AUDUBON DERMATOLOGY
INNOVATIVE COMPREHENSIVE SKINCARE

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Kybella Informed Consent

KYBELLA™ (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 KYBELLA™ for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

KYBELLA™ is injected into the fat under the chin (no more than 50 injections or 10mL under the skin). KYBELLA™ 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 KYBELLA™ 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 KYBELLA™:

- KYBELLA™ injections commonly cause swelling, bruising, pain, numbness, redness, and areas of hardness in the treatment area. KYBELLA 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**: KYBELLA™ 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**: KYBELLA™ injections can temporarily cause trouble with swallowing.
    - **Skin Ulceration**: KYBELLA™ injections could cause superficial skin erosions.
    - **Alopecia;** KYBELLA™ injections could cause small patches of alopecia in the treatment area.
    - **Unsatisfactory results**: There is a possibility of an unsatisfactory result from injections of KYBELLA™. The procedure may result in unacceptable visible deformities or asymmetry in the treatment area.

BEFORE RECEIVING KYBELLA™ INJECTIONS
KYBELLA™ should not be injected if there is an infection in the treatment area.

Before receiving KYBELLA™, patients should tell their healthcare provider about all of their medical conditions, including if they:
• have had or plan to have surgery on the face, neck, or chin
• have had cosmetic treatments on the face, neck, or chin
• have had or have medical conditions in or near the neck area

• have had or have trouble swallowing
• have bleeding problems or are taking blood thinners
• are pregnant or plan to become pregnant. It is not known if KYBELLA™ will harm an unborn baby.
• are breastfeeding or plan to breastfeed. It is not known if KYBELLA™ passes into your breast milk.

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).

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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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.

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.

I understand and agree that all services rendered to me are charged to me directly and that I am personally responsible for payment.

I am not pregnant or trying to become pregnant nor am I nursing at this time.

The nature and purpose of the treatment have been explained to me. I have read and understand this agreement in its entirety. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. Alternative methods of treatment and their risks and benefits have been explained to me and I understand that I have the right to refuse treatment.

I release Audubon Dermatology, LLC, Dr. Hooper, Dr. Jackson and all medical staff, from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Client's Name (Please Print):_____

Client's Signature:_____

Date:_____