

(EN)

UCderm volume mit Lidocain

Patient information leaflet

Please read this important information before your treatment.

Product description

What is UCderm volume?

UCderm volume is a sterile, colourless and transparent gel of hyaluronic acid in a ready-to-use syringe. The gel is injected directly into the facial skin to temporarily even out skin imperfections or increase lip volume. It is considered an implant that is degraded by the body over time.

The hyaluronic acid used in UCderm volume is of non-animal origin. It is similar to hyaluronic acid, which also occurs naturally in the body. Its molecules, however, are cross-linked in the manufacturing process so that it binds optimally into the skin tissue of the treatment area and remains there for a longer period of time - usually more than 6 months.

In addition to hyaluronic acid, the gel contains a small amount of the local anaesthetic lidocaine, which reduces any pain that may occur during and a short time after the treatment.

Intended use / Indications

What is UCderm volume used for?

UCderm volume is used on the face to:

- Lift various types of medium wrinkles,
- Fill and contour lips,
- Refine scars and
- Balance anatomical or injury-related asymmetries.

Furthermore, it is also intended for correction of facial fat loss caused by illness, medication or predisposition.

How is UCderm volume applied?

The hyaluronic acid gel is injected with a fine needle into the middle to deep skin layer of the respective treatment area or into the tissue layer of the lips.

The lidocaine contained in the gel reduces pain sensitivity during and a short time after the injection.

Important: Only appropriately trained, legally licensed, medical professionals may administer UCderm volume.

Contraindications and restrictions for use

When must treatment with UCderm volume not be carried out?

Before using UCderm volume, your practitioner will talk to you about your initial situation and medical history to determine if you are suitable for treatment. You will be asked questions about any previous medical procedures, accidents, illnesses, medications, allergies and other simultaneous treatments to ensure that UCderm volume can be administered safely. Please inform your practitioner fully.

You **must not** be treated with UCderm volume if you:

- Are under 18 years of age.
- Are pregnant and/or breastfeeding.
- Have an incipient or existing cold.
- Have an acute infectious disease where the pathogens spread throughout the body.
- Have inflamed skin (e.g. due to acne, herpes, rashes, psoriasis or other aesthetic medicine procedures such as laser treatment, chemical peel or dermabrasion).
- Have a hypersensitivity / allergy to sodium hyaluronate, lidocaine hydrochloride or "amide-type" local anaesthetics.

- Have an autoimmune disease.
- Have a blood clotting disorder or are being treated with anti-coagulant drugs (e.g. aspirin, non-steroidal anti-inflammatory drugs).
- Have acute articular rheumatism with cardiac localization.
- Have a tendency to excessive, bulging (hypertrophic) scarring.
- Have untreated epilepsy.
- Suffer from porphyria.
- Take medications that slow down or inhibit liver metabolism (such as cimetidine, beta blockers) .
- Have cardiac arrhythmias.

If you are not sure which of these applies to you, please discuss this with your practitioner.

What is UCderm volume not intended for?

Please note that UCderm volume **must not** be applied:

- In the area of the eyes (eyelids, eye shadows, crow's feet).
- In the area of the forehead.
- In tendons, muscles, bones, joints or eyes.
- To enlarge or reconstruct the breast.
- In areas of skin that have undergone treatment with permanent implants, implants of animal origin or implants containing substances other than hyaluronic acid.
- In skin areas containing hyaluronic acid implants from other manufacturers that have not yet completely degraded. The last injection should be 6 months ago.
- If other aesthetic medicine procedures (e.g. laser treatment, chemical peeling or dermabrasion) have been performed simultaneously and the skin area to be treated has not yet healed completely.

Course of treatment

What happens during treatment with UCderm volume?

Please note that each practitioner has his or her own approach to implementation in order to be able to respond individually to each patient's initial situation and needs.

Before the treatment, he will, among other things:

- Talk to you about your medical history and ask you questions about any previous medical procedures, simultaneous treatments, accidents, illnesses, allergies, and medications you have been taking.
- Discuss with you the desired outcome of the procedure.
- Examine your face and decide whether UCderm volume is the right treatment for you and what you can expect from treatment with UCderm volume.
- Fully inform you about the intended use, contraindications, warnings, precautions and possible adverse side effects associated with the injection of hyaluronic acid-based dermal fillers.
- Inform you what to do if undesirable side effects occur or persist.

During the treatment, he will, among other things:

- Thoroughly disinfect your skin.
- Start the treatment with the first injection and continue until the area to be treated shows the desired result.
- Once the injection is complete, gently massage the treated area to ensure that the hyaluronic acid gel is evenly distributed and looks natural.

The users received appropriate training on the conditions to safely use the device.

What must be considered after treatment with UCderm volume?

Your practitioner will also tell you what to look for after the treatment.

Avoid touching and irritating the treated area unnecessarily immediately after the treatment.

Initially, have your condition monitored for about an hour after treatment so that your practitioner has the opportunity to detect any unwanted side effects immediately.

You should not wear make-up for the first 12 hours after treatment and avoid prolonged exposure to the sun, UV light or temperatures below 0°C for at least 14 days.

Refrain from visits to the sauna or hammam for up to 2 weeks after the injection.

What can you expect from a treatment with UCderm volume?

Please note that the result of a treatment with UCderm volume differs from patient to patient. Your practitioner will talk to you about the possibilities and limitations of UCderm volume and explain what effect can be achieved for you.

These may include

- Visibly reduced wrinkles.
- A larger lip volume.
- A symmetrical lip shape.
- An even skin texture.
- A fresher, younger appearance.

The results are usually visible for 6 months or longer. Exactly how long the effect lasts varies from patient to patient, as each body degrades hyaluronic acid at a different rate.

Please discuss your expectations with the practitioner to make sure they are realistic and feasible.

Risks and side effects

What are the risks of treatment with UCderm volume?

Any medically performed procedure carries the risk of negative side effects that may occur immediately or after a period of time.

To help you understand the risks of treatment with UCderm volume, your practitioner should talk to you about possible unwanted side effects that may occur when injecting hyaluronic acid gels.

These include (list not exhaustive):

- **Mild bleeding** during treatment, which resolves spontaneously as soon as the injection is completed.
- Inflammatory reactions usually associated with injections and lasting for about 3-5 days, such as **redness, swelling, pain, overwarming**, occasionally accompanied by **itching, burning** or unpleasant body sensations such as **tingling or numbness**.
- Delayed inflammatory reactions such as **persistent redness, formation of non-inflammatory and inflammatory nodules or pimples**.
- Non-inflammatory and inflammatory **granuloma formation** (foreign body reactions, often palpable induration).
- **Bleeding, bruising or visibly dilated blood vessels** in the treated area.
- **Swelling effect due to tissue shift** to other areas of the skin.
- Immediate or delayed **hypersensitivity reaction / allergy** to any of the ingredients of the product, especially sodium hyaluronate and lidocaine hydrochloride.
- **Infections, abscess formation, biofilm formation or recurrent herpes**.
- **Formation of abnormal new connective tissue (skin fibrosis), induration, asymmetry, ulceration, scarring or cellulitis**.
- Discolouration at the injection site:
 - A **bluish discolouration of the skin** due to superficial injection, also known as the Tyndall effect.
 - **Darkening of the skin** especially in patients with Fitzpatrick skin type IV to VI (light brown to dark brown, black skin).
 - **Reddening (venous occlusion) or blanching (arterial occlusion)** due to reduced or absent blood flow to tissues.
- **Lack of efficacy or reduced effect**.

Cases of **necrosis, muscle degeneration and inflammation of bone tissue (osteitis)** have been described in the literature after injections with sodium hyaluronate. These possible risks are rare, but must nevertheless be taken into account.

One of the biggest risks of using this type of product is **accidental injection into a blood vessel**. The possibility of this happening is very low, but if it does, the complications can be severe and possibly permanent. These complications, which have occurred with injections in the face, can include **visual disturbances, blindness, temporary scabbing or permanent scarring of the skin**.

Note that the product contains substances that may cause a positive reaction in a doping test.

When should a doctor be consulted?

Have your condition monitored for about an hour immediately after the treatment. This gives your practitioner the opportunity to recognise undesirable side effects immediately and to take appropriate countermeasures

(e.g. with ice, massages, medication or hyaluronidase).

If you experience **visual disturbances, numbness or weakness in the face, severe headache, dizziness, white appearance of the skin or unusual pain** during or shortly after treatment, notify your practitioner or doctor **immediately**.

Most side effects such as bruising, swelling, pain and redness usually subside within a week. Report any side effects that last longer than a week or occur even weeks after treatment to your doctor immediately. He or she can then prescribe a suitable treatment.

What if I have a problem or further questions?

If you think you have experienced a serious problem with UCderm volume, you should contact your doctor immediately.

We at UniCare GmbH can answer product questions about UCderm volume personally.

Manufacturer:

UniCare GmbH

Mittelstrasse 7

D-12529 Schoenefeld

Website: www.unicare.berlin

Phone: +49 (0) 30 63415601

Item number (IFU): UDVP001xx003

Revision (IFU): 1 (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.

The following information must be completed by the practitioner in the case of a performed treatment with UCderm volume:

Location of the injections Number of injections Used quantity

Place, date Signature