

JUVÉDERM® Injectable Gel Fillers Important Information

APPROVED USES

JUVÉDERM® VOLUMA™ XC injectable gel is for deep injection in the cheek area to correct age-related volume loss and for augmentation of the chin region to improve the chin profile in adults over 21.

JUVÉDERM® VOLLURE™ XC and JUVÉDERM® XC injectable gels are for injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. JUVÉDERM® VOLLURE™ XC injectable gel is for adults over 21.

JUVÉDERM® VOLBELLA™ XC injectable gel is for injection into the lips for lip augmentation and for correction of perioral lines in adults over 21.

JUVÉDERM® Ultra XC injectable gel is for injection into the lips and perioral area for lip augmentation in adults over 21.

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive any JUVÉDERM® formulation?

Do not use these products if you have a history of multiple severe allergies or severe allergic reactions (anaphylaxis), or if you are allergic to lidocaine or the Gram-positive bacterial proteins used in these products.

What precautions should my doctor advise me about?

- Minimize strenuous exercise and exposure to extensive sun or heat within the first 24 hours following treatment. Exposure to any of these may cause temporary redness, swelling, and/or itching at the injection site
- Tell your doctor if you are pregnant or breastfeeding. The safety of these products for use during pregnancy or while breastfeeding has not been studied
- The safety of JUVÉDERM® VOLUMA™ XC has not been studied in patients under 35 years or over 65 years for cheek augmentation, or under 22 years and over 80 years for chin augmentation. The safety of JUVÉDERM® VOLLURE™ XC and JUVÉDERM® VOLBELLA™ XC has not been studied in patients under 22 years, and the safety of JUVÉDERM® XC and JUVÉDERM® Ultra XC has not been studied in patients under 18 years
- The safety and effectiveness of JUVÉDERM VOLUMA® XC in areas other than the cheek area, JUVÉDERM® XC and JUVÉDERM VOLLURE™ XC for areas other than facial wrinkles and folds, and JUVÉDERM® Ultra XC and JUVÉDERM VOLBELLA® XC in areas other than the lips and perioral area have not been established in clinical studies
- JUVÉDERM® VOLUMA™ XC is intended for use in the chin and cheek areas. JUVÉDERM® VOLLURE™ XC and JUVÉDERM® XC are intended for use in facial wrinkles and folds. JUVÉDERM® VOLBELLA™ XC and JUVÉDERM® Ultra XC are intended for use in the lips and perioral area. The safety and effectiveness for treatment in other areas have not been established in clinical studies

- Tell your doctor if you have a history of excessive scarring (thick, hard scars) or pigmentation disorders. The safety of JUVÉDERM® products has not been studied in these patients and may result in additional scars or changes in pigmentation
- Tell your doctor if you are on therapy used to decrease the body's immune response (immunosuppressive therapy). Use may result in an increased risk of infection
- Tell your doctor before treatment if you are using substances that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may result in increased bruising or bleeding at the injection site
- Patients who experience skin injury near the site of injection may be at a higher risk for adverse events
- JUVÉDERM® VOLUMA™ XC was not studied in patients with significant loose skin of the chin, neck, or jaw
- The effect of JUVÉDERM® VOLUMA™ XC injection into the chin on facial hair growth has not been studied

What are possible side effects?

The most commonly reported side effects with JUVÉDERM® injectable gels included redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM® VOLBELLA™ XC, dryness was also reported. For JUVÉDERM® VOLUMA™ XC, most side effects resolved within 2 to 4 weeks. For JUVÉDERM® VOLLURE™ XC, JUVÉDERM® XC, and JUVÉDERM® Ultra XC injectable gels, most resolved within 14 days or less. For JUVÉDERM® VOLBELLA™ XC, most resolved within 30 days or less. These side effects are consistent with other facial injection procedures.

Most side effects will resolve with time. Your doctor may choose to treat side effects persisting over 30 days with antibiotics, steroids, or hyaluronidase (an enzyme that breaks down hyaluronic acid).

One of the risks with these products is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

As with all skin injection procedures, there is a risk of infection.

Visit Juvederm.com or talk to your doctor for more information. To report a side effect with any JUVÉDERM® product, please call Allergan at 1-800-433-8871.

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