

## JUVÉDERM VOLBELLA® XC FACT SHEET

- In 2016, the U.S. Food and Drug Administration (FDA) approved JUVÉDERM VOLBELLA® XC, for use in the lips for lip augmentation and for correction of perioral rhytids, commonly referred to as perioral lines, in adults over the age of 21.<sup>1</sup>
- In clinical trials, JUVÉDERM VOLBELLA® XC was found to effectively increase lip fullness and soften the appearance of lines around the mouth in a majority of subjects through one year.<sup>1,2\*</sup>
- VYCROSS® blends different molecular weights of hyaluronic acid which contributes to the gel's duration.<sup>2,3</sup> In addition, JUVÉDERM VOLBELLA® XC has a lower HA concentration (15 mg/mL), while still providing the long-lasting results healthcare providers expect from the JUVÉDERM® collection of fillers.<sup>1,4,5,6,7,8</sup> This makes JUVÉDERM VOLBELLA® XC a soft, smooth gel appropriate for adding subtle volume to the lips and softening the appearance of perioral lines.<sup>1</sup>
- Allergan first debuted this innovative VYCROSS® technology in the U.S. in 2013 with the FDA approval of JUVÉDERM VOLUMA® XC for age-related mid-face volume loss.<sup>4</sup> Now JUVÉDERM VOLBELLA® XC is the latest addition to the JUVÉDERM® collection of fillers, the number one selling collection of dermal filler products in the world,<sup>9</sup> to receive FDA approval.
- At three months, 80.3% of patients had at least a 1-point improvement in lip fullness and 96.1% of patients treated with JUVÉDERM VOLBELLA® XC reported improvement in satisfaction with their lips.<sup>1</sup>

### JUVÉDERM VOLBELLA® XC Important Information

#### APPROVED USES

JUVÉDERM VOLBELLA® XC injectable gel is for injection into the lips for lip augmentation and for correction of perioral rhytids 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 these products 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 these products.

##### **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

Please see additional Important Safety Information on the following pages.

- JUVÉDERM VOLBELLA® XC is a smooth gel formulation made up of a modified form of HA (Hyaluronic Acid).<sup>2</sup>
- HA is a naturally occurring sugar found in the human body. The role of HA in the skin is to deliver nutrients and help the skin retain its natural moisture and softness.<sup>2</sup>
- The gel formulation also contains a small quantity of local anesthetic (lidocaine) which helps minimize discomfort during injection.<sup>2</sup>
- Optimal treatment may require not only lip augmentation, but also correction of perioral lines.<sup>10</sup> Research shows that patients are actually more interested in treating their perioral lines than their lips, making JUVÉDERM VOLBELLA® XC an especially valuable product.<sup>11</sup>
- Allergan, the maker of the JUVÉDERM® collection of fillers, is committed to offering healthcare providers access to comprehensive training programs to help ensure they are administering their products correctly, achieving the best possible outcomes for patients.
- Approximately two-thirds of subjects treated with JUVÉDERM VOLBELLA® XC showed improvement in lip fullness and perioral lines through 1 year. At 1 year, 61.8% (76/123) had a 1-point improvement in lip fullness and 66.2% (45/68) had a 1-point improvement in perioral lines severity.<sup>1\*</sup>
- The safety and effectiveness of JUVÉDERM VOLBELLA® XC has been demonstrated in several clinical trials including the U.S. pivotal study where 168 subjects were treated with JUVÉDERM VOLBELLA® XC. A 5-point scale was used to evaluate the effectiveness of the product for lip fullness and a 4-point scale to evaluate the effectiveness of the product for smoothing lines around the mouth.<sup>2</sup>
- The safety of JUVÉDERM VOLBELLA® XC was observed to be similar to that of the control. The most common side effects were temporary responses at the treatment site such as swelling, tenderness, bruising, firmness lumps/bumps, redness, pain, discoloration, and itching. Most of these side effects resolved within 30 days.<sup>2</sup>

For more information about JUVÉDERM VOLBELLA® XC and the JUVÉDERM® collection of fillers, visit [www.Juvederm.com](http://www.Juvederm.com).

### **JUVÉDERM VOLBELLA® XC Important Information (continued)**

- Tell your doctor if you have a history of excessive scarring (e.g., 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

## JUVÉDERM VOLBELLA® XC Important Information (continued)

### What are possible side effects?

The most common side effects include swelling, tenderness, bruising, firmness, lumps/bumps, redness, pain, discoloration, and itching. Most side effects are mild or moderate and last 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 or for product information, please call Allergan at 1-800-624-4261. Please also visit [Juvéderm.com](http://Juvéderm.com) for more information.**

Available by prescription only.

## JUVÉDERM VOLUMA® XC IMPORTANT SAFETY INFORMATION

### 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

Please see additional Important Safety Information on the following pages.

**JUVÉDERM VOLUMA® XC Important Information (continued)**

- 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 [Juvéderm.com](http://Juvéderm.com) or call Allergan Medical Information at 1-800-433-8871.**

Available by prescription only.

\* Including optional touch up at 1 month for optimal correction

**References:**

1. JUVÉDERM VOLBELLA® XC Directions for Use, 2016.
2. JUVÉDERM VOLBELLA® XC Patient Labeling, 2016.
3. Data on File VYCROSS™: An Innovative Dermal Filler Technology, 2013.
4. JUVÉDERM VOLUMA® XC Directions for Use, 2013.
5. JUVÉDERM® Ultra XC Directions for Use, 2015.
6. JUVÉDERM® Ultra Plus XC Directions for Use, 2011.
7. Data On File, Allergan, DOF Swelling Comparison, 2013.
8. Pierre S, Liew S, Bernardin A. Basics of Dermal Filler Rheology. *American Society for Dermatologic Surgery*. 2015; 1:S120-6.
9. Data on File, Allergan, Proforma Sales JUVÉDERM VOLUMA®, 2015.
10. de Maio M, Rzany B. *Injectable Fillers in Aesthetic Medicine*. Berlin, Germany: Springer; 2006:32-65. The most common indications.
11. Data on file, Allergan, Lip Lines Rank Higher Than Lips Amongst All Filler Considerers by a Wide Margin, 2015.

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