**KYBELLA® (deoxycholic acid)/ Lippo Dissolve injection**

**INDICATION**

KYBELLA® (deoxycholic acid)/Lippo dissolve injection 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 this drug is for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

Alternative treatments to this procedure include doing nothing, having fat worked off with exercise and for some patient's surgical procedures such as removal of the fat may be appropriate.

**CONTRAINDICATIONS**

KYBELLA® /Lippo Dissolve is contraindicated in the presence of infection at the injection sites. Pregnant or nursing.

**WARNINGS AND PRECAUTIONS**

*Marginal Mandibular Nerve Injury*

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, were reported in 4% of subjects in the clinical trials; all cases resolved spontaneously (range 1-298 days, median 44 days). This should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve.

*Dysphagia*

Dysphagia occurred in 2% of subjects in the clinical trials in the setting of administration-site reactions, eg, pain, swelling, and induration of the submental area; all cases of dysphagia resolved spontaneously (range 1-81 days, median 3 days). Avoid use of this medication in patients with current or prior history of dysphagia as treatment may exacerbate the condition.

*Injection-Site Hematoma/Bruising*

In clinical trials, 72% of subjects treated with KYBELLA® experienced hematoma/bruising. This medication 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.

*Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures*

To avoid the potential of tissue damage, this medication should not be injected into or in close proximity (1 cm-1.5 cm) to salivary glands, lymph nodes, and muscles. Care should be taken to avoid inadvertent injection directly into an artery or a vein as it can result in vascular injury.

*Injection Site Alopecia*

Cases of injection site alopecia have been reported with administration of this medication. Onset and duration may vary among individuals and may persist. Consider withholding subsequent treatments until resolution.

*Injection Site Ulceration and Necrosis*

Injections that are too superficial into the dermis may result in skin ulceration and necrosis. Cases of injection site ulceration and necrosis have been reported with administration of KYBELLA®/Lippo dissolve. Do not administer this medication into affected area until complete resolution.

**ADVERSE REACTIONS**

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

Even though Brandy Marie Family & Aesthetic Care & Brandy Tafoya, APRN-C, strives to give you the best results possible, we cannot guarantee, that you will be happy, the fees for the procedure are for the cost of materials and labor.

I certify that I am a competent adult of at least 18 years of age. I understand that if I have questions or concerns regarding my treatment, I will notify Brandy Tafoya, APRN-C, immediately so that timely follow-up and intervention can be provided.

Attestation:

This procedure is cosmetic and therefore not covered by insurance. I understand that I am responsible for all costs and that there are *NO REFUNDS*. I certify that I have read or have had a provider read to me the contents of this form. I understand the risks and alternatives involved with this procedure. I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction. I hereby release Brandy Marie Family & Aesthetic Care & Brandy Tafoya, APRN-C from liability associated with this procedure.

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

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



Witness Signature: