

Patient Information

Sculptra Dermal Filler Frequently Asked Questions

Sculptra®... a sculpting agent that restores volume to correct the signs of facial fat loss

Sculptra® is an enduring treatment approved by the FDA for restoration and/or correction of the signs of facial fat loss. It is the first FDA-approved product of its kind for this condition.

Facial fat loss, or lipoatrophy, is the loss of fat beneath the skin, which can result in sunken cheeks, indentations, and hollow eyes. Sculptra® is a safe, synthetic, and biocompatible material that is injected below the surface of the skin in the area of fat loss. It provides a gradual and significant increase in skin thickness, improving the appearance of folds and sunken areas. No skin testing is required.

Sculptra® has been safely used outside the United States since 1999 in over 150,000 patients under the trade names New-Fill™ and Sculptra®.

What is Sculptra®?

Sculptra® is a synthetic injectable material known as "poly-L-lactic acid." Poly-L-lactic acid is biocompatible (a material that does not harm the body) and biodegradable (able to be broken down by the body). Poly-L-lactic acid has been widely used for many years in dissolvable stitches, soft tissue implants, and other types of implants.

How does Sculptra® work?

Sculptra® is injected below the surface of the skin in the area of fat loss. Sculptra® provides a gradual increase in skin thickness. Visible results appear within the first few treatment sessions.

Sculptra® will not correct the underlying cause of the facial fat loss, but will help improve the appearance by increasing skin thickness in the treated area.

Do I need a skin test before being treated with Sculptra®?

No skin testing is required prior to use.

Are the results from Sculptra® immediate?

No. At your first treatment visit, it may appear that Sculptra® worked immediately because of swelling from the injections and the water used to dilute Sculptra®. In a

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few days, when the swelling goes down and the water is absorbed by your body, you may look as you did before your treatment. Sculptra® takes time to gradually correct the depression in your skin. Your healthcare provider will see you again in a few weeks to decide if you need more Sculptra® injections.

How many treatments are required?

Your healthcare provider will decide the appropriate number of treatment sessions and the amount of Sculptra® you will need at each session. Patients with severe facial fat loss may require 3 to 6 treatment sessions.

How long do treatment results last?

Treatment results will differ for each person. In a clinical study, the treatment results lasted for up to 2 years after the first treatment session, in most patients. Touch-up treatments may be needed to maintain the desired effect.

Do injections of Sculptra® hurt?

As with any injection, injections with Sculptra® may hurt. Sculptra® is injected in small amounts using a very fine needle. Your healthcare provider may apply a topical or local anesthetic.

What can I expect to happen at a treatment session?

Your healthcare provider will answer all of your questions and prepare you for the treatment.

- Make-up should be removed.
- The area where the injections will be given will be cleaned with an antiseptic.
- You and your healthcare provider will determine if a topical or local anesthetic is needed.
- Sculptra® will be injected in small amounts into the skin using a very fine needle. Multiple injections will be needed.
- An ice pack should be applied to the treatment area to help reduce swelling.
- After the treatment session, the area should be thoroughly massaged to distribute the product evenly.

What can I expect after treatment?

Immediately following a treatment session with Sculptra®, redness, swelling, pain, bruising or all of these signs can happen in the treatment area. These signs usually go away in a few hours to a few days. Some have been known to last up to 17 days. Your healthcare provider will give you specific post-treatment care instructions. You should massage the treated area (a few times each day) for several days after the treatment session. Within the first 24 hours after treatment, an ice pack should be applied for a few minutes at a time to the treatment area to

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help reduce swelling. Wrap the ice in a cloth and avoid putting ice directly on your skin. Avoid excessive sun and UV lamp exposure until any initial swelling and redness has resolved.

Report any worsening or longer-lasting symptoms or signs to your healthcare provider.

How quickly can I get back to my daily activities?

Most patients feel comfortable going back to their normal activities following treatment.

When will I be able to apply make-up after treatment?

Make-up may be applied a few hours after treatment if no complications are present (for example, open wounds or bleeding).

What are the possible side effects of treatment with Sculptra®?

The most common side effects with the use of Sculptra® include injection-related side effects at the site of the injection such as bleeding, tenderness or pain, redness, bruising, or swelling. These side effects generally last, on average, 3 to 17 days.

One possible delayed side effect with Sculptra® can be small bumps under the skin in the treated area. These small bumps may not be visible, and you may notice them only when you press on the treated skin. These bumps tend to happen within the first 6 to 12 months after the first treatment. Occasionally, these bumps go away on their own. Visible bumps, sometimes with redness or color change to the treated area, have also been reported. As with all procedures that involve an injection through the skin, there is a risk of infection.

Report any side effects to your doctor.

Who should not use Sculptra®?

You should not use Sculptra® if you are allergic to any ingredient of Sculptra®. Talk to your healthcare provider about your medical history when deciding on treatment options.

Where can I get more information?

For more information, visit us at www.carolinaeye.com or contact our patient services counselor by phone at 910.295.1501 or 800.733.9355, or by email at info@carolinaeye.com.

If at any time you need to reach our main center, please call 910.295.2100 or 800.733.5357.

Information obtained from www.sculptra.com