JUVÉDERM VOLBELLA® XC Before-and-After Photo Files

INSTRUCTIONS FOR USE

This zip file contains PDF files with images and Important Safety Information to copy and paste into your practice materials, as needed. Follow these guidelines when using the branding images or photo files:

1. The Indication and Important Safety Information must be displayed whenever the branding images or photo files appear.

2. The Important Safety Information should not be changed in any way. It cannot be abbreviated nor altered.

JUVÉDERM VOLBELLA® XC Indication and Important Safety Information

JUVÉDERM VOLBELLA® XC Important Information

INDICATION

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

This product 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 this product.

WARNINGS

- Do not inject into blood vessels. Introduction of this product 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, this product 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 the lips and perioral area for lip augmentation and correction of perioral rhytids with JUVÉDERM VOLBELLA® 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 with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- The safety for use of JUVÉDERM VOLBELLA® XC in patients under 22 years has not been established
- 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 may experience late onset adverse events with use of dermal fillers, including JUVÉDERM VOLBELLA® XC

ADVERSE EVENTS

The most commonly reported side effects for JUVÉDERM VOLBELLA® XC injectable gel were temporary injection-site redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, itching, and dryness. They were predominantly mild or moderate, with a duration of 30 days or less.

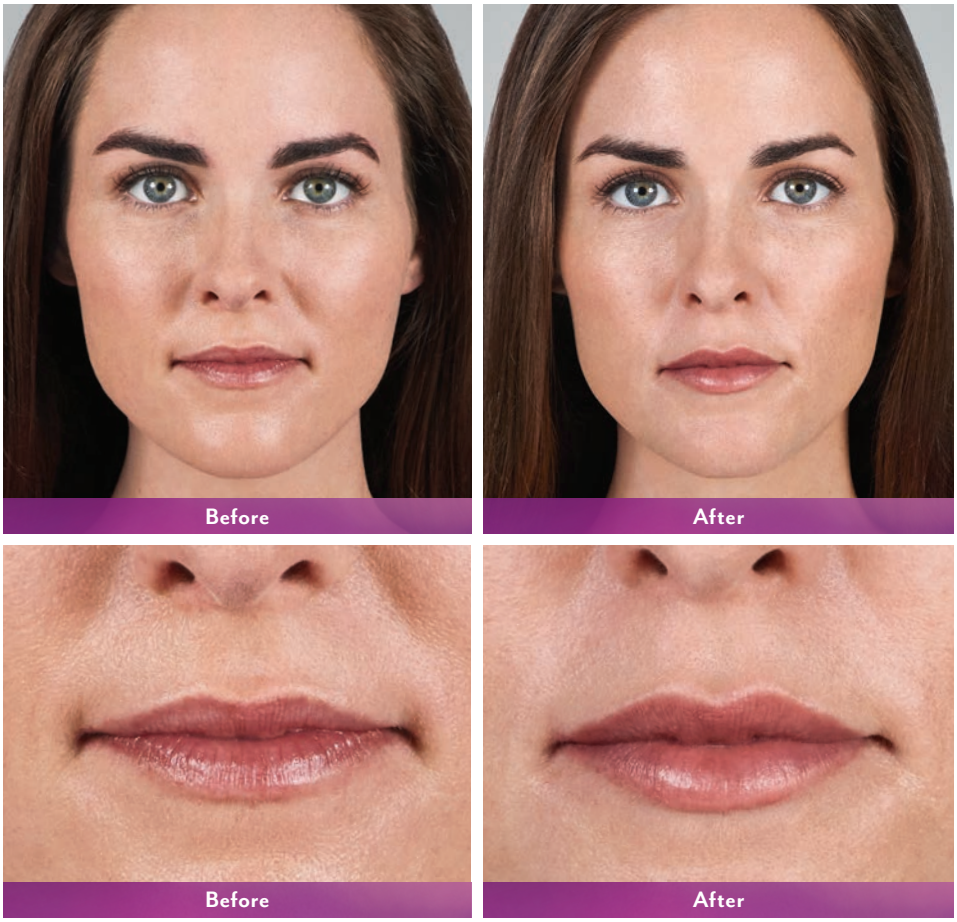
To report an adverse reaction with JUVÉDERM VOLBELLA® XC, please call Allergan at 1-800-433-8871. Please also visit JuvedermDFU.com for more information.

JUVÉDERM VOLBELLA® XC injectable gel is available by prescription only.

Allergan

Juvederm.com/professional JUV104908 03/17 170521

JUVÉDERM VOLBELLA® XC Before-and-After Photos (Bridgham 1)



Actual patient. Results may vary. Unretouched photos of paid patient taken before treatment and 1 month after treatment. A total of 1.1 mL of JUVÉDERM VOLBELLA® XC was injected—0.05 mL into the corner lines and 1.05 mL into the lips for lip augmentation.

APPROVED USES

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

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive JUVÉDERM VOLBELLA® XC injectable gel?

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

What precautions should my doctor advise me about?

- Tell your doctor if you are pregnant or breastfeeding. The safety of JUVÉDERM VOLBELLA® XC for use during pregnancy or while breastfeeding has not been studied
- The safety of JUVÉDERM VOLBELLA® XC in patients under 22 years has not been studied
- The safety and effectiveness of JUVÉDERM VOLBELLA® XC in areas other than the lips and perioral area have not been established in controlled clinical studies
- Tell your doctor if you have a history of excessive scarring (eg, hypertrophic scarring and keloid formation) or pigmentation disorders, as use of JUVÉDERM VOLBELLA® XC may result in additional scars or changes in pigmentation
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of JUVÉDERM VOLBELLA® XC may result in an increased risk of infection
- Tell your doctor if you are using medications that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners, as this may result in increased bruising or bleeding at the injection site
- Minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages within the first 24 hours following treatment

What are possible side effects?

The most common side effects included swelling, tenderness, bruising, firmness, lumps/bumps, redness, pain, discoloration, itching, and dryness. Most side effects were mild or moderate and lasted 30 days or less.

One of the risks with using this product is unintentional injection into a blood vessel, and while rare, 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.

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

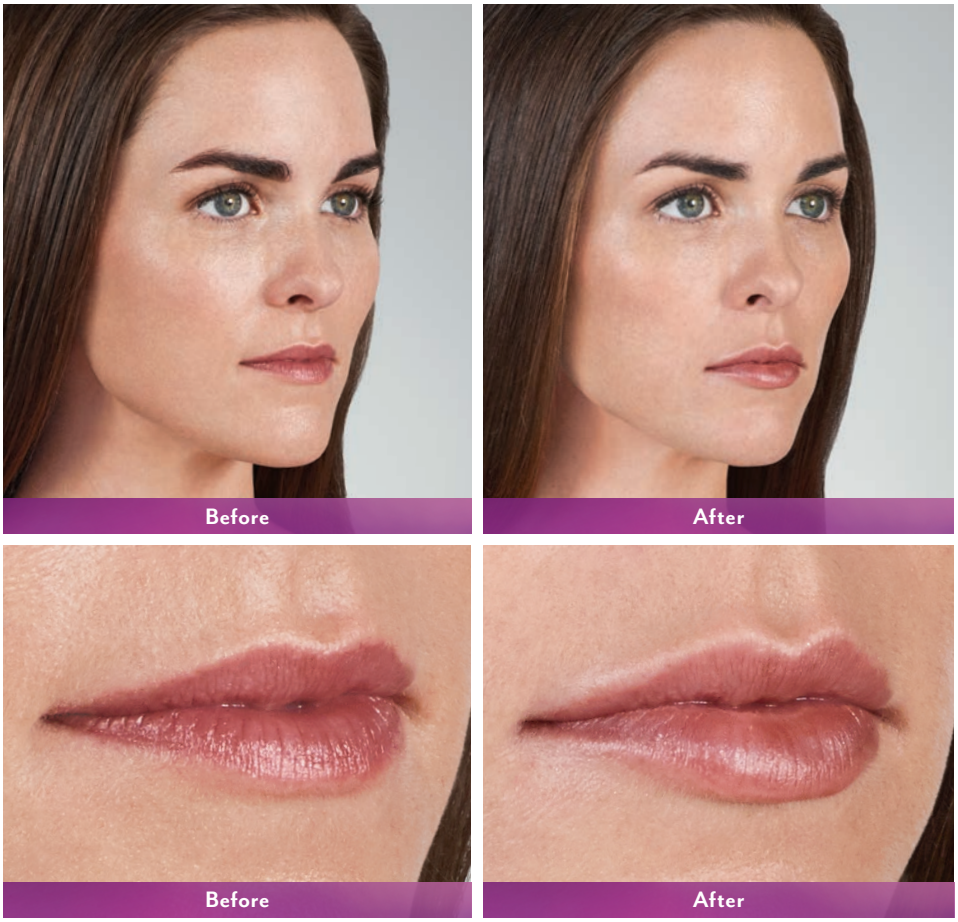
To report a side effect with JUVÉDERM VOLBELLA® XC, please call Allergan at 1-800-433-8871. Please also visit Juvederm.com for more information.

Available by prescription only.

Allergan

Juvederm.com JUV104908 03/17 170521

JUVÉDERM VOLBELLA® XC Before-and-After Photos (Bridgham 2)



Actual patient. Results may vary. Unretouched photos of paid patient taken before treatment and 1 month after treatment. A total of 1.1 mL of JUVÉDERM VOLBELLA® XC was injected—0.05 mL into the corner lines and 1.05 mL into the lips for lip augmentation.

APPROVED USES

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

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive JUVÉDERM VOLBELLA® XC injectable gel?

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

What precautions should my doctor advise me about?

- Tell your doctor if you are pregnant or breastfeeding. The safety of JUVÉDERM VOLBELLA® XC for use during pregnancy or while breastfeeding has not been studied
- The safety of JUVÉDERM VOLBELLA® XC in patients under 22 years has not been studied
- The safety and effectiveness of JUVÉDERM VOLBELLA® XC in areas other than the lips and perioral area have not been established in controlled clinical studies
- Tell your doctor if you have a history of excessive scarring (eg, hypertrophic scarring and keloid formation) or pigmentation disorders, as use of JUVÉDERM VOLBELLA® XC may result in additional scars or changes in pigmentation
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of JUVÉDERM VOLBELLA® XC may result in an increased risk of infection
- Tell your doctor if you are using medications that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners, as this may result in increased bruising or bleeding at the injection site
- Minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages within the first 24 hours following treatment

What are possible side effects?

The most common side effects included swelling, tenderness, bruising, firmness, lumps/bumps, redness, pain, discoloration, itching, and dryness. Most side effects were mild or moderate and lasted 30 days or less.

One of the risks with using this product is unintentional injection into a blood vessel, and while rare, 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.

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

To report a side effect with JUVÉDERM VOLBELLA® XC, please call Allergan at 1-800-433-8871. Please also visit Juvederm.com for more information.

Available by prescription only.

Allergan

Juvederm.com JUV104908 03/17 170521