KYBELLA® (deoxycholic acid) injection 10 mg/mL
Indication and Important Safety Information

INDICATION

KYBELLA® (deoxycholic acid) 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 KYBELLA® for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

KYBELLA® is contraindicated in the presence of infection at the injection sites.

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). KYBELLA® 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 KYBELLA® 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. 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.

Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures

To avoid the potential of tissue damage, KYBELLA® should not be injected into or in close proximity (1 cm-1.5 cm) to salivary glands, lymph nodes, and muscles.

Injection Site Alopecia

Cases of injection site alopecia have been reported with administration of KYBELLA®. 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®. Do not administer KYBELLA® 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.

Please see accompanying KYBELLA® full Prescribing Information.

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