



## Kybella Consent

### INTRODUCTION

KYBELLATM (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat, also called “double chin,” in adults. The safe and effective use of KYBELLATM for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

KYBELLATM is injected into the fat under the chin (no more than 50 injections or 10mL under the skin). KYBELLATM injections will be given at least 1 month apart. Healthcare providers, in conjunction with the patient, will decide how many treatments are needed.

### RISKS OF KYBELLATM INJECTIONS

Every injection of a drug involves a certain amount of risk. Below are risks reported during clinical studies that are specific to the injection of KYBELLATM:

**KYBELLATM injections commonly cause swelling, bruising, pain, numbness, redness, and areas of hardness in the treatment area. KYBELLATM injections can also cause tingling, nodule, itching, skin tightness, and headache. These side effects typically resolve without treatment and do not commonly result in patients discontinuing treatment.**

Other less common potential side effects include:

Nerve injury: KYBELLATM injections could cause nerve injury in the area of the jaw resulting in an uneven smile or facial muscle weakness. In the clinical trials these all resolved without treatment in an average of 6 weeks.

Swallowing: KYBELLATM injections can temporarily cause trouble with swallowing.

Skin Ulceration: KYBELLATM injections could cause superficial skin erosions.

Alopecia: KYBELLATM injections could cause small patches of alopecia in the treatment area.

**Unsatisfactory results: There is a possibility of an unsatisfactory result from injections of KYBELLATM. The procedure may result in unacceptable visible deformities or asymmetry in the treatment area. Once product is administered, refunds are not possible. Meesha Aesthetics will work with you as much as possible to resolve any dissatisfaction**



## BEFORE RECEIVING KYBELLATM INJECTIONS

KYBELLATM should not be injected if there is an infection in the treatment area.

Patients should be advised to inform their healthcare provider if they develop signs of marginal mandibular nerve paresis (e.g., asymmetric smile, facial muscle weakness), difficulty swallowing, or if any existing symptom worsens.

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In clinical trials, 72% of subjects treated with KYBELLATM experienced injection site hematoma/bruising. KYBELLATM 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, KYBELLATM 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.**



**Before receiving KYBELLATM, Please complete the following.**

Have had or plan to have surgery on the face, neck, or chin	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have had cosmetic treatments on the face, neck, or chin	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have had or have medical conditions in or near the neck area	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have had or have trouble swallowing	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have bleeding problems or are taking blood thinners	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are pregnant or plan to become pregnant within 4 months	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are breastfeeding or plan to breastfeed within 4 months	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b><u>Have you been diagnosed with an auto-immune disease?</u></b>	Yes <input type="checkbox"/> No <input type="checkbox"/>

Patients should tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. They should especially tell their healthcare provider if they take a medicine that prevents the clotting of blood (antiplatelet or anticoagulant medicine).

I hereby certify that I have read this consent form and understand the risks and benefits associated with Kybella.

Patient Name (Print): \_\_\_\_\_ Date: \_\_\_\_\_

Patient Signature: \_\_\_\_\_

