



Consent for Treatment with BELKYRA (deoxycholic acid)

BELKYRA (deoxycholic acid) injections are indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat, also called 'double chin,' in adults. The safe and effective use of BELKYRA for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

Contraindications: BELKYRA is contraindicated when there is an infection at the injection site. There are no studies on safety during pregnancy or breast feeding. If you are pregnant or breast feeding then you should not proceed with treatment.

Risks: Every injection of any medication involves a certain amount of risk. Below are risks reported during clinical studies that are specific to the injection of BELKYRA.

BELKYRA injections commonly cause swelling (87%), bruising (72%), pain (70%), numbness (66%), redness (27%), and areas of hardness in the treatment area (23%). BELKYRA injections may also cause tingling, nodule, itching, skin tightness, and headache. These side effects typically resolve without treatment and do not commonly result in patients discontinuing treatment. Other less common potential side effects include:

Nerve Injury: BELKYRA injections may cause nerve injury in the area of the jaw resulting in an uneven smile or facial muscle weakness (4%). In clinical trials, these all resolved without treatment in an average of 6 weeks.

Swallowing: BELKYRA injections may temporarily cause trouble swallowing (2%).

Skin Ulceration: BELKYRA injections may cause superficial skin erosions.

Alopecia: BELKYRA injections may cause small patches of hair loss in the treatment area.

Unsatisfactory Results: There is a possibility of an unsatisfactory result from injections of BELKYRA. The procedure may result in unacceptable visible deformities, such as asymmetry in the treatment area and prominence of platysmal (neck muscle) bands.

Redundant Skin: Increased laxity (looseness) of the neck skin was not observed in clinical trials, however the possibility exists whenever fat is removed.

Incomplete Fat Removal: Approximately 50% of neck fat is below the muscle. BELKYRA injections do not target this fat, and residual fullness may remain.

Consent for Treatment:

I have requested treatment with BELKYRA. The side effects and risks associated with this treatment have been explained to me. I have been told about the potential benefits of treatment, and alternative treatments, including no treatment at all.

I understand clinical trials show multiple treatments are necessary to produce permanent results, and that increase in body weight may diminish the effects of treatment. I have read, and fully understand this Consent Form. I have been able to ask questions about the treatment and all of my questions have been answered to my satisfaction. I hereby consent to treatment with BELKYRA.

I consent to administration of an injected local anesthetic (lidocaine or Marcaine) to decrease discomfort during the procedure. Risks of local anesthetics include allergic reactions, such as hives, anaphylaxis (difficulty breathing, which in rare cases may result in death), and temporary nerve paralysis.

Patient initials

Patient Signature:

Date:

Physician Signature:

Date:

Witness Signature:

Date: