

WHAT IS SUBMENTAL FULLNESS?

- Submental fullness, sometimes referred to as “double chin,” is a common, yet undertreated facial aesthetic condition.¹ It can detract from an otherwise balanced and harmonious facial appearance² – leading to an older and heavier look.³
- Submental fullness can impact a broad range of adults, including both women and men, and can be caused by aging, genetics and weight gain.⁴
- According to a 2015 survey by the American Society for Dermatologic Surgery (ASDS), over 2/3 of consumers are bothered by submental fullness – nearly as many as those bothered by lines and wrinkles around the eyes.⁵

WHAT IS KYBELLA® (DEOXYCHOLIC ACID) INJECTION?⁶

- KYBELLA® (deoxycholic acid) injection, is the first and only FDA-approved injectable drug that contours and improves the appearance of submental fullness due to submental fat.
- KYBELLA® is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.
- The safe and effective use of KYBELLA® for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

HOW DOES KYBELLA® WORK?

- KYBELLA® is a non-human and non-animal formulation of deoxycholic acid, a naturally-occurring molecule in the body that aids in the breakdown and absorption of dietary fat.⁷
- When injected into subcutaneous fat, KYBELLA® causes the destruction of fat cells. Once destroyed, those cells cannot store or accumulate fat. After the aesthetic response is achieved, retreatment with KYBELLA® is not expected.¹
- To avoid potential tissue damage, KYBELLA® should not be injected into or in close proximity (1-1.5 cm) to the marginal mandibular nerve, salivary glands, lymph nodes and muscles.

WHAT ARE THE RESULTS OF KYBELLA®?⁶

- 68.2% of subjects treated with KYBELLA® experienced a ≥1-grade improvement with KYBELLA® compared to 20.5% of placebo-treated subjects, based upon validated physician and patient measurements.
- 16% of patients experienced a ≥ 2-grade improvement with KYBELLA®, compared to 2% of patients who responded to placebo, based on validated physician and patient measurements.
- KYBELLA® treatment resulted in high patient satisfaction – 79% of KYBELLA®-treated patients reported satisfaction with their appearance in association with their face and chin.
- Patients also reported improvement in the visual and emotional impact of submental fat when asked how happy, bothered, self-conscious, embarrassed, old and overweight they felt following treatment in relation to the amount of their submental fat.
- Marginal mandibular nerve (MMN) injury occurred in 4% and dysphagia occurred in 2% of subjects. To avoid potential tissue damage, KYBELLA® should not be injected into or in close proximity (1-1.5 cm) to the MMN, salivary glands, lymph nodes and muscles.
- The most common adverse reactions were edema/swelling, hematoma/bruising, pain, numbness, erythema and induration.

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Important Safety Information

KYBELLA® should only be administered by a trained healthcare professional.

KYBELLA® is contraindicated in the presence of infection at the injection sites.

Avoid injecting in proximity to vulnerable anatomic structures due to the increased risk of tissue damage.

For full Prescribing Information, visit mykybella.com.

WHAT ARE THE SIDE EFFECTS WITH KYBELLA®?

- The safety profile of KYBELLA® is well-characterized.
- KYBELLA® has been the focus of a global clinical development program involving over 20 clinical studies with more than 2,600 patients worldwide, of which over 1,600 have been treated with KYBELLA®.
- The most common adverse reactions were edema/swelling, hematoma/bruising, pain, numbness, erythema and induration.⁶
- KYBELLA® is manufactured through a highly-controlled, FDA-regulated process and approved facility to ensure patient safety.
- For more information, please see Important Safety Information.

Important Safety Information

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, were reported during clinical trials. To avoid the potential for nerve injury, KYBELLA® should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve. All marginal mandibular nerve injuries reported from the trials resolved spontaneously (range 1-298 days, median 44 days).

Difficulty swallowing (dysphagia) occurred in the clinical trials in the setting of administration site reactions, e.g., pain, swelling, and induration of the submental area. Cases of dysphagia spontaneously resolved (range 1-81 days, median 3 days). Subjects with current or prior history of dysphagia were excluded from clinical trials. Avoid use of KYBELLA® in these patients as current or prior history of dysphagia may exacerbate the condition.

In clinical trials, 72% of subjects treated with KYBELLA® experienced injection site hematoma/bruising. KYBELLA® should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur.

To avoid the potential of tissue damage, KYBELLA® should not be injected into or in close proximity (1-1.5 cm) to salivary glands, lymph nodes and muscles.

The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

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REFERENCES: 1. KYTHERA Biopharmaceuticals, Data on File. 2. Swift A, Remington K. BeautiPHication: a global approach to facial beauty. *Clin Plast Surg*. 2011; 38:347-77. 3. Dayan S. Neck rejuvenation. In: Hirsch, *Aesthetic Rejuvenation: A Regional Approach*. 1st ed. New York, NY: McGraw Hill Professional Publishing; 2008: 123-147. 4. DeFatta R, Ducic Y. Liposuction of the face and neck. *Operative Techniques in Otolaryngology*. 2007; 18:261-266. 5. American Society for Dermatologic Surgery 2015 Consumer Survey on Cosmetic Dermatologic Procedures (N= 7,315); Exact survey language was, "How bothered are you by excess fat under the chin/neck?" 6. KYBELLA® Prescribing Information, April 2015. 7. Stryer L, ed. *Biochemistry*. 4th Edition. New York, NY: WH Freeman and Co.; 2015: 691-707.