

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

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.

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.

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 KYBELLA[®] full prescribing information.

KYBELLA® (deoxycholic acid) injection 10 mg/mL Before-and-After Photos (Lisa V. 1)

Results are represented over the course of treatment; not all treatments are shown. Up to 6 treatments may be administered, spaced no less than 1 month apart.¹ In clinical trials, 59% of people treated with KYBELLA® received all 6 treatments.¹

Approved Use

What is KYBELLA®?

KYBELLA® is a prescription medicine used in adults to improve the appearance and profile of moderate to severe fat below the chin (submental fat), also called “double chin.”

It is not known if KYBELLA® is safe and effective for use outside of the submental area or in children less than 18 years of age.

Important Safety Information

Who should not receive KYBELLA®?

You should not receive KYBELLA® if you have an infection in the treatment area.

Before receiving KYBELLA®, tell your healthcare provider about all of your medical conditions, including if you: Have had or plan to have surgery on your face, neck, or chin; have had cosmetic treatments on your 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; are pregnant or plan to become pregnant (it is not known if KYBELLA® will harm your unborn baby); are breastfeeding or plan to breastfeed (it is not known if KYBELLA® passes into your breast milk; talk to your healthcare provider about the best way to feed your baby if you receive KYBELLA®).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take a medicine that prevents the clotting of your blood (antiplatelet or anticoagulant medicine).

What are the possible side effects of KYBELLA®?

KYBELLA® can cause serious side effects, including nerve injury in the jaw (which can cause an uneven smile or facial muscle weakness) and trouble swallowing.

The most common side effects of KYBELLA® include swelling, bruising, pain, numbness, redness, and areas of hardness in the treatment area.

These are not all of the possible side effects of KYBELLA®. Call your healthcare provider for medical advice about side effects.

Ask your healthcare provider or visit MyKybella.com for full prescribing information.

Reference: 1. KYBELLA® Prescribing Information, April 2015.