

Juvederm®Volite with Lidocain

Succinct Statement (CH)

Composition: sterile pyrogen-free physiological solution of cross-linked hyaluronic acid (12 mg/mL) which is not of animal origin. Lidocaine HCl (3 mg/mL), phosphate buffer pH 7.2. **Indications:** Superficial cutaneous depressions. For additional improvement of skin quality (hydration, elasticity). **Administration:** intra-dermal injection by a qualified health care professional. **Contra-Indications:** eyelids. Do not inject into the blood vessels (intravascular). Intravascular injection may lead to embolization, occlusion of the vessels, ischemia or infarction. Do not overcorrect. Untreated epilepsy; tendency to develop hypertrophic scarring; hypersensitivity to hyaluronic acid, gram positive bacterial proteins, lidocaine or to amide-type local anaesthetics, porphyria, women who are pregnant or breast-feeding, patients <18y, must not be used on areas showing skin problems such as inflammation and/or infections (acne, cold sores, etc.), must not be used in immediate association with laser treatment, chemical peeling, or dermabrasion. **Precautions for use:** only for intra-dermal injections. Not for breast augmentation/reconstruction. Precaution required for injections on areas that have already been treated with another dermal filler or permanent implant, in patients with a prior or active auto-immune disease, presenting a 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 nonsteroidal anti-inflammatory drugs, 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. Not recommended: combination with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.). No make-up, exposure to sun, UV rays and temp. <0°C for 12 hours following the inj. No sauna or hammam session during the two weeks following the inj. 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 after inj.). Haematomas. Induration or nodules at the inj. site. Coloration or discolouration of inj. area. Poor efficiency or 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. **Administration by a qualified health care professional only. Package:** 2x 1 syringes containing 1 mL, 4 sterile single-use needles 32G1/2", instruction leaflet, labels to ensure traceability. **Status of information:** September 2019. Detailed product information see package insert. **Distribution / report of undesirable effects:** Allergan AG, Hardturmstrasse 11, 8005 Zürich or via email: quality.switzerland@allergan.com.