal fillers act by mechanically lifting and providing structural support to the surrounding soft tissues, thus, for example, filling out facial wrinkles and folds. The variable cross-linking helps them to retain their shape. The gel parts with higher density refill and expand the tissue, whereas those with lower density diffuse into the spaces around the tissue cells.

The presence of lidocaine in the product may reduce any pain or discomfort during and directly after injection.

The period over which the filler provides the desired result for which it is being used is known as the expected lifetime. Data from use in humans show that BELOTERO Volume Lidocaine has shown a lifetime of up to 18 months for treatment of nasolabial folds and up to 12 months for treatment of cheeks, temples, and chin.

You and your healthcare professional will decide how much filling is right for you to get the desired effect.

5 Target Population

BELOTERO Volume Lidocaine is intended for adults over the age of 18 years who do not meet any of the contraindicated criteria described in Section 6 below.

6 Contraindications

BELOTERO Volume Lidocaine is contraindicated:

- If there is known hypersensitivity (allergy) to one of the product's components or ingredients (see Section 1)
- In pregnant and breast-feeding women,
- In persons under 18 years old,
- In persons with a general infection,
- In persons with an active auto-immune disease.

It must not be injected into:

- blood vessels
- skin that is infected or inflamed due to any cause
- an area previously treated with a permanent dermal filler
- the nose or glabellar region (area that is above the nose and between the eyebrows)
- infra-orbital hollows (hollows below the eye), eyelids and crow's feet
- the lips
- the superficial skin for correction of superficial wrinkles and fine lines.

7 Potential Side-effects

Potential Side-effects that may be associated with BELOTERO Volume Lidocaine treatment

BELOTERO Volume Lidocaine may be associated with side effects at the site of injection. They are generally of mild or moderate intensity and most often disappear spontaneously within a few days. These include: swelling, irritation, itching, redness (erythema), lumps, bumps, milia (milk spots), injection site nodule or hardening (induration), injection site discoloration, bleeding under the skin near injection site, bruising (hematoma), or scabbing at injection site. Additional effects could also include pain, discomfort, tenderness, tingling, numbness, or reduced sensation.

Bleeding at the injection site, when it occurs, usually stops spontaneously soon after the injection is finished.

Additional events may occur with the use of the whole Belotero product range including BELOTERO Volume Lidocaine either immediately or some time after use of the Belotero filler product. It is not known whether these events were definitively caused by treatment with Belotero filler. Such additional events include:

headache, nausea, vomiting, fever, shivering, anxiety, feeling faint, hot flush, fatigue, rash, hives, swelling (including swollen glands), warmth at the injection site, hypersensitivity or serious allergic reactions (including asthma or anaphylaxis), sinusitis, nasal congestion / runny nose, nose bleeds, throat pain, taste alterations, transient hearing loss, muscle twitching or injury, pain or paralysis of the nerves in the face, pain on chewing, muscle tension, salivary gland enlargement, increased or decreased skin pigmentation, acne, rough or peeling skin, exfoliation, blisters, vesicle, papule, injection site ulcer or discharge, inflammatory mass (including foreign body reactions or granuloma), veins just under the skin becoming more noticeable or spider veins, product migration, shifting or accumulation of the injected gel, or indentation at the injection site.

Side effects from the local administration of lidocaine are generally unlikely to occur. Reactions affecting the whole body (systemic reactions) due to administration of lidocaine are also unlikely, but cannot be excluded, since lidocaine is intended for local use at low concentrations/doses. In the very rare event of poisoning (systemic toxicity) due to local administration of lidocaine, early signs of such poisoning may include dizziness, a sensation of everything spinning around (vertigo), restlessness accompanied by irritability (agitation), hallucinations, feeling high (euphoria), feeling fearful (apprehension), yawning, excessive and possibly incoherent speech (logorrhoea), headaches, nausea, vomiting, tingling lips (labial paraesthesia), numb tongue, ringing in the ears (tinnitus), difficulty speaking (dysarthria), hearing and sight problems, disorientation. In rare cases, the use of lidocaine may be associated with hypersensitivity and allergic reactions (including tightening of the airways [bronchospasm], swelling of the face, hands or feet [angioedema], a very severe, potentially life-threatening allergic reaction [anaphylactic shock] or difficulty breathing). If signs of poisoning occur, stop the administration immediately and seek emergency medical assistance.

Hyaluronic Acid Fillers

Rare instances of additional events have been reported with hyaluronic acid dermal fillers such as the Belotero products. These have included: infections (e.g. erysipelas, phlegmon, cellulitis), including open or draining wounds, impetigo, scarring, sarcoid granuloma formation in subjects with hepatitis C and interferon treatment, non-thrombotic lung embolism, and eye disorders such as: iris adhesions, cataract, bleeding of the conjunctival hemorrhage, drooping eyelid, and discharge.

Isolated reports of visual impairment or blindness following unintentional product injection into an artery have been reported in the scientific literature with hyaluronic acid dermal filler treatment such as the Belotero products. Accidental filler injection could cause blocked or reduced flow in blood vessels of the arms and legs, resulting in localized ischaemia (decreased blood supply to tissue) or necrosis (local tissue death), or peripheral venous disease. Filler might produce clot formation in vessels resulting in embolization, heart attack or stroke.

Persons with lighter skin types are more likely to develop injection-related adverse events. People with darker skin are more likely to develop post-inflammatory increases in pigmentation or keloid scarring. Persons of Asian heritage might be at increased risk for site-specific reactions, including itching, swelling, redness, or inflammation.

8 Recommendations for After the Injection

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

You must avoid applying makeup (including skin care products) for at least 12 hours after treatment as well as avoid saunas, peeling, Turkish baths and prolonged exposure to the sun, UV rays, extreme heat and cold for 2 weeks after the treatment. You should also avoid putting pressure on and/or handling the treated area and should avoid strenuous physical activity following treatment.

9 Reporting Side-effects to your Healthcare Professional

All side-effects, should be reported to the healthcare professional who administered your treatment. You should contact your healthcare professional immediately if you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your 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. The healthcare professional may then refer you to the appropriate treatment.

You may also contact Merz Aesthetics GmbH to report any side effects via Ax-Safety@merz.de.

10 Implant Card

After the injection, your healthcare professional will provide you with an implant card. Keep this card with you and show it to your healthcare professional during any other appointments. Information about previous treatment must be shown to your healthcare professional before new treatment is started. Present your implant card to a radiologist prior to undergoing a Magnetic Resonance Imaging (MRI) scan.

This card contains all information related to your injection.

11 Electronical Patient Information Leaflet (ePIL)

A printable PDF version of the patient information leaflet in your local language can be found on the following website: <https://www.patientinfo.merzaesthetics.com>. For the most recent version of the patient information leaflet, please always refer to the website.

12 Used Harmonized Standards and Common Specifications

All harmonized standards and common specifications applied are listed within the Summary of Safety and Clinical Performance (SSCP). The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the UDI-DI as presented on the labelling. Eudamed may be accessed using following URL: <https://ec.europa.eu/tools/eudamed>

Until Eudamed is fully functional, the SSCP may be requested via Ax-Safety@merz.de.

Updated documentation may be available from ANTEIS SA, Switzerland.

Table 1: Implant Card Information

	Person identification
	Date of implantation
	Name and address of healthcare professional
	Number of injections
	Total volume injected
	Injection site(s)
	Website for more information
	Name and address of the manufacturer
	EC Representative of the manufacturer
	Product traceability information EXP: Use-by-date; LOT: Batch code; REF: Catalogue number

Manufacturer and Authorized Representative**Manufacturer****Anteis SA**

Chemin des Aulx 18
1228 Plan-les-Ouates
Switzerland

Authorized Representative in the European Community

Merz Aesthetics GmbH
Eckenheimer Landstrasse 100
60318 Frankfurt am Main
Germany

BELOTERO Volume Lidocaine is CE marked

**Corresponding Instructions for Use reference:**

2.0

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