

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC

Indications and Important Safety Information

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC 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® 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.

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soft-tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary.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 risks of potential complications, these products should only be used by healthcare professionals with appropriate experience and training on facial anatomy and product use in indicated area(s), 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 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® 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® VOLBELLA® XC in patients under 22 years has not been established
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection
- 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 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 use of these dermal fillers, 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 (130 lbs) body mass per year. The safety of injecting greater amounts has not been established

ADVERSE EVENTS

The most commonly 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. For JUVÉDERM® VOLUMA® XC, side effects were predominantly moderate in severity, with duration of 2 to 4 weeks; and for JUVÉDERM® VOLBELLA® XC, they were predominantly mild or moderate in severity, with duration of 30 days or less.

To report an adverse reaction with JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC, please call the Allergan® Product Support Department at 1-877-345-5372. Please visit JuvedermDFU.com for more information.

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC injectable gels are available only by a licensed physician or properly licensed practitioner.

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC Before-and-After Photos (Sarah)



BEFORE



AFTER TREATING THE CHEEKS
WITH
JUVÉDERM®
VOLUMA® XC



AFTER TREATING THE UNDEREYE HOLLOWS
WITH
JUVÉDERM®
VOLBELLA® XC



Actual patient. Results may vary.

Unretouched photos of paid patient taken before treatment and 1 month after treatment. A total of 5.0 mL of JUVÉDERM® VOLUMA® XC was injected into the cheek area, and a total of 1.4 mL of JUVÉDERM® VOLBELLA® XC was injected into the undereye hollows.

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC 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® VOLBELLA® XC injectable gel is for injection into the lips for lip augmentation and correction of perioral lines, and for injection into the undereye hollows to improve the appearance of undereye hollows in adults over the age of 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), if you are allergic to lidocaine or the Gram-positive bacterial proteins used in these products, or if you have had previous allergic reactions to hyaluronic acid fillers.

What warnings should my doctor advise me about?

- One of the risks with using dermal fillers is the 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
- The use of dermal fillers where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed, as this may delay healing or make skin problems worse

What precautions should my doctor advise me about?

- JUVÉDERM® VOLBELLA® XC should only be injected into undereye hollows by doctors who have completed the necessary training for this treatment area. To find a doctor, visit Juvéderm.com/find-a-specialist. Doctors who complete the training will be listed with a symbol
- 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® VOLBELLA® XC has not been studied in patients under 22 years
- The safety and effectiveness of treatment with JUVÉDERM® products in anatomical regions outside of their approved uses have not been established in clinical studies
- If you have a history of excessive scarring (thick, hard scars) or pigmentation disorders, treatment in these patients has not been studied and may result in additional scars or changes in pigmentation

- If you are planning other procedures including laser treatments or a chemical peel, there is a possible risk of inflammation at the treatment site if these procedures are performed closely before or after JUVÉDERM® injectable gel treatment
- Tell your doctor if you are on therapy used to reduce your body's natural defense system (such as steroids, chemotherapy, and medicines to treat autoimmune diseases, HIV, and AIDS), as these may increase your risk of infection; and medications that can prolong bleeding (such as aspirin, ibuprofen, or other blood thinners), as these 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, as these may cause temporary redness, swelling, and/or itching at the injection site
- 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
- Patients who experience skin injury near the site of JUVÉDERM® VOLUMA® XC injection may be at a higher risk for adverse events

What are possible side effects of treatment?

The most commonly reported side effects with JUVÉDERM® injectable gels were redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM® VOLBELLA® XC, dryness was also reported.

These side effects are consistent with other facial injection procedures and most 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).

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

To report a side effect with any product in the JUVÉDERM® Collection, please call the Allergan® Product Support Department at 1-877-345-5372. Please also visit Juvéderm.com or talk to your doctor for more information.

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLBELLA® XC injectable gels are available only by a licensed physician or properly licensed practitioner

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