



### **Kybella (Deoxycholic Acid) Injection Informed Consent**

Kybella is a cytolytic drug indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental (neck) fat in adults. The safe and effective use of Kybella for the treatment of subcutaneous fat outside the submental region (neck) has not been established. Kybella is FDA approved to be injected into the fat under the chin. More than one treatment may be necessary to achieve desired results. Additional injections will be administered with at least one-month intervals. Some injection sites may not be FDA approved.

There are alternative treatments to Kybella that are both non-surgical and surgical. The non-surgical alternatives consist of topical neck products, weight loss, and homeopathic neck treatments; the surgical alternatives include neck lifts, neck liposuction, and several other procedures.

#### **Risks and possible complications**

Risks and potential complications are associated with Kybella, as well as alternate forms of treatment. Although most patients do not experience complications, there are risks of using Kybella. Risks and complication can include, but are not limited to the following:

- **Irritation:** Kybella injections can cause tingling, swelling, itching, skin tightness, and headache. These side effects typically resolve without treatment and do not commonly result in patients discontinuing treatment.
- **Nerve injury:** Although unlikely, Kybella injections could cause nerve injury in the area of the jaw, resulting in an uneven smile or muscle weakness. In clinical trials, these all resolved without treatment in an average of six weeks. Tell your provider if you develop signs of marginal mandibular nerve paresis (e.g. asymmetric smile or facial muscle weakness), difficulty swallowing, or if any existing symptom worsens.
- **Swallowing:** Although unlikely, Kybella injections can temporarily cause trouble with swallowing. Tell your provider if you have had a history of troubled swallowing before your treatment. If you experience any problems swallowing after your treatment, notify your provider immediately.
- **Skin ulceration:** Although unlikely, Kybella injections could cause superficial skin erosions.

- **Alopecia:** Although unlikely, Kybella injections could cause small patches of alopecia (hair loss) in the treatment area. The hair of a man's beard can potentially experience patches of hair loss that may be permanent.
- **Bleeding:** It is possible to experience bleeding during or after injections. Should post-procedure bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Ask your provider before taking any aspirin or anti-inflammatory medications for 10 days before your procedure, as this may contribute to a greater risk of bleeding.
- **Infection:** Kybella should not be injected if there is a pre-existing infection in the treatment area. In the rare event an infection occurs after treatment, additional treatment—including antibiotics or an additional procedure—may be necessary.
- **Bruising and swelling:** Kybella injections commonly cause swelling, bruising, pain, numbness, redness, and firmness in the treatment area. You may have bruising for a week or more after receiving any injectables, so time your treatments with your schedule accordingly. Although healing after an injectable procedure is expected, you will want to keep cool compresses on the affected area until it subsides. Contact your provider if bruising lasts longer than a week, or anytime you are concerned.
- **Damage to deeper structures:** Deeper structures—such as nerves, blood vessels and muscles—may be damaged during treatment with aesthetic injectables. The potential for this to occur varies according to where the treatment is being administered. Injury to deeper structures may be temporary or permanent.
- **Allergic reactions:** In rare cases, local allergies to injectables, lidocaine or topical preparations have been reported. Systemic reactions, which are more serious, may result. Allergic reactions may require additional treatment. Lidocaine is an ingredient in many injectables. Tell your provider if you have an allergy to lidocaine or other substances.
- **Medication reaction:** Tell your provider if you are on or recently were on any medications as they may interfere with the ability of the aesthetic injectables to function. Even the use of antibiotics and aspirin should be brought to your provider's attention. It is not recommended that you undergo this treatment if you are on blood thinners for any reason, including bleeding disorders.

### **Contraindications**

Kybella has a few contraindications and you may not be a good candidate for the treatment if you:

- Have herpes simplex virus.
- Are pregnant, may become pregnant or are breastfeeding.
- Have had previous surgery in the area.

Inform your provider if you have had any of these conditions.

I recognize, that during the course of the injectable treatment, unforeseen conditions may necessitate different procedures than those mentioned above. I, therefore, authorize the above physician or nurse

practitioner to perform such other procedures that are, in the exercise of his or her professional judgment, necessary, and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician or nurse practitioner at the time the procedure is begun.

I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthetics involve risk and the possibility of complications, injury, and sometimes death.

I acknowledge that while good results are expected, I may be disappointed with the results of the procedure. I understand there is no guarantee of results of any treatment. Even though appropriate measures are taken to reduce side effects, they cannot be completely eliminated in every case. I understand that the treatment may involve the risk of complication or injury from both known and unknown causes. I agree to follow the pre- and post-treatment instructions carefully. I understand that compliance with the recommended pre- and post-procedure guidelines is crucial for healing and reducing the risk of complications.

We provide this literature for patients and family members. It is intended to be an educational supplement that highlights some of the important points of what we have previously discussed in the office. Alternative treatments, the purpose of the procedure / surgery and the points in this handout have been covered in our face-to-face consultation(s).

**Preprocedural Checklist** (Please Complete):

- Is there a chance you may be pregnant? YES/NO
- Are you breastfeeding? YES/NO
- Are you currently taking antibiotics for an infection? YES/NO
- Are you currently suffering from an infection? YES/NO
- Are you currently taking and medications that may increase bleeding? YES/NO:

I/We have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedure to be used, and I/we have sufficient information to give this informed consent.

I/We certify this form has been fully explained to me/us, and I/we understand its contents.

I/We understand every effort will be made to provide a positive outcome, but there are no guarantees.

\_\_\_\_\_  
Physician/Nurse Practitioner      Date                      Witness                      Date

\_\_\_\_\_  
Patient                                      Date