

Sculptra®

injectable poly-L-lactic acid

A PATIENT'S GUIDE TO TREATMENT WITH SCULPTRA™

GLOSSARY

Anesthetic: A substance that causes loss of feeling or awareness. A topical or local anesthetic causes temporary loss of feeling in a part of the body.

Antiseptic: An agent that kills bacteria or prevents or slows growth of germs.

Biocompatible: A material that does not harm the body.

Biodegradable: Able to be broken down by the body.

Induration: Any hardening or thickening of tissue or skin.

Keloids: An overgrowth of scar tissue at the site of a skin injury. Keloids may occur around surgical cuts, traumatic wounds, vaccination sites, burns, or minor scratches.

Lipatrophy: The loss of body fat.

Palpable: Able to be touched and felt.

Poly-L-lactic acid: A synthetic material that is biocompatible and bioabsorbable and has been used for over 25 years in dissolvable stitches, soft tissue implants and other implants.

Side effect: An undesirable event caused by use of the product.

Synthetic: "man-made."

BACKGROUND INFORMATION

WHAT IS SCULPTRA?

SCULPTRA is a synthetic injectable material known as "poly-L-lactic acid." Poly-L-lactic acid is a biocompatible, biodegradable material that has been widely used for many years in dissolvable stitches, soft tissue implants, and other types of implants.

WHO MIGHT BENEFIT FROM TREATMENT WITH SCULPTRA?

SCULPTRA is intended for restoration and/or correction of the signs of facial fat loss (lipatrophy) in people with human immunodeficiency virus.

WHO SHOULD NOT USE SCULPTRA?

Talk to your health care provider about your medical history when deciding on treatment options. You should not use **SCULPTRA** if:

- you are allergic to any ingredient of **SCULPTRA**.

ARE SKIN TESTS NEEDED BEFORE TREATMENT WITH SCULPTRA?

No skin testing is required prior to use.

HOW DOES SCULPTRA WORK?

SCULPTRA is injected below the surface of the skin in the area of fat loss. **SCULPTRA** provides an 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.

ARE THE RESULTS FROM SCULPTRA IMMEDIATE?

No. At your first treatment visit it may appear that **SCULPTRA** worked immediately. That is because of swelling from the injections and the water used to dilute **SCULPTRA**. In a 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 health care provider will see you again in a few weeks to decide if you need more **SCULPTRA** injections.

HOW MANY TREATMENTS ARE REQUIRED?

Your health care provider will decide with you the number of treatment sessions and the amount of **SCULPTRA** you will need at each treatment session. Patients with **severe** facial fat loss may require three to six treatment sessions. Touch-up treatments may be needed to maintain the desired effect.

HOW OFTEN ARE TREATMENTS GIVEN?

Your health care provider will see you two or more weeks after each treatment to assess whether you need additional treatments.

HOW LONG DO TREATMENT EFFECTS LAST?

Treatment effects 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. Dermik® is studying the long-term effects beyond two years.

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 health care provider may apply a topical or local anesthetic.

WHAT CAN I EXPECT TO HAPPEN AT A TREATMENT SESSION?

Your health care 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 health care 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 ARE THE POSSIBLE SIDE EFFECTS OF TREATMENT WITH SCULPTRA?

Talk to your health care provider about the possible side effects of **SCULPTRA**.

TABLE 1:
NUMBER OF PATIENTS WITH TREATMENT-RELATED SIDE EFFECTS
OBSERVED IN CLINICAL STUDIES WITH ONE TO TWO YEARS OF FOLLOW-UP

	277 Patients
INJECTION PROCEDURE RELATED SIDE EFFECTS	
Bruising	59 (21%)
Swelling*	27 (10%)
Pain	37 (13%)
Redness	6 (2%)
DEVICE-RELATED SIDE EFFECTS	
Small bumps under the skin	54 (19%)

*Occasionally accompanied with redness

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 six to twelve 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 health care provider.

SHOULD I TELL MY HEALTHCARE PROVIDER WHAT MEDICATIONS I AM TAKING?

Yes. You should tell your healthcare provider about all the medicines you are taking, even over the counter medicines or treatments. If you are taking blood thinners or medications that may interfere with clotting of the blood, such as aspirin, you might be more likely to have bruising or bleeding at the injection site. There have been no studies of possible interactions between **SCULPTRA** and drugs or other substances or implants. Talk to your health care provider about your medical history when deciding on treatment options.

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 health care 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 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 health care 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).

ADDITIONAL INFORMATION

What are my other options for treatment?

At present there are no other medical devices for restoration and/or correction of facial fat loss (lipatrophy) in people with human immunodeficiency virus.

Prescribing Information as of August 2004.

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