

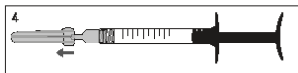
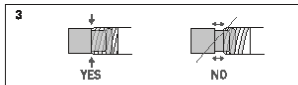
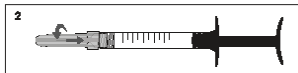
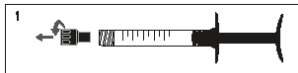
FILLMED
LABORATOIRES

ART FILLER®
UNIVERSAL



HEALTHCARE PROFESSIONALS LEAFLET

USE

ART FILLER®
UNIVERSALEXPLANATION OF
INTERNATIONAL SYMBOLSNON-STERILE
PROTECTIVE PACKAGING
WITH STERILE BARRIER
SYSTEM INSIDESTERILE SYRINGE
FOR SINGLE USESTERILE, STERILISED
WITH MOIST HEATSTERILE NEEDLE
FOR SINGLE USESTERILE, RADIATION
STERILISED

QUICK AUTHENTICITY CHECK



③

①

②

Thank you for buying a FILL-MED product.
You can check this product's authenticity using our special protection:
the Bubble Tag™ ③ on the Proof tag placed on the outer packaging.

You have two options:

- option A: scan the QR code ①,
- option B: enter the authentication number ② on www.proof.fillmed.com.

PROOFTAG

- ① QR code to scan with your smartphone.
- ② Authentication number.
- ③ Bubble Tag™ to compare with the information available on the www.proof.fillmed.com.

USE

ART FILLER®
UNIVERSAL

DO NOT RESTERILIZE



DO NOT RE-USE



PROTECT FROM SUNLIGHT



THE PACKAGING MUST REMAIN DRY

DO NOT USE IF THE PACKAGING
IS DAMAGED

CONTAINS A MEDICINAL SUBSTANCE



STORAGE TEMPERATURE

READ THE NOTICE/THE
INSTRUCTIONS BEFORE USE

EXPIRY DATE



BATCH CODE



DATE OF MANUFACTURE



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EMERGO EUROPE B.V
Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands

* The needles contained in the pack are CE marked under
the responsibility of their manufacturer.



HEALTHCARE PROFESSIONALS LEAFLET

Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

DESCRIPTION

ART FILLER® UNIVERSAL is a viscoelastic cross-linked hyaluronic acid gel of non-animal origin gradually absorbed over time. It is colourless, transparent, sterile, non-pyrogenic and saline and contains a 0.3% volume of lidocaine hydrochloride for its anaesthetic properties. It is available in a pre-filled and single-use 1.2 mL syringe. Each pack contains 2 UNIVERSAL syringes, 4 sterile and single-use 27G½" needles intended for injection of UNIVERSAL, a product leaflet and 4 traceability labels. In order to guarantee the traceability of the product, one of the two labels must be attached to the patient medical file and the other must be stuck on the implant card, to be delivered to the patient.

COMPOSITION

Cross-linked sodium hyaluronate[25 mg/g] (constituent responsible for intended action)
Function: filling effect and moisturizing.

Average molecular weight: 1.0 to 1.5 x 10⁶ Dalton (long chain HA) / 3.7 to 4.5 x 10⁵ Dalton (very long chain HA).

Degree of cross-linking: 4.3% (modification degree) and determination method: RMN.

Lidocaine hydrochloride[3 mg/g]

Function: local anaesthetic agent.

Phosphate buffer solution (6.50 ≤ pH ≤ 7.50)

Function: adjustment of pH.

1, 4-butanediol diglycidyl ether (BDDE)[residual BDDE content] < 2 ppm

Function: crosslinking agent.

A syringe contains 1.2 mL of UNIVERSAL gel.

STERILISATION

The content of the UNIVERSAL syringes is sterilised using moist heat. The 27G½" needles are sterilised using radiation.

INTENDED USE / INDICATIONS

ART FILLER® products are intended to restore changes to skin structure caused by ageing, by filling the lines and creases in the facial skin and restoring volume. UNIVERSAL filler is an injectable implant indicated to fill in medium to deep nasolabial folds with or without marionette lines, and cheeks folds by dermal or subdermal injection. UNIVERSAL is indicated to add volume to define the shape of the nose by subdermal or dermal injection and restore volume to the midface by subdermal injection. UNIVERSAL is indicated to increase the volume of the lip and enhance the lip outline by submucous, intradermal or subdermal injection. The inclusion of lidocaine aims to reduce painful sensations for the patient during treatment.

CONTRAINDICATIONS

UNIVERSAL must not be injected:

- For correction of superficial and fine lines.
- Into the eye area (eyelids, crows' feet, under eye area).
- Into blood vessels.
- Into an area where a non-absorbable filler implant has already been injected.
- Do not over-correct.
- In patients with known hypersensitivity to hyaluronic acid, lidocaine and amide type local anesthetics.
- In patients with a medical history of auto-immune illness or receiving immunotherapy.
- In patients who have a medical history of severe multiple allergies or anaphylactic shock.
- In patients suffering from epilepsy that is not controlled with treatment.



- In patients affected by porphyria.
- In patients with a tendency to develop hypertrophic scars.
- In patients with medical history of recurring sore throats related to rheumatic fever localised in the heart.
- Do not use in conjunction with a medical treatment with inhibitors of cytochrome P450, due to interactions with lidocaine.
- In persons who are less than 18 years old.
- In pregnant or breastfeeding women.
- In areas that are inflamed and/or contagious skin lesions (acne, herpes, etc.).
- Immediately after or before laser treatment, deep chemical peeling or dermabrasion.

WARNINGS

- UNIVERSAL is not indicated for areas other than intradermal or subdermal areas and the mucous membrane of the lips.
- Do not inject into blood vessels, bones, tendons, ligaments or beauty spots.
- Unintentional injection of soft tissue fillers into blood vessels in the face can result in rare, but serious side effects such as embolization which can cause vision impairment, blindness, stroke and damage and/or skin and underlying facial structures necrosis. These rare cases of blood vessels embolization are mostly reported in glabella, in and around the nose, forehead, and periorbital region.
- Check the expiry date.
- Do not use if the packaging is opened or damaged.
- Check the integrity of the sterile barrier immediately prior to using the product.
- Do not use a syringe with opened or shifted tip cap within the blister.
- Do not re-use vial, needles and syringes for more than one patient.
- The re-use of a product bears a risk (e.g. cross-contamination) for the patient.

- Do not re-sterilize.
- Dispose of the syringe and the remaining product after use.
- After use, the needles must be thrown away in a suitable safe container. Refer to the guidelines in force for their disposal.
- Never try to straighten a bent needle. Dispose of it and replace it.
- Do not inject excessive volume, it can potentially lead to side effects.

PRECAUTIONS PRIOR TO USE

- There are no clinical data available in terms of efficacy and tolerance of the UNIVERSAL injections for an area that has already been treated with another "permanent" (no resorbable) filling product.
- There are no clinical data available in terms of efficacy and tolerance of the UNIVERSAL injections for Fitzpatrick phototypes V and VI.
- The healthcare professional must decide about the indication on a case by case basis according to the nature of the allergy and (s)he must specifically monitor patients who present a risk. In particular, (s)he may decide to offer a double test or adapted preventive treatment prior to any injection.
- UNIVERSAL must be used with precaution in patients with cardiac conduction conditions.
- UNIVERSAL must be used with a great deal of precaution in patients suffering from hepatocellular insufficiency with coagulation disorders as well as patients receiving treatment with medicinal products that reduce or inhibit hepatic metabolism which are prone to result in coagulation disorders.
- UNIVERSAL must be used with special care in patients with chronic herpes labialis.
- Patients must receive the following advice:
 - Avoid taking aspirin and vitamin C and/or vitamin E in high doses the week prior to the injection.
 - Patient receiving anticoagulant treatment must be warned of the increased risk of bruising and bleeding during injection.
 - Do not apply any make-up at all for 12 hours after the injection.



- Avoid exposure to extreme temperatures (extreme cold, sauna, steam room) as well as prolonged sun exposure or ultraviolet light for 2 weeks following the injection.
- If the needle is obstructed, do not increase the pressure on the tip of the plunger. Stop the injection and use a new needle.
- Healthcare professionals are reminded to bear in mind that this product contains lidocaine, they must take this into account.
- Lidocaine should be used with caution in patients receiving other local anaesthetics or other agents structurally related to amide -type local anaesthetics such as certain anti-arrhythmic medication, since the systemic toxic effects can be additive.
- Lidocaine should be used with caution in patients receiving a medical treatment, the patient must refer to the healthcare professional to evaluate the possible interaction with lidocaine.

INCOMPATIBILITIES

Hyaluronic acid is incompatible with quaternary ammonium compounds, such as benzalkonium chloride solutions. This is why UNIVERSAL must never come into contact with medical and surgical instruments treated with this type of product.

ADVERSE EFFECTS

The healthcare professional must inform the patient that the following potential adverse effects exist that are related to implantation of this device, such as:

- Vascular complications (embolism, ischemia, necrosis, loss of vision, thrombosis, paralysis, paraesthesia, hair loss).
- Systemic and local allergic reactions (itching sensation, Quincke edema/angioedema, anaphylactic shock).
- Inflammatory reactions (burning sensation, swelling, erythema, nodule, granuloma, fibrosis, skin

inflammation, fever, pain, local reaction – induration/pruritus).

- Infections (abscess, skin infection).

Other adverse events (hematoma, bruise, skin discoloration/Tyndall effect, poor filling effectiveness or poor filling effect, ecchymosis, migration, pain). The healthcare professional must ensure that the patient notifies them of any undesirable effects.

DECLARATION OF ADVERSE EFFECTS

The patient must inform the healthcare professionals as soon as possible if any side effect (cited above or other) occurs or if any side effect (cited above or other) persists for longer than one week. The implant must be checked and treated appropriately. The healthcare professionals will treat these adverse effects appropriately (see next section). The distributor and/or manufacturer must be alerted of any other adverse effect related to the injection of UNIVERSAL. Any serious incident must be reported to the authorities of the Member State in which the user and/or patient is established. You can report adverse reactions at the manufacturer directly by contacting: vigilance@fillmed.com or on website: <https://fillmed.com>. The Summary of Safety and Clinical Performance (SSCP) is available on Laboratoires FILL-MED's website.

TREATMENTS OF ADVERSE EFFECTS

- Vascular complications (ischemia, necrosis, loss of vision, embolism, paralysis...) can be treated by: oxygen therapy, antibiotics, analgesics, non-steroidal anti-inflammatory drugs (NSAID).
- Systemic and local allergic reactions (itching sensation, Quincke edema/angioedema...) can be treated by: antihistamines and corticosteroids, steroids, and hospitalization in case of angioedema/Quincke edema.
- Inflammatory reactions (swelling, erythema, pain, fever, local reaction-induration, nodule, granuloma, skin inflammation...) can be treated by: analgesics, NSAIDs, steroids, antibiotics and hyaluronidase.



- Infections (abscess...) can be treated by: antibiotics, analgesics, NSAIDs and surgical intervention.

Other adverse effects:

- Bruise, hematoma and ecchymosis can be treated with arnica and local cold compress.
 - Skin discoloration/Tyndall effect can be treated with hyaluronidase or massage of the involved zone.
- The prolonged use of any medication in treatment of adverse events has to be carefully assessed, since this may carry a risk for the patient.

INSTRUCTIONS FOR USE

The filler is intended to be injected slowly into the deep dermis or into the mucous membranes of the lips by healthcare professional trained in injection techniques. The healthcare professional can use injection techniques adapted to the area being treated with cannula or needle, such as: bolus, withdrawal/retrotracing (simple or fanning or criss-cross) and point per point. Before beginning the treatment, the patient must be informed of the indications of the device, its contraindications, its incompatibilities, and its potential adverse effects. All asepsis and hygiene precautions must be taken to prepare the site, the material and the patient prior to the injection. Injection can be performed in association with sterile single-use needles in accordance with their intended use. Use the 27G½" needle provided with the syringe. Remove the stopper of the syringe by pulling it out as indicated in diagram 1. Insert the needle correctly and firmly into the tip of the pre-filled syringe, twist it on carefully and ensure that the needle is in the correct position according to diagrams 2 and 3. Remove the cap of the needle (diagram 4) and slowly inject it into the dermis using the appropriate injection technique. After injection, the healthcare professional may massage the area lightly in order to distribute the product evenly. Graduations printed on the syringe label are intended to help the healthcare professional and cannot be considered as a measurement device. Use of the supplied needle is recommended. However, depending on the healthcare professional's preferred injection technique, it is possible to use sterilized cannula (between 22G½" and 25G½") not provided by manufacturer. Injection by cannula provides

subcutaneous delivery of the product.

After the treatment: the healthcare professional must provide the patient with both the patient leaflet and the completed implant card. The implant card is included inside the patient leaflet. The healthcare professional must remove the card, fill in the required information, affix the traceability label, and then give it to the patient along with the patient leaflet. Additionally, data relating to the injection (patient details and the product batch number from the traceability label) must be kept by the healthcare professional.

PROTOCOL

The injection volume depends on the correction required and is under the discretion of the healthcare professional. The recommended dose per treatment site is 1.0 mL per lip, 2.4 mL for the mid face and 1.2 mL for the other sites. A maximum of two treatment sessions per year is recommended. Possible touch-up sessions enable the sought-after degree of correction to be maintained. The recommended maximal dose per year is 15 mL. It is recommended to wait until side effects are resolved (with a minimal interval of 3 weeks) between two injections. Crosslinked hyaluronic acid resorption time is expected to be between 6 months and 12 months.

STORAGE CONDITIONS

Store ART FILLER® between 5°C and 25°C in a dry place protected from light and moisture. Handle with caution.

STANDARDS

The product is certified CE and compliant with harmonised standards and common specifications applicable to ART FILLER® UNIVERSAL referenced in SSCP-ARTFILLER-CL.

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LABORATOIRES

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