

JUVÉDERM VOLUMA® XC Indication and Important Safety Information

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INDICATION

JUVÉDERM VOLUMA® XC injectable gel is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

This product should not be used in patients who have severe allergies, marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to gram-positive bacterial proteins or lidocaine contained in this product.

WARNINGS

- Do not inject into blood vessels. Introduction of this product into the vasculature may lead to embolization, occlusion of the vessels, ischemia or infarction. Take extra care when injecting soft-tissue fillers; for example, inject the product slowly and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft-tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and, possibly, evaluation by an appropriate healthcare professional specialist should an intravascular injection occur
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled

PRECAUTIONS

- In order to minimize risk of potential complications, this product should only be used by healthcare professionals who have appropriate training, experience, and knowledge of facial anatomy
- Healthcare professionals are encouraged to discuss the potential risks of soft-tissue injections with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications
- The safety and effectiveness for the treatment of anatomic regions other than the mid-face have not been established in controlled clinical studies
- The safety for use during pregnancy and in breastfeeding females has not been established
- The safety for use in patients under 35 or over 65 years has not been established
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection. Follow standard precautions associated with injectable materials
- The safety for use in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- Use with caution in patients on immunosuppressive therapy
- Patients who are using products that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events
- The safety for use in patients with very thin skin in the mid-face has not been established
- Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM VOLUMA® XC

ADVERSE EVENTS

Side effects in > 5% of subjects were temporary injection-site tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. They were predominantly moderate in severity, with a duration of 2 to 4 weeks.

To report an adverse reaction, please call Allergan Product Surveillance at 1-877-345-5372.

For more information, please see JuvedermDFU.com or call the Allergan Medical Information line at 1-800-433-8871.

JUVÉDERM VOLUMA® XC injectable gel is available by prescription only.

