

Juvederm®Volux with Lidocain

Succinct Statement (CH)

Composition: sterile pyrogen-free physiological solution of cross-linked hyaluronic acid (25 mg/mL which is not of animal origin). Lidocaine hydrochloride (3 mg/mL), phosphate buffer. **Indications:** restore and create volume of the face. **Method of use:** subcutaneous and supraperiosteal injection by a qualified healthcare professional. **Contra-Indications:** periorbital area (eyelid, under-eye area, crow's feet), glabellar region, lips. No inj. into blood vessels (intravascular). Intravascular inj. may lead to embolization, occlusion of the vessels, ischemia or infarction. Do not overcorrect. Untreated epilepsy, hypertrophic scarring. Known hypersensitivity to hyaluronic acid, gram positive bacterial proteins, lidocaine or amide-type local anaesthetics. Porphyria. Pregnant/breast-feeding women. Patients <18y. No use in areas presenting inflammation and/or infections (acne, herpes, etc.). No simultaneous use with laser treatment, chemical peels or dermabrasion. **Precautions for use:** for subcutaneous and supraperiosteal inj. only. Not for breast augmentation/reconstruction. Risk of injection. No inj. in areas with permanent implants. Increased risk of vascular compromise/injury in the non-midline areas of the nose, nasal tip and in the post-surgical/traumatic nose. Caution in patients with a history of or currently suffering from auto-immune disease, history of severe multiple allergies or anaphylactic shock, history of streptococcal disease (recurrent angina and rheumatoid arthritis; double test before each injection), cardiac arrhythmia. No inj. in case of acute rheumatic fever with cardiac localisation. Risk of haematomas and bleeding under anti-coagulation medication (anticoagulants, aspirin or NAIDs, herbal supplements with garlic or ginkgo biloba, etc.). No data available regarding the safety of injecting greater amount than 20 mL per 60 kg body mass per year. The combination with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is inadvisable. No make-up, exposure to sun, UV rays and temp. <0°C during 12 hours following the inj. No sauna or hammam session during the two weeks following the inj. Avoid massaging the implementation area or putting pressure on it for a few days following inj. Information: Compatible with magnetic resonance imaging (MRI). **Incompatibilities:** quaternary ammonium salts (e.g. benzalkonium chloride). **Undesirable effects:** inflammatory reactions (redness, oedema, erythema, etc.) with itching or pain on pressure or paraesthesia (up to one week), haematomas, induration or nodules at inj. site, staining or discolouration of inj. site, poor effect or weak filling/restoration effect. Rare but serious adverse events: temporary or permanent vision impairment, blindness, cerebral ischemia or haemorrhage, stroke, skin necrosis and damage to underlying structures. Abscesses, granuloma, immediate or delayed hypersensitivity. **Package:** 2x 1 syringes containing 1 mL, 4 sterile single-use needles 27G1/2", instruction leaflet, labels to ensure traceability. **Administration by a qualified health care professional only. Status of information:** June 2019. Detailed product information on instruction leaflet. **Distribution / report of undesirable effects:** Allergan AG, Hardturmstrasse 11, 8005 Zürich or via email to quality.switzerland@allergan.com.