JUVÉDERM® XC Indication and Important Safety Information

JUVÉDERM® XC Important Information

INDICATION

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

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, JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC injectable gels 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® XC, and the lips and perioral area for lip augmentation with JUVÉDERM® Ultra 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 under 18 years has not been established
- The safety 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

ADVERSE EVENTS

The most commonly reported side effects are temporary injection-site redness, swelling, pain/tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. Most side effects are mild or moderate in nature, lasting 14 days or less.

To report a problem with JUVÉDERM® Ultra XC or JUVÉDERM® Ultra Plus 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 and JUVÉDERM® Ultra Plus XC injectable gels are available by prescription only.

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