



Colorado *Facial*
Plastic Surgery
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Creating Beautiful Faces

Aesthetics by Design
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Kybella™ Consent

Patient Name _____

Kybella™ is a non-human and non-animal synthetic formulation of deoxycholic acid, a naturally-occurring molecule in the body that aids in the breakdown and absorption of dietary fat. When injected into subcutaneous fat, Kybella causes lysis of adipocytes (destruction of fat cells). Once destroyed, those cells cannot store or accumulate fat. Kybella (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults (“double-chin”).

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. Treatment with Kybella is customized by the physician to the patient’s aesthetic goals for an improved chin profile. Once the aesthetic response is achieved with Kybella, re-treatment is not expected.

What to know about Kybella dosing and administration:

- Kybella is administered by subcutaneous injections directly into submental fat via 0.2 ml injections spaced 1 cm apart using a 30G (or smaller) 0.5 inch needle
- In clinical trials, the average dose was typically 2-3 vials (4-6 mL) per treatment session
- In-office treatment sessions are typically 20-30 minutes
- In clinical studies, many patients experienced visible results in two to four treatment sessions spaced at least one month apart. Up to six treatments may be administered.
- The safe and effective use of Kybella depends on the use of the correct number and locations of injections, proper needle placement, and administration techniques
- Health care professionals administering Kybella must understand the relevant submental anatomy and associated neuromuscular structures in the area involved, and any alterations to the anatomy due to prior surgical or aesthetic procedures
- Kybella should only be administered by a trained healthcare professional. Kybella is contraindicated in the presence of infection at the injection sites.

What to Expect After Kybella Treatment:

- Bruising and/or Redness. Some degree of bruising and swelling will occur in the majority of patients. This is usually mild to moderate and lasts for approximately 1 week.
- Swelling. All patients will experience some degree of swelling which onsets shortly after the injections and lasts a variable period of time. Initially the swelling is due to the inflammation caused by the toxic effect of Kybella on fat cells. After 2 to 3 days, there will be fullness that is due to the breakdown of fat released from the fat cells. This fullness gradually dissipates as the fat is resorbed from the area and can last from 1 to 6 weeks following injection.

_____ ***Patient Initials***



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Risks

In general, Kybella is a very safe treatment. Complications can be grouped into either early or late occurrences:

- Early Complications/Risks
 - Prolonged irritation at the injection site. Persistent redness and tenderness may occur beyond the typical 1 to 2 weeks in a small group of patients.
 - Lower facial weakness. In a very small percentage of patients, temporary weakness in the distribution of the marginal mandibular branch of the facial nerve will result. Clinically this will manifest as an asymmetric smile or lower lip posture during animation. In all cases during clinical trials, the weakness was temporary and resolved with time, usually by 3 months.
 - Facial/neck numbness. Loss of sensation may persist beyond the first 1 to 4 weeks in a very small group of patients but almost always recovers.
 - Ulceration of the skin surface. This is an extremely uncommon potential complication.
 - Damage to submandibular glands. The submandibular glands are in close proximity to the submental fat being treated. Conceivably these could be damaged by the Kybella product. No cases of proven submandibular necrosis occurred during the clinical trials.
- Late complications/Risks.
 - The long term complications relate to the cosmetic outcome. In very rare cases the skin contour may heal with slight irregularities or deep dermal scarring. This was not noted during clinical trials but is a rare possibility.
 - KYBELLA, as with any facial injection can potentially cause serious side effects, including nerve injury in the jaw (which can cause an uneven smile or facial muscle weakness) and/or trouble swallowing.

_____ **Patient Initials**

I, _____ (print name) understand the risks and benefits of the procedure and wish to proceed with injections.

Patient's Signature: _____ Date: _____

Clinician's Name: _____ Signature: _____ Date: _____