



# Modern Aesthetics



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## FDA Approves Juvéderm Volbella XC for Use in Lips and Perioral Rhytids

From AestheticsWire

Allergan plc, has received FDA approval 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. 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.

"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. 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, 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."

Vycross blends different molecular weights of hyaluronic acid which contributes to the gel's duration. 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. This makes Juvéderm Volbella XC a soft, smooth gel appropriate for adding subtle volume to the lips and softening the appearance of perioral lines.

The safety and effectiveness of Juvéderm Volbella XC has been demonstrated in several clinical trials including the US 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 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.

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.

### Welcome News

"Juvéderm Volbella joins Juvéderm Voluma as the second member of the Vycross family of hyaluronic acid fillers to be approved by the US FDA," says Hema Sundaram, MD, a dermatologist with offices in Fairfax, Virginia and Rockville, Maryland. "Volbella has been available in Europe and other parts of the world for a number of years. It is suited to treatments that require softer filler products, such as fine lines and lip enhancement [and] It can be layered over Voluma in areas where it is appropriate to combine deep and superficial volumizing," she says.

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A Global Aesthetics Consensus statement in Plastic & Reconstructive Surgery contains guidelines for combining hyaluronic acid fillers in this way, using Volbella and Voluma as a paradigm, and also for combining them with botulinum toxin, she says. "It links the scientific engineering of these products to how they behave clinically, based on new studies and the long term, international experience of the consensus group members."

Joe Niamtu, III, DMD, FAAC, Cosmetic Facial Surgery in Midlothian, Va says the latest filler approval is in line in what is happening in the advancement of filler science and rheology. "Initially the goal of a filler was to have a biocompatible material that felt normal and had respectable longevity," he says. "The simultaneous advancement of filler science and the huge demand for them has brought an increased level of customization and specificity for both injectors and patients."

Various advancements in cross-linking filler composition have produced "thicker and thinner" fillers that last longer. "Whereas more robust fillers such as Voluma and Lyft are intended for more lifting and deeper injections, the newer Vobella (similar to Restylane Silk) is intended for more superficial dermal injection in the case of vertical lip rhytids, but can also be used for traditional lip filling," he says. "The addition of these new players is a boon for experienced injectors who have the skills to fine tune filler treatments," he says. "They may add confusion for novice injectors that can be overwhelmed by too many choices. The same thing can apply to patients, who can also be confused by the growing number of available fillers."

Juvéderm Volbella XC will be available to patients in October 2016. For more information, visit [www.juvederm.com](http://www.juvederm.com).

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