

(EN)

UCderm
Instructions for use for UCderm volume with Lidocaine

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

Abb. 1

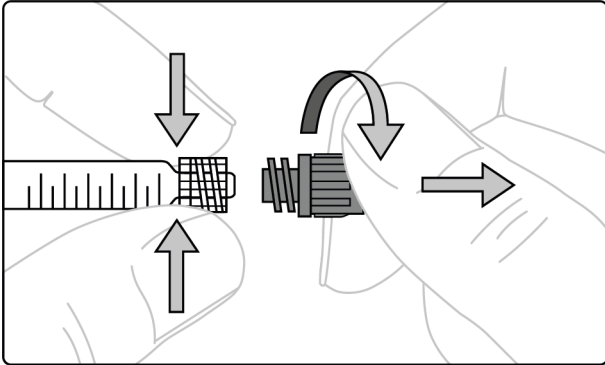


Abb. 2

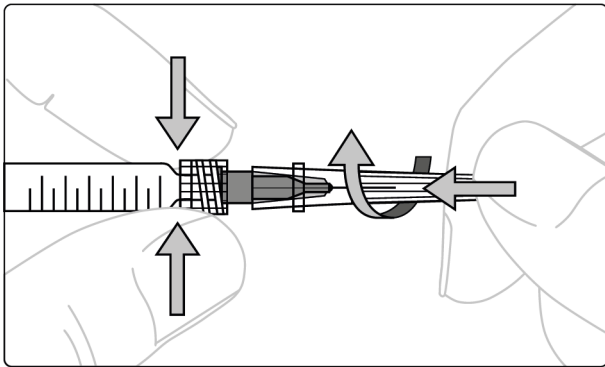
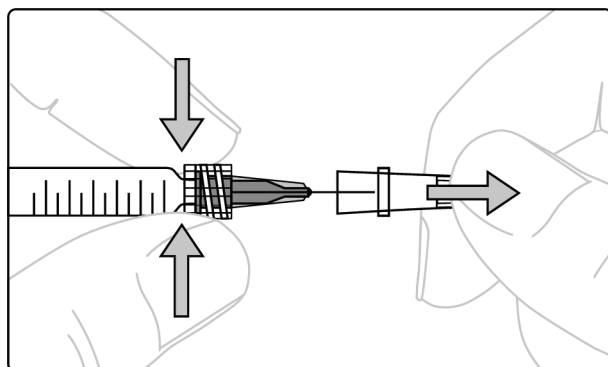


Abb. 3



Description:

UCderm volume is a sterile, isotonic, pyrogen-free, colourless and transparent gel with medium lifting power made of highly purified, crosslinked hyaluronic acid of non-animal origin in a physiological phosphat buffer. UCderm volume contains 0.3% lidocaine hydrochloride.

Content:

Each package contains one single-use glass syringe, pre-filled with 1 ml UCderm volume and sterilised by moist heat. In addition, there is one single-use 27G sterile needle to be used only for injecting UCderm volume, an instruction leaflet, a patient information leaflet, a patient card and two labels in order to ensure traceability in it.

Composition:

UCderm volume contains:

- 26 mg/ml of hyaluronic acid medium cohesively cross-linked by BDDE with a entry molecular weight of SZE 2.9 m3/kg,
- 3 mg/ml Lidocaine hydrochloride
- Phosphate buffer

The amount of gel in each syringe is 1 ml. The endotoxin content is <0.5 EU/ml, the pH value is between 6.8-7.2. The residual BDDE content is ≤0.002 mg/ml.

Indications/Intended use:

UCderm volume is a sterile, injectable, absorbable implant for augmenting the volume of facial soft tissues. This implant is indicated to lift different types of medium facial wrinkles, to fill and contour lips, to refine scars and to balance anatomical or injury-related asymmetries. Moreover, it is also intended for correction of facial fat loss caused by illness, medication or predisposition.

The product is intended to be used for injection into the mid to deep dermis or in the mucous membrane of the lips.

The lidocaine contained in the product is meant to reduce the patient's local pain during and for a short time after the injection.

Contraindications:

Do not apply UCderm volume in the following cases:

- In youths under 18 years of age.
- During pregnancy and breast-feeding.
- In case of incipient or existing influenza infections.
- In case of acute systemic infections.
- In case of skin inflammations (e.g. acne, herpes, psoriasis).
- In case of a known hypersensitivity to sodium hyaluronate or lidocaine hydrochloride or amide-based local anaesthetics.
- In case of known autoimmune diseases.
- In patients with blood clotting disorders or patients on anti-coagulation medication (e.g. aspirin, non-steroidal anti-inflammatory drugs).
- In case of acute articular rheumatism with cardiac localization.
- In patients with a tendency to hypertrophic scarring.
- In case of untreated epilepsy.
- In patients who suffer from porphyria.
- During treatment with drugs tending to slow down or inhibit the liver metabolism (e.g. cimetidine, beta-blockers).
- In case of cardiac arrhythmia.

Precautions for use:

Familiarise yourself completely with the product, the product information materials and the entire package leaflet.

In order to be prepared for the treatment of the most common adverse reactions associated with dermal fillers (e.g. overdose, swelling, nodules, immune reactions) and in case of intravascular injection, it is recommended to:

- ensure that appropriate consumables (such as cooling pads, corticosteroid, hyaluronidase, nitropaste) are immediately available for countermeasures.
- Identify a local ophthalmology specialist who is immediately available in case of an adverse ophthalmological event related to the injection.

The information given here does not constitute medical advice, a recommendation for the treatment of an adverse event or a complete list of possible measures.

You should assess each case individually and decide independently, based on your professional experience, which treatment is appropriate for your patients.

UCderm volume must not be injected in the periorbital area (eyelids, eye shadows, crow's feet) and glabellar region (forehead).

When treating facial areas with limited soft tissue support or soft tissue coverage, special care should be taken to avoid the formation of palpable lumps, discoloration or granulomas.

UCderm volume must not be injected into tendons, muscles, bones, joints or eyes.

UCderm volume is not intended for use in breast augmentation or breast reconstruction.

UCderm volume must not be injected into blood vessels. Introduction of product into the vasculature may lead to embolization or arterial ischemia or infarction. Therefore, the product should always be injected slowly and at the lowest possible pressure.

Do not overcorrect.

UCderm volume must not be used simultaneously with other aesthetic medicine techniques such as laser treatments, chemical peelings or dermabrasion.

If inflamed skin areas occur after the treatment with these techniques, injection into those areas is not recommended. The treated skin area has to heal completely first.

UCderm volume must not be injected into skin areas which had been subjected to a treatment with permanent implants, implants of animal origin or implants containing other substances than hyaluronic acid since this might trigger intolerances.

UCderm volume must not be mixed with other products.

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. Therefore, UCderm volume must never get into contact with these substances or with medical instruments which has been treated with these substances.

Application:

Before treatment with UCderm volume, inquire about any previous medical procedures, accidents, illnesses, medications, allergies or other concurrent treatments the patient may have that may interfere with or preclude the procedure.

Before treatment, inform the patient of the indications, contraindications, warnings, precautions, intolerances and possible undesirable side effects associated with the injection of hyaluronic acid-based dermal fillers. Ensure that the patient is aware of the signs and symptoms of possible complications.

Give the patient the enclosed mandatory patient information leaflet before treatment. In the event of treatment being carried out, add the position, number and quantity of injections of UCderm volume to this patient information sheet.

This product is indicated for injection into the mid to deep dermis or in the mucous membrane of the lips by a legally qualified, medical practitioner.

For successful treatment it is essential that the practitioner has been trained in injection technique for soft tissue augmentation. He/she has to be knowledgeable about the anatomy and physiology of the areas to be treated.

The treatment must be carried out under appropriate aseptic conditions. The area to be treated has to be disinfected thoroughly.

UCderm volume may be injected into healthy, non-inflamed skin areas only.

UCderm volume must not be injected into skin areas that contain residues of hyaluronic acid implants by other manufacturers. The last injection should be 6 months ago.

UCderm volume must not be injected into skin areas previously treated with an implant that is not based on hyaluronic acid.

Use the supplied, single-use sterile needle. For optimum use, assemble the needle as shown in Figures 1, 2 and 3 above.

1. Firmly hold the glass cylinder of the syringe and the Luer-lock between the thumb and the index finger of one hand. Carefully remove the protective cap from the syringe with the other hand.
2. Screw the supplied needle onto the syringe as far as it will go. Ensure not to twist the Luer lock.
3. Keep holding the Luer-lock and carefully remove the protective cap of the needle.

UCderm volume should be injected slowly and evenly. The amount to be injected depends on the correction to be achieved and the area to be treated. Do not overcorrect.

The syringe has an indexing scale.

Do not inject into blood vessels.

If the needle is blocked, do not increase the pressure on the plunger. Instead, stop the injection immediately and use a new needle.

Never bend a straight needle for injection.

Never try to straighten a bent needle. Discard the bent needle and replace it.

If a needle appears dull, discard the blunt needle and use a new needle.

Gently massage the treated area after the injection to distribute the product uniformly.

After treatment, the patient should be informed not to touch and irritate the treated area unnecessarily. The patient should avoid wearing make-up for at least 12 hours as well as prolonged exposure to the sun, UV light or temperatures below 0°C for at least 14 days.

In addition, visits to the sauna or hammam should be avoided for up to 2 weeks after the injection.

It is recommended to monitor the patient's condition for about one hour after the treatment to detect possible undesirable side effects.

Consider that the product contains substances which may produce a positive result in anti-doping tests.

Side effects:

The patient must be informed that they are possible side effects, which may occur immediately or may be delayed. These include, but are not limited to:

- Slight bleeding during the treatment which spontaneously subsides as soon as the injection is completed.
- Inflammatory reactions usually associated with injections such as redness, oedema, erythema, swelling, pain or hyperthermia sometimes accompanied with itching, burning or paraesthesia. These reactions may last for 3-5 days.
- Delayed injection-related inflammation such as persistent erythema or acne papule formation.
- Bleeding, haematomas or telangiectasia in the treated area.
- Swelling effect in other areas through displacement of adjacent structures or product migration.
- Immediate or delayed hypersensitivity or allergy (urticaria, in single cases anaphylaxis or Quincke's edema) to one of the product's components, especially to sodium hyaluronate and lidocaine hydrochloride.
- Infections, abscess, biofilm formation or recurrent herpetic lesions.
- Non-inflammatory and inflammatory nodule formation, induration or asymmetry.
- Skin discolouring at the injection site:
 - Due to superficial injection leading to bluish discoloration known as Tyndall Effect.
 - Due to ischemia leading to redness if vein is occluded or whiteness if artery is occluded.
 - Hyperpigmentation particularly in patients with Fitzpatrick skin type IV to VI.
- Non-inflammatory and inflammatory granuloma formation (foreign body reactions).
- Dermal fibrosis, ulcer, scarring or cellulitis.
- Lack of efficacy or reduced effect.

Cases of necrosis, muscle degeneration and osteitis after sodium hyaluronate injections have been reported in the literature. These rare potential risks must nevertheless be considered.

As a matter of general principle, injection of a medical device is associated with a risk of infection.

Possible treatments include ice, massages, warm compresses, medicines that dilate blood vessels, anti-inflammatory medicines (corticosteroids), antibiotics, medicines to relieve allergy symptoms (antihistamines), painkillers (analgesics), medicines that remove excess fluid from the body (diuretics), surgical procedures (incision, drainage or excision), operations or an enzyme that helps break down hyaluronic acid (hyaluronidase).

Again, this information does not constitute medical advice, a recommendation for the treatment of an adverse event, or a complete list of possible interventions.

You should assess each case individually and decide independently, based on your professional experience, which treatment is appropriate for your patients.

The patient should be instructed to report any side effects lasting longer than one week or occurring even weeks after treatment to their doctor immediately. The doctor can then prescribe a suitable treatment for the patient.

Warnings:

- Check the integrity of the package and the expiry date prior to use. Do not use the product if the package has already been opened or is visibly damaged or expiration date has been exceeded. UCderm volume has a shelf life of 3 years after the date of manufacture.
- Do not re-sterilise the product.
- Do not re-use the product.
- Used and partially used syringes and injection needles should be handled and disposed in accordance with facility medical practices and applicable regulations. Do not remove the needle from the syringe or put the protective cap back on the needle.

Storage:

Store UCderm volume between 2°C and 25°C and protect it from freezing and direct sunlight. Avoid mechanical shocks.

Manufacturer:

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Website: www.unicare.berlin
Phone: +49 (0) 30 63415601

Item number (IFU): UDBZ001xx003

Revision (IFU): 4 (2022-03)

UDI-DI (UCderm volume): 04260632410028

Please note: The summary report on safety, clinical performance, harmonised standards and common specifications of UCderm volume is deposited with Eudamed and can be found via the UDI-DI.

Symbole / Symbols (im Anhang):



- Hersteller / *Manufacturer*



- Steril, Sterilisierung mit feuchter Hitze / *Sterile, sterilisation with moist heat*



- Nicht resterilisieren / *Do not re-sterilise*



- Nur zum Einmalgebrauch. Nicht wiederverwenden / *Single use product. Not for re-use*



- Bei beschädigter Verpackung nicht verwenden / *Do not use if the package is damaged*



- Gebrauchsanweisung beachten / *See instructions for use*



- Begrenzung der Lagertemperatur: 2 °C – 25 °C / *Temperature limit of storage: 2 °C – 25 °C*



- Verwendbar bis / *Expiration date*



- Chargennummer / *Batch Code*



- Kennzeichnung CE entsprechend der Verordnung (EU) - 2017/745 für Medizinprodukte. Diesem Zeichen folgt die Nummer der benannten Stelle. / *CE mark in accordance with Regulation (EU) - 2017/745 relating to medical devices. This mark is followed by the notified body number.*