

## JUVÉDERM VOLBELLA® XC FDA Approval for Lips

### Physician Key Messages

- NEW JUVÉDERM VOLBELLA® XC is approved by the U.S. Food and Drug Administration (FDA) 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>
- 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> This includes optional touch up at one month for optimal correction.
- JUVÉDERM VOLBELLA® XC is formulated with VYCROSS®,<sup>2</sup> a proprietary filler technology from Allergan, which yields smooth products that have been engineered to address specific patient concerns.<sup>3</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 been customized with 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.
- I am excited about JUVÉDERM VOLBELLA® XC for correction of perioral rhytids, more commonly called perioral lines.<sup>1</sup> In the past this area has been difficult to treat. Now, I have a product from

the JUVÉDERM® Collection of Fillers that is approved to address this specific patient concern.

- When it comes to treating the lips, most patients want a smooth-looking result. With JUVÉDERM VOLBELLA® XC, there is now a solution available for patients bothered specifically by lines around the lips, known as perioral lines.<sup>1</sup>
- JUVÉDERM VOLBELLA® XC adds fullness to the lips and softens the appearance of the lines around the lips.<sup>2</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> Approximately two-thirds of subjects treated with JUVÉDERM VOLBELLA® XC showed improvement in lip fullness and perioral lines through 1 year. 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>
- JUVÉDERM VOLBELLA® XC will be available to patients in October 2016. For more information about JUVÉDERM VOLBELLA® XC and the JUVÉDERM® collection of fillers or to find a doctor, please visit [www.juvederm.com](http://www.juvederm.com) or like JUVÉDERM® on Facebook @Juvederm

## **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
- 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

### **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 [Juvederm.com](http://Juvederm.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
- 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 or for product information, please call Allergan at 1-800-624-4261. Please also visit [Juvederm.com](http://Juvederm.com) for more information.**

For more information, please see [Juvederm.com](http://Juvederm.com) or call Allergan Medical Information at 1-800-433-8871.

Available by prescription only.

**References:**

- <sup>1</sup>. JUVÉDERM VOLBELLA® XC Directions for Use, 2016.
- <sup>2</sup>. JUVÉDERM VOLBELLA® XC Patient Labeling, 2016.
- <sup>3</sup>. Data on File VYCROSS™: An Innovative Dermal Filler Technology, 2013.
- <sup>4</sup>. JUVÉDERM VOLUMA® XC Directions for Use, 2013.
- <sup>5</sup>. JUVÉDERM® Ultra XC Directions for Use, 2015.
- <sup>6</sup>. JUVÉDERM® Ultra Plus XC Directions for Use, 2011.
- <sup>7</sup>. Data On File, Allergan, DOF Swelling Comparison, 2013.
- <sup>8</sup>. Pierre S, Liew S, Bernardin A. Basics of Dermal Filler Rheology. *American Society for Dermatologic Surgery*. 2015; 1:S120-6.
- <sup>9</sup>. Data on File, Allergan, Proforma Sales JUVÉDERM VOLUMA®', 2015.

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