



## **JUVÉDERM<sup>®</sup> XC Fact Sheet**

### **About JUVÉDERM<sup>®</sup> XC, the new formulation with lidocaine**

- JUVÉDERM<sup>®</sup> with lidocaine, marketed under the trade name JUVÉDERM<sup>®</sup> XC, is the latest advancement in hyaluronic acid (HA) dermal filler options from Allergan Inc., offering a JUVÉDERM<sup>®</sup> experience that is enhanced for patient comfort.<sup>1</sup>
- JUVÉDERM<sup>®</sup> XC dermal filler was approved by the U.S. Food and Drug Administration (FDA) in January, 2010 and is the first and only smooth-consistency HA dermal filler, formulated with the local anesthetic lidocaine, to smooth the “parentheses” – facial wrinkles around the nose and mouth – for up to one year with just one treatment.<sup>2</sup>
- With lidocaine in its formulation, JUVÉDERM<sup>®</sup> XC provides a more comfortable patient injection experience when compared to the non-lidocaine formulation. Now, patients can feel the local anesthetic effect within just three seconds from initial injection, potentially reducing the need for an additional anesthetic.
  - In the clinical study (n=72) leading up to the FDA approval of JUVÉDERM<sup>®</sup> XC, 93 percent of patients reported less pain compared to that experienced with the non-lidocaine formulation.<sup>3</sup>
- The FDA approved the following formulations of JUVÉDERM<sup>®</sup> XC dermal filler providing physicians with the flexibility to tailor each treatment to the particular needs of the patient, while offering them a comfortable experience.<sup>1</sup>

Product formulations include:

  - JUVÉDERM<sup>®</sup> Ultra XC, a highly cross-linked formulation for more versatility in contouring and volumizing of facial wrinkles and folds with 0.3% preservative-free lidocaine
  - JUVÉDERM<sup>®</sup> Ultra Plus XC, a more highly cross-linked robust formulation for volumizing and correction of deeper folds and wrinkles with 0.3% preservative-free lidocaine

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<sup>1</sup> Compared to the non-lidocaine JUVÉDERM<sup>®</sup> formulation

<sup>2</sup> This includes all JUVÉDERM<sup>®</sup> injectable gel formulations. Most subjects acquired optimal correction at initial treatment.

<sup>3</sup> Weinkle SH, Bank DE, Boyd CM, Gold MH, Thomas JA, Murphy DK. A multi-center, double-blind, randomized controlled study of the safety and effectiveness of Juvéderm injectable gel with and without lidocaine. J Cosmet Dermatol. 2009 Sep;8(3):205-10

- JUVÉDERM<sup>®</sup> dermal fillers are the only HA dermal fillers developed using the proprietary HYLACROSS<sup>™</sup> technology, an advanced manufacturing process resulting in a malleable, smooth gel that flows easily and consistently into the skin and provides a predictable result.
  - All other HA dermal fillers currently on the market have a granular consistency gel. These granules can be seen under 2.4X magnification as opposed to the smooth consistency gel of JUVÉDERM<sup>®</sup> dermal fillers.
- In addition, JUVÉDERM<sup>®</sup> dermal fillers contain a high concentration of non-animal, cross-linked hyaluronic acid. This provides optimal results with just one treatment in the majority of patients, delivering a sustained result for up to one year.
- JUVÉDERM<sup>®</sup> dermal fillers are biodegradable and have demonstrated safety and effectiveness in patients of color.
  - Studies with JUVÉDERM<sup>®</sup> dermal fillers demonstrated no increased risk of hyperpigmentation or hypertrophic scarring in patients of color.<sup>4</sup>

### **How JUVÉDERM<sup>®</sup> XC Works**

- The key component in JUVÉDERM<sup>®</sup> XC dermal filler is hyaluronic acid, a naturally occurring, biodegradable complex sugar found in the human body and in mammals. Among other things, hyaluronic acid hydrates the skin and adds volume, contributing to the overall appearance of the skin.
- The ability of cells to produce hyaluronic acid diminishes with age, often resulting in the formation of facial wrinkles and folds as the skin loses volume. JUVÉDERM<sup>®</sup> XC is administered by intradermal injection directly into moderate to severe facial wrinkles and folds, such as nasolabial folds (the “parentheses” along the side of the nose and mouth), temporarily filling and augmenting the treated area.
- JUVÉDERM<sup>®</sup> XC contains 0.3% preservative-free lidocaine, a local anesthetic that provides pain relief at the injection site and allows patients to experience reduced discomfort during treatment, compared to the non-lidocaine JUVÉDERM<sup>®</sup> formulation.
- JUVÉDERM<sup>®</sup> XC is available in two formulations, JUVÉDERM<sup>®</sup> Ultra XC and JUVÉDERM<sup>®</sup> Ultra Plus XC. The two JUVÉDERM<sup>®</sup> XC formulations have a similar safety and effectiveness profile compared to previous FDA-approved non-lidocaine JUVÉDERM<sup>®</sup> formulations, JUVÉDERM<sup>®</sup> Ultra and Ultra Plus.<sup>3</sup>
- JUVÉDERM<sup>®</sup> XC dermal filler should only be administered by a trained and qualified health care provider. Further product and patient risk information is available by visiting [www.Juvederm.com](http://www.Juvederm.com).

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<sup>4</sup> Grimes, Pearl E, Thomas, Jane A, Murphy, Diane K. Safety and effectiveness of hyaluronic acid fillers in skin of color. *J. Cosmet. Dermatol.* 2009 Sep; 8 (162-168).

## **A Brief Description of Indications for Use, Contraindications, Warnings, Precautions, and Adverse Events for JUVÉDERM® Injectable Gel**

**Indication:** In the United States, JUVÉDERM® injectable gel (including JUVÉDERM® Ultra, JUVÉDERM® Ultra Plus, JUVÉDERM® Ultra XC, and JUVÉDERM® Ultra Plus XC) is indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

**Contraindications:** JUVÉDERM® injectable gel should not be used in patients who have severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies. JUVÉDERM® injectable gel should not be used in patients with a history of allergies to Gram-positive bacterial proteins. JUVÉDERM® Ultra XC and JUVÉDERM® Ultra Plus XC should not be used in patients with a history of allergies to lidocaine.

**Warnings:** JUVÉDERM® injectable gel should not be injected into blood vessels. If there is an active inflammatory process or infection at specific injection sites, treatment should be deferred until the underlying process is controlled.

**Precautions:** The safety of JUVÉDERM® injectable gel for use during pregnancy, in breastfeeding females, or in patients under 18 years has not been established. The safety and effectiveness of JUVÉDERM® injectable gel for the treatment of areas other than facial wrinkles and folds (such as lips) have not been established in controlled clinical studies. Patients who are using substances that can prolong bleeding, such as aspirin or ibuprofen, as with any injection, may experience increased bruising or bleeding at injection site. Patients should inform their physician before treatment if they are using these types of substances. As with all skin-injection procedures, there is a risk of infection. JUVÉDERM® injectable gel should be used with caution in patients on immunosuppressive therapy, or therapy used to decrease the body's immune response, as there may be an increased risk of infection. The safety of JUVÉDERM® injectable gel in patients with a history of excessive scarring (eg, hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied. If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment with JUVÉDERM® injectable gel, or if JUVÉDERM® injectable gel is administered before the skin has healed completely after such a procedure, there is a possible risk of an inflammatory reaction at the treatment site.

**Adverse events:** The most commonly reported side effects are temporary injection-site redness, swelling, pain/tenderness, firmness, lumps/bumps, and bruising. Most side effects are mild or moderate in nature, and their duration is short lasting (7 days or less).

**Important:** For full safety information, please visit [www.Juvederm.com](http://www.Juvederm.com) or call Allergan Product Support at 1-877-345-5372.

**CAUTION:** Rx Only

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**For more information, please contact Kellie Lao (714) 246-2278 at Allergan, Inc.**

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