

JUVÉDERM® VOLUX™ XC and JUVÉDERM® VOLUMA® XC

Important Information

INDICATIONS

JUVÉDERM® VOLUX™ XC injectable gel is indicated for subcutaneous and/or supraperiosteal injection for improvement of jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition.

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.

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 For example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular.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, or 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 risk of potential complications, these products should only be used by healthcare professionals who are knowledgeable about the anatomy and the product(s) for use in indicated area(s), and who have appropriate training in facial anatomy, 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 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® VOLUX™ XC in patients under 22 years has not been established.
- The safety for use during pregnancy and in breastfeeding females has not been established.
- Dermal filler implantation carries a risk of infection. Follow standard precautions.
- 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.
- 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 for use 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 injectable gel implants, 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 (132 lb) body mass per year. The safety of injecting greater amounts has not been established.
- Injection of more than 9 mL of JUVÉDERM® VOLUX™ XC for improvement of jawline definition has not been studied.

ADVERSE EVENTS

The most common reported side effects for JUVÉDERM® injectable gels were redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. The majority were mild or moderate in severity.

To report an adverse reaction with any product in the JUVÉDERM® Collection, please call Allergan® Product Support at 1-877-345-5372. Please visit JuvedermDFU.com for more information.

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

JUVÉDERM® VOLUX™ XC and JUVÉDERM® VOLUMA® XC Before-and-After Photos (Mykol)

BEFORE

AFTER



Actual patient. Results may vary.

Unretouched photos of paid patient taken before treatment and 1 month after treatment. A total of 7.0 mL of JUVÉDERM® VOLUX™ XC was injected into the jawline. A total of 4.0 mL of JUVÉDERM® VOLUMA® XC was injected into the chin area. Note: In the JUVÉDERM® VOLUMA® XC chin study, the primary effectiveness endpoint was below 50% for male subjects. However, the satisfaction rates were high and the secondary endpoints were met in this subgroup.¹

JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLUX™ XC Injectable Gel Important Information

APPROVED USES

JUVÉDERM® VOLUX™ XC injectable gel is for deep injection to improve moderate to severe loss of jawline definition in adults over the age of 21.

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.

Please see more Important Safety Information continued on next page.

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JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLUX™ XC Injectable Gel Important Information (continued)

IMPORTANT SAFETY INFORMATION

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

Do not use 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, 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. Most of these events are irreversible.
- If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment, you should notify your health care practitioner immediately.
- The use of dermal fillers where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete, as these could delay healing or make your skin problems worse.
- The effectiveness of removal of any dermal filler has not been studied.

What precautions should my doctor advise me about?

- Avoid applying makeup for 12 hours after treatment and 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 and effectiveness of treatment with JUVÉDERM® products in anatomical regions outside of their approved uses 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® VOLUMA® XC and JUVÉDERM® VOLUX™ XC in patients with a history of excessive scarring or pigmentation disorders has not been studied. Use in these patients may result in additional scars or changes in pigmentation
- 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
- 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
- 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 have already been injected with dermal fillers in the same area as the one(s) you are about to be treated for

What are possible side effects?

The most common reported side effects with JUVÉDERM® VOLUMA® XC and JUVÉDERM® VOLUX™ XC were tenderness, swelling, firmness, lumps/bumps, bruising, redness, pain, discoloration, and itching. For JUVÉDERM® VOLUMA® XC, side effects were usually moderate in severity and lasted 2 to 4 weeks. For JUVÉDERM® VOLUX™ XC, side effects were usually mild or moderate in severity and lasted up to 2 weeks although 35% lasted up to 30 days.

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 Juvederm.com or talk to your doctor for more information.

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

Reference: 1. JUVÉDERM® VOLUMA™ XC Directions for Use, November 2020.