



NEWS RELEASE

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JUVÉDERM VOLBELLA® XC APPROVED BY U.S. FDA FOR USE IN LIPS AND PERIORAL RHYTIDS

JUVÉDERM VOLBELLA® XC found to increase lip fullness and soften the appearance of lines around the mouth through one year.^{1,2}*

Dublin, (June 1, 2016) – Allergan plc, (NYSE: AGN), a leading global pharmaceutical company, today announced that the company has received approval from the U.S. Food and Drug Administration (FDA) to market 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 21.¹ 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.^{1,2*}

"Many of my patients are very bothered by the lines that can appear around the lips, known as perioral rhytids. Additionally, when seeking lip augmentation, patients want a smooth, result that is not drastic" said Dr. David E. Bank, clinical trial investigator and founder of The Center for Dermatology, Cosmetic & Laser Surgery. "JUVÉDERM VOLBELLA® XC adds fullness to the lips and softens the appearance of the lines around the lips.² With JUVÉDERM VOLBELLA® XC I am able to subtly enhance my patients' pout."

"The FDA approval of JUVÉDERM VOLBELLA® XC further demonstrates Allergan's commitment to developing advanced products and technologies that allow healthcare providers to better address evolving patient needs," said Bill Meury, Chief Commercial Officer, Allergan. "Additionally, this approval brings to market a product unlike anything that is currently available

in the United States. JUVÉDERM VOLBELLA® XC is formulated with VYCROSS®,² a proprietary filler technology from Allergan, which yields smooth products that have been engineered to address specific patient concerns such as lip fullness, age-related volume loss in the cheek area, or perioral rhytids.³

VYCROSS® blends different molecular weights of hyaluronic acid which contributes to the gel's duration.^{2,3} 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.^{1,4,5,6,7,8} This makes JUVÉDERM VOLBELLA® XC a soft, smooth gel appropriate for adding subtle volume to the lips and softening the appearance of perioral lines.¹ 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.⁴ 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,⁹ to receive FDA approval.

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.² 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.²

JUVÉDERM VOLBELLA® XC was first approved in Europe in 2011. Currently, JUVÉDERM VOLBELLA® XC is distributed in more than 70 countries, including markets in Europe, Latin America, Middle East, Asia Pacific, and Canada. The JUVÉDERM® family of products, including JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC are marketed and sold in more than 80 countries outside the United States.¹⁰

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.

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 for more information.

Available by prescription only.

JUVÉDERM® XC, JUVÉDERM® ULTRA XC, AND JUVÉDERM VOLUMA® XC IMPORTANT SAFETY INFORMATION

APPROVED USES

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.

JUVÉDERM VOLUMA® XC injectable gel is for deep injection in the cheek area to correct age-related volume loss 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 **1-800-624-4261**.

For more information, please see Juvederm.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.
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. Data on File, Allergan, Inc. Filler Distribution Matrix, 2016

About Allergan

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a unique, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing innovative branded pharmaceuticals, high-

quality generic and over-the-counter medicines and biologic products for patients around the world.

Allergan markets a portfolio of best-in-class products that provide valuable treatments for the central nervous system, eye care, medical aesthetics, gastroenterology, women's health, urology, cardiovascular and anti-infective therapeutic categories, and operates the world's third-largest global generics business, providing patients around the globe with increased access to affordable, high-quality medicines. Allergan is an industry leader in research and development, with one of the broadest development pipelines in the pharmaceutical industry and a leading position in the submission of generic product applications globally.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives.

For more information, visit Allergan's website at www.Allergan.com.

Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2015 (certain of such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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