JUVÉDERM VOLUMA® XC, JUVÉDERM® XC, and JUVÉDERM® Ultra XC
Indications and Important Safety Information

JUVÉDERM VOLUMA® XC, JUVÉDERM® XC, and JUVÉDERM® Ultra 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 in adults over the age of 21.

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).

JUVÉDERM® Ultra XC injectable gel is indicated for injection into the lips and perioral area for lip augmentation 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, 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, these products 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® Ultra XC and JUVÉDERM® Ultra Plus XC, the lips and perioral area for lip augmentation with JUVÉDERM® Ultra XC, and the mid-face with JUVÉDERM VOLUMA® 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® Ultra XC and JUVÉDERM® Ultra Plus XC in patients under 18 years has not been established
- The safety for use of JUVÉDERM VOLUMA® XC in patients under 35 or over 65 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 who experience skin injury near the site of implantation may be at a higher risk for adverse events
- The safety of JUVÉDERM VOLUMA® XC injectable gel for use in patients with very thin skin in the mid-face has not been established
- Patients may experience late onset nodules with use of dermal fillers, including JUVÉDERM VOLUMA® XC

ADVERSE EVENTS

The most commonly reported side effects for JUVÉDERM® XC injectable gels were temporary injection-site redness, swelling, pain/tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM® Ultra XC or JUVÉDERM® Ultra Plus XC, they were mostly mild or moderate in severity, with a duration of 14 days or less; and for JUVÉDERM VOLUMA® XC, they were predominantly moderate in severity, with a duration of 2 to 4 weeks.

To report an adverse reaction with JUVÉDERM® Ultra XC, JUVÉDERM® Ultra Plus XC, or JUVÉDERM VOLUMA® XC, please call Allergan Product Surveillance at 1-800-433-8871.

For more information, please see JuvedermDFU.com or call the Allergan Medical Information line at 1-800-678-1605.

JUVÉDERM VOLUMA® XC, JUVÉDERM® Ultra Plus XC, and JUVÉDERM® Ultra XC injectable gels are available by prescription only.

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JUVÉDERM® Collection of Fillers Before-and-After Photos (Connie)

Before

Actual patient. Results may vary.
Unretouched photo taken before treatment.

After
1 syringe of
JUVÉDERM VOLUMA® XC

Actual patient. Results may vary.
Unretouched photo taken 1 month after treatment with JUVÉDERM VOLUMA® XC. A total of 1.0 mL of JUVÉDERM VOLUMA® XC was injected into the cheek area.

After
optimal correction with
JUVÉDERM VOLUMA® XC

Actual patient. Results may vary.
Unretouched photo taken 1 month after second treatment with JUVÉDERM VOLUMA® XC. An additional 2.0 mL of JUVÉDERM VOLUMA® XC was injected into the cheek area for a total of 3.0 mL.

After
lifting in the cheek area with JUVÉDERM VOLUMA® XC,
smoothing lines with JUVÉDERM® XC,
and plumping lips with JUVÉDERM® Ultra XC

Actual patient. Results may vary.
Unretouched photo taken 1 month after final treatment. A total of 3.0 mL of JUVÉDERM VOLUMA® XC was injected into the cheek area. A total of 2.5 mL of JUVÉDERM® XC was injected into the parentheses, marionette, and vertical lip lines. A total of 1.8 mL of JUVÉDERM® Ultra XC was injected into the lips.

APPROVED USES

JUVÉDERM VOLUMA® XC injectable gel is for deep injection in the cheek area to correct age-related volume loss in adults over 21.

JUVÉDERM® XC injectable gel is for injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

JUVÉDERM® Ultra XC 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® injectable gel 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?

- 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® XC and JUVÉDERM® Ultra XC injectable gels in patients under 18 years, and the safety of JUVÉDERM VOLUMA® XC in patients under 35 years or over 65 years has not been studied
- The safety and effectiveness of JUVÉDERM® XC for areas other than facial wrinkles and folds, and JUVÉDERM® Ultra XC for areas other than the lips and perioral area for lip augmentation, or facial wrinkles and folds, have not been established in clinical studies
- The safety and effectiveness of JUVÉDERM VOLUMA® XC in areas other than the cheek area have not been established in clinical studies
- Tell your doctor if you have a history of excessive scarring (eg, hypertrophic scarring and keloid formations) or pigmentation disorders, as use of these products 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
- Patients who experience skin injury near the site of injection with these products may be at a higher risk for side effects
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of these products 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 include tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. With JUVÉDERM® XC and JUVÉDERM® Ultra XC injectable gels, most side effects are mild or moderate and last 14 days or less. For JUVÉDERM VOLUMA® XC, side effects are moderate (uncomfortable) and last 2 to 4 weeks.

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® XC, JUVÉDERM® Ultra XC, or JUVÉDERM VOLUMA® XC, please call Allergan Product Surveillance at **1-800-433-8871.**

For more information, please see Juvederm.com or call Allergan Medical Information at 1-800-678-1605.

Available by prescription only.

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JUVÉDERM® Collection of Fillers Before-and-After Photos (Connie)

Actual patient. Results may vary. Unretouched photos taken before treatment and 1 month after final treatment. A total of 3.0 mL of JUVÉDERM VOLUMA® XC was injected into the cheek area. A total of 2.5 mL of JUVÉDERM® XC was injected into the parentheses, marionette, and vertical lip lines. A total of 1.8 mL of JUVÉDERM® Ultra XC was injected into the lips.

APPROVED USES

JUVÉDERM VOLUMA® XC injectable gel is for deep injection in the cheek area to correct age-related volume loss in adults over 21.

JUVÉDERM® XC injectable gel is for injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

JUVÉDERM® Ultra XC 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® injectable gel 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?

- 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® XC and JUVÉDERM® Ultra XC injectable gels in patients under 18 years, and the safety of JUVÉDERM VOLUMA® XC in patients under 35 years or over 65 years has not been studied
- The safety and effectiveness of JUVÉDERM® XC for areas other than facial wrinkles and folds, and JUVÉDERM® Ultra XC for areas other than the lips and perioral area for lip augmentation, or facial wrinkles and folds, have not been established in clinical studies
- The safety and effectiveness of JUVÉDERM VOLUMA® XC in areas other than the cheek area have not been established in clinical studies
- Tell your doctor if you have a history of excessive scarring (eg, hypertrophic scarring and keloid formations) or pigmentation disorders, as use of these products 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
- Patients who experience skin injury near the site of injection with these products may be at a higher risk for side effects
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of these products 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 include tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. With JUVÉDERM® XC and JUVÉDERM® Ultra XC injectable gels, most side effects are mild or moderate and last 14 days or less. For JUVÉDERM VOLUMA® XC, side effects are moderate (uncomfortable) and last 2 to 4 weeks.

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® XC, JUVÉDERM® Ultra XC, or JUVÉDERM VOLUMA® XC, please call Allergan Product Surveillance at **1-800-433-8871.**

For more information, please see Juvederm.com or call Allergan Medical Information at 1-800-678-1605.

Available by prescription only.

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JUVÉDERM VOLUMA® XC Indication and Important Safety Information

JUVÉDERM VOLUMA® XC Important Information

INDICATION

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 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 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 mid-face have not been established in controlled clinical studies
- The safety for use during pregnancy and in breastfeeding females has not been established
- The safety for use in patients under 35 or over 65 years has not been established
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection. Follow standard precautions associated with injectable materials
- The safety for use 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
- Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events
- The safety for use in patients with very thin skin in the mid-face has not been established
- Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM VOLUMA® XC

ADVERSE EVENTS

Side effects in > 5% of subjects were temporary injection-site tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. They were predominantly moderate in severity, with a duration of 2 to 4 weeks.

To report an adverse reaction, please call Allergan Product Surveillance at 1-877-345-5372.

For more information, please see JuvedermDFU.com or call the Allergan Medical Information line at 1-800-433-8871.

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

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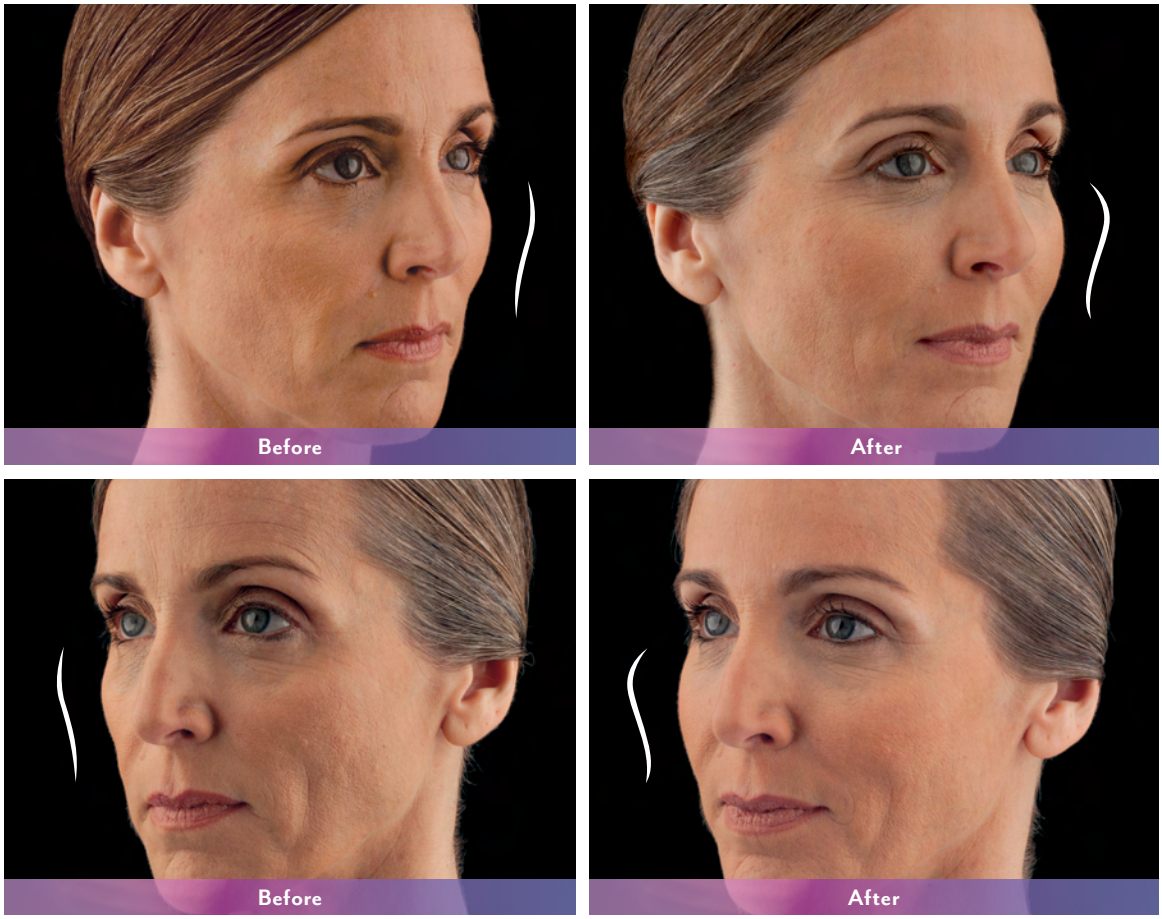
JUVÉDERM VOLUMA® XC Before-and-After Photos (Kathy)



Actual patient. Results may vary. Unretouched photos taken before treatment and 1 month after treatment with JUVÉDERM VOLUMA® XC. A total of 3.5 mL of JUVÉDERM VOLUMA® XC was injected into the cheek area.

APPROVED USE

JUVÉDERM VOLUMA® XC injectable gel is for deep injection in the cheek area to correct age-related volume loss in adults over the age of 21.

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive JUVÉDERM VOLUMA® XC?
Do not use if you have a history of multiple severe allergies or severe allergic reactions (anaphylaxis), or if you are allergic to the proteins (gram-positive bacterial proteins) used to make hyaluronic acid (HA) or to the lidocaine in this product.

What precautions should my doctor advise me about?

- 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 in patients under 35 years or over 65 years has not been studied
- The safety and effectiveness of JUVÉDERM VOLUMA® XC in areas other than the cheek area have not been established in clinical studies
- Tell your doctor if you have a history of excessive scarring (eg, hypertrophic scarring and keloid formations) or pigmentation disorders, as use of these products 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
- Patients who experience skin injury near the site of injection with these products may be at higher risk for side effects
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of these products 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 include temporary reactions at the treatment site such as tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. Side effects are moderate (uncomfortable) and generally last 2 to 4 weeks.

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 VOLUMA® XC, please call Allergan Product Surveillance at **1-800-624-4261.**

For more information, please see Juvederm.com or call Allergan Medical Information at 1-800-433-8871.

Available by prescription only.

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