Combined Professional Full ISI

JUVÉDERM® Ultra XC, JUVÉDERM® Ultra Plus XC, and JUVÉDERM® VOLUMA® XC Important Information

INDICATIONS

JUVÉDERM® Ultra XC injectable gel is indicated for injection into the lips and perioral area for lip augmentation in adults over the age of 21.

JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC injectable gels are indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

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

These products 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 these products.

WARNINGS

- Do not inject into blood vessels. Introduction of these products into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra carewhen 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 the risk of potential complications, these products 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 moderate to severe facial wrinkles and folds with JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC, the lips and perioral area for lip augmentation with JUVÉDERM® Ultra XC, and the mid-face with JUVÉDERM® VOLUMA® XC, have not been established in controlled clinical studies
- 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 known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- The safety for use of JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC in patients under 18 years has not been established
- The safety for use of JUVÉDERM® VOLUMA® XC in patients under 35 or over 65 years has not been established
- 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
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or if the product is administered before the skin has healed completely, there is a possible risk of an inflammatory reaction at the treatment site
- Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events
- The safety of JUVÉDERM® VOLUMA® XC injectable gel 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

The most commonly reported side effects for JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC injectable gels were temporary injection-site redness, swelling, pain/tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM® Ultra XC or JUVÉDERM® Ultra Plus XC, they were mostly mild or moderate in severity, with a duration of 14 days or less; and for JUVÉDERM® VOLUMA® XC, they were predominantly moderate in severity, with a duration of 2 to 4 weeks.

To report an adverse reaction with JUVÉDERM® Ultra XC, JUVÉDERM® Ultra Plus XC, or JUVÉDERM® VOLUMA® XC, please call Allergan Product Surveillance at 1-800-624-4261.

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

JUVÉDERM® Ultra XC, JUVÉDERM® Ultra Plus XC, and JUVÉDERM® VOLUMA® XC injectable

gels are available by prescription only.