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JUVÉDERM® XC and JUVÉDERM VOLUMA® XC Important Information

INDICATIONS

JUVÉDERM® 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).

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® XC and JUVÉDERM VOLUMA® XC 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.

WARNINGS

- JUVÉDERM® XC injectable gel and 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 or infection is present should be deferred until resolved

PRECAUTIONS

- The safety for use in patients under 18 years for JUVÉDERM® XC, and for patients under 35 years or over 65 years for JUVÉDERM VOLUMA® XC, has not been established
- The safety and effectiveness of JUVÉDERM® XC for the treatment of anatomic regions other than facial wrinkles and folds, and of JUVÉDERM VOLUMA® XC for regions other than the mid-face, have not been established
- 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
- 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
- Dermal filler implantation carries the risk of infection. Standard precautions associated with injectable materials should be taken
- The safety of JUVÉDERM VOLUMA® XC injectable gel for use in patients with very thin skin in the mid-face has not been established
- The long-term safety of repeat treatments with JUVÉDERM VOLUMA® XC has not been established
- Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM VOLUMA® XC
- JUVÉDERM VOLUMA® XC should only be used by healthcare professionals 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

The most commonly reported side effects for JUVÉDERM® XC injectable gel were temporary injection-site redness, swelling, pain/tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. They were predominantly mild or moderate in severity, with a duration of 7 days or less.

Side effects for JUVÉDERM VOLUMA® XC injectable gel 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 www.JuvedermDFU.com or call the Allergan Medical Information line at 1-800-433-8871.

JUVÉDERM® XC and JUVÉDERM VOLUMA® XC injectable gels are available by prescription only.

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