

JUVÉDERM® Collection of Fillers Important Information

INDICATIONS

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.

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 VOLLURE™ XC injectable gel is indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) in adults over the age of 21.

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 VOLBELLA® XC injectable gel is indicated for injection into the lips for lip augmentation and for correction of perioral rhytids 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 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 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 the mid-face with JUVÉDERM VOLUMA[®] XC; facial wrinkles and folds with JUVÉDERM[®] Ultra XC, JUVÉDERM[®] Ultra Plus XC, and JUVÉDERM VOLLURE[™] XC; and the lips and perioral area with JUVÉDERM[®] Ultra XC and JUVÉDERM VOLBELLA[®] 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 VOLUMA[®] XC in patients under 35 or over 65 years, JUVÉDERM[®] Ultra XC and JUVÉDERM[®] Ultra Plus XC in patients under 18 years, and JUVÉDERM VOLLURE[™] XC and JUVÉDERM VOLBELLA[®] XC in patients under 22 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
- Patients may experience late onset adverse events with use of dermal fillers

ADVERSE EVENTS

The most commonly reported side effects for JUVÉDERM[®] injectable gels were injection-site redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM VOLBELLA[®] XC, dryness was also reported. For JUVÉDERM VOLUMA[®] XC, side effects were predominantly moderate in severity, with duration of 2 to 4 weeks; for JUVÉDERM[®] Ultra XC, JUVÉDERM[®] Ultra Plus XC, or JUVÉDERM VOLLURE[™] XC, they were mostly mild or moderate in severity, with duration of 14 days or less; and for JUVÉDERM VOLBELLA[®] XC, they were predominantly mild or moderate, with duration of 30 days or less.

Products in the JUVÉDERM® Collection are available by prescription only.