

JUVÉDERM VOLUMA™ XC IMPORTANT INFORMATION

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

JUVÉDERM VOLUMA™ XC is contraindicated for patients with severe allergies, manifested by a history of anaphylaxis or history or presence of multiple severe allergies, and a history of allergies to gram-positive bacterial proteins or lidocaine.

WARNINGS

- JUVÉDERM VOLUMA™ XC injectable gel must not be injected into blood vessels and should not be used in vascular-rich areas. Use in these areas, such as glabella and nose, has resulted in cases of vascular embolization, occlusion of the vessels, ischemia or infarction, or blindness. Symptoms of vessel occlusion and embolization include pain that is disproportionate to the procedure or remote to the injection site, immediate blanching extending beyond the injected area, and color changes that reflect ischemic tissue such as a dusky or reticular appearance
- 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

- The safety and effectiveness for the treatment of anatomic regions other than the mid-face have 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 during pregnancy, in breastfeeding females, and in patients with very thin skin in the mid-face region has not been established
- The safety for use in patients under 35 years or over 65 years has not been established
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- JUVÉDERM VOLUMA™ XC injectable gel should be used 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 JUVÉDERM VOLUMA™ XC implantation may be at a higher risk for adverse events
- Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM VOLUMA™ XC
- Patients should be limited to 20 mL of JUVÉDERM VOLUMA™ XC per 60 kg (130 lbs) body mass per year. The safety of injecting greater amounts has not been established
- JUVÉDERM VOLUMA™ XC should only be used by physicians who have appropriate experience and who are knowledgeable about facial anatomy and the product for use in deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation

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 the About Safety page at www.juvederm.com or call the Allergan Medical Information line at 1-800-433-8871.

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