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 and for augmentation of the chin region to improve the chin profile in adults over the age of 21.

JUVÉDERM® VOLUX™ XC injectable gel is indicated for subcutaneous and/or supraperiosteal injection for improvement of jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition.

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® VOLBELLA® XC injectable gel is indicated for injection into the lips for lip augmentation and correction of perioral rhytids, and for the improvement of infraorbital hollowing 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® Ultra XC injectable gel is also 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soft tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary.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 are knowledgeable about the anatomy and the product(s) for use in indicated area(s), and who have appropriate training in facial anatomy, vasculature, safe injection techniques, and identification and management of potential adverse events, including intravascular complications
- 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 indicated areas for each product have not been established in controlled clinical studies
- The safety for use of these products in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- The safety for use during pregnancy and in breastfeeding females has not been established

- The safety for use of JUVÉDERM® VOLUMA® XC has been established in patients between 35 and 65 years of age for cheek augmentation and in 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 the safety for use of JUVÉDERM® VOLUX™ XC, JUVÉDERM® VOLLURE® XC, and JUVÉDERM® VOLBELLA® XC in patients under 22 years, has not been established
- Dermal filler implantation carries a risk of infection. Follow standard precautions
- Dermal fillers should be used with caution in patients on immunosuppressive therapy
- Patients taking medications 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
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or before skin has healed from a procedure prior to treatment, there is a possible risk of eliciting an inflammatory reaction at the injection site
- 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 for use 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 adverse events with injectable gel implants, and late- onset nodules with use of JUVÉDERM® VOLUMA® XC
- Based on preclinical studies, patients should be limited to 20 mL of any JUVÉDERM® injectable gel per 60 kg (132 lb) body mass per year. The safety of injecting greater amounts has not been established
- Injection of more than 9 mL of JUVÉDERM® VOLUX™ XC for improvement of jawline definition has not been studied

ADVERSE EVENTS

The most common 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.

To report an adverse reaction with any product in the JUVÉDERM® Collection, please call Allergan® Product Support at 1-877-345-5372. Please visit JuvedermDFU.com for more information.

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