HCP Full ISI: JUVÉDERM® Collection

JUVÉDERM® Collection of Fillers Important Information

INDICATIONS

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

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 Plus XC and JUVÉDERM® Ultra 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® 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.

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.

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

- 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 and product use in indicated areas

- The potential risks of soft-tissue injections should be discussed with patients prior to treatment to ensure they are aware of signs and symptoms of complications
- The safety and effectiveness for the treatment of anatomic regions other than the mid-face, chin, and prejowl sulcus regions with JUVÉDERM® VOLUMA™ XC; facial wrinkles and folds with JUVÉDERM® VOLLURE™ XC, JUVÉDERM® Ultra Plus XC, and JUVÉDERM® Ultra XC; and the lips and perioral area with JUVÉDERM® VOLBELLA™ XC and JUVÉDERM® Ultra XC have not been established in controlled clinical studies
- The safety for use of these products 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 has been established in patients between 35 and 65 years of age in cheek augmentation and for patients between 22 and 80 years of age for chin augmentation
- The safety for use of JUVÉDERM® Ultra Plus XC and JUVÉDERM® Ultra XC in patients under 18 years, and JUVÉDERM® VOLLURE™ XC and JUVÉDERM® VOLBELLA™ XC in patients under 22 years, has not been established
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection
- Use dermal fillers 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 of JUVÉDERM® VOLUMA™ XC injectable gel in patients with very thin skin in the mid-face has not been established
- The safety of JUVÉDERM® VOLUMA™ XC with cannula for cheek augmentation has not been established in patients with Fitzpatrick Skin Types V and VI
- JUVÉDERM® VOLUMA™ XC was not evaluated in subjects with significant skin laxity of the chin, neck, or jaw in the chin augmentation study
- The effect of JUVÉDERM® VOLUMA™ XC injection into the chin on facial hair growth has not been studied
- 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 redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM® VOLBELLA™ XC, dryness was also reported. The majority were mild or moderate in severity. For JUVÉDERM® VOLUMA™ XC, most resolved within 2 to 4 weeks. For JUVÉDERM® VOLLURE™ XC, JUVÉDERM® Ultra Plus XC, or JUVÉDERM® Ultra XC, most resolved within 14 days; and for JUVÉDERM® VOLBELLA™ XC, most resolved within 30 days.

To report an adverse reaction with any product in the JUVÉDERM® Collection, please call Allergan at 1-800-433-8871. Please visit JuvedermDFU.com for more information.

Products in the JUVÉDERM® Collection are available only by a licensed physician or properly licensed practitioner.