

Important Safety Information

Indication: *Sculptra*® *Aesthetic* (injectable poly-L-lactic acid) is indicated for use in people with healthy immune systems as a single regimen for the correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate.

Sculptra Aesthetic should not be used by people that are allergic to any ingredient of the product or have a history of keloid formation or hypertrophic scarring. Safety has not been established in patients who are pregnant, lactating, breastfeeding, or under 18 years of age. *Sculptra Aesthetic* has unique injection requirements and should only be used by a trained healthcare practitioner. Contour deficiencies should not be overcorrected because they are expected to gradually improve after treatment.

Sculptra Aesthetic should not be injected into the blood vessels as it may cause vascular occlusion, infarction or embolic phenomena. Use at the site of skin sores, cysts, pimples, rashes, hives or infection should be postponed until healing is complete. *Sculptra Aesthetic* should not be injected into the red area (vermillion) of the lip or in the peri-orbital area.

The most common side effects after initial treatment include injection site swelling, tenderness, redness, pain, bruising, bleeding, itching and lumps. Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration, have also been reported.

Sculptra Aesthetic is available only through a licensed practitioner. Complete Instructions for Use are available at www.SculptraAesthetic.com.

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