TIPS FOR CONSULTATION

SAMPLE QUESTIONS

- How does Sculptra work?
- Will it make me look like I've had work done?
- Is there any other treatment that works like Sculptra?
- I know that more than one treatment session may be required. How many do you think I would need?
- How long might the treatment effects last?
- What are the possible side effects of treatment with Sculptra?
- When can I expect to see results?
- How soon after treatment can I resume my normal activity?
- Is there any ingredient in Sculptra that I may be allergic to?

TIP:

BE SURE TO CHOOSE A DOCTOR WITH WHOM YOU'RE COMFORTABLE.

MY QUESTIONS

NOTES

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IMPORTANT SAFETY INFORMATION[1]

CONTRAINDICATIONS

- Sculptra should not be used in any person who has hypersensitivity to any of the components of the product.

WARNINGS

- Use of Sculptra in any person with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled.
- Do not overcorrect (overfill) a contour deficiency because the depression should gradually improve within several weeks as the treatment effect of Sculptra occurs **(see INSTRUCTIONS FOR USE)**.
- Injection procedure reactions to Sculptra have been observed consisting mainly of hematoma, bruising, edema, discomfort, inflammation, and erythema. The most common device related adverse effect was the delayed occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable, asymptomatic and non-visible. Refer to **ADVERSE REACTIONS** for details.
- Special care should be taken to avoid injection into the blood vessels. An introduction into the vasculature may occlude the vessels and could cause skin infarction or embolism.
- Do not inject into the red area of the lip (vermillion). The long term efficacy and safety of Sculptra has not been established in the red area of the lip.

PRECAUTIONS

- Sculptra should only be used by health care providers with expertise in the correction of volume deficiencies after fully familiarizing themselves with the product, the product educational materials, and the entire instruction leaflet.
- Sculptra vials are for single patient and single session use only. Do not reuse or resterilize the vial. Discard immediately after use. Do not use if package or vial is opened or damaged.
- Long-term safety and effectiveness of Sculptra beyond two years have not been studied in controlled clinical trials.
- Sculptra should be used in the deep dermis or subcutaneous layer. Avoid superficial injections in order to avoid the appearance of early papules or nodules at the injection site, which could be suggestive of improper injection techniques (superficial placement, excessive amount of product, incorrect reconstitution). In addition, massaging the treatment area to ensure proper distribution of the product may also minimize the appearance of papules or nodules.
- Special care must be taken when using Sculptra in areas of thin skin, such as the periorbital area. An increased risk of papules and nodules in the periorbital area has been reported (see section "**ADVERSE REACTIONS**"). Refer to the **INSTRUCTIONS FOR USE** regarding injection techniques.
- As with all transcutaneous procedures, Sculptra injection carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- As with all injections, patients treated with anti-coagulants may run the risk of a hematoma or localized bleeding at the injection site.
- The safety of Sculptra for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- No studies of interactions of Sculptra with drugs or other substances or implants have been made.
- The safety of using Sculptra in patients with susceptibility to keloid formation and hypertrophic scarring has not been established. Sculptra should not be used in patients with known history of or susceptibility to keloid formation or hypertrophic scarring.
- The patient should be informed that he or she should minimize exposure of the treatment area to excessive sun and avoid UV lamp exposure until any initial swelling and redness has resolved.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with Sculptra, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if Sculptra is administered before the skin has healed completely after such a procedure.

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ADVERSE REACTIONS

The side effects usually resulting from the injections are transient bleeding from an area the size of the point of the needle or transient pain, localized redness at the injection site, ecchymosis, hematoma.

Based on data obtained through post-marketing surveillance and clinical studies, nodules have also been reported. Subcutaneous papules invisible but palpable, or visible nodules including periorbital nodules or areas of induration have been noted in the injection area and may be due to over-correction. Nodules are occasionally associated with inflammation or discoloration.

The early occurrence of subcutaneous nodules (within 3 to 6 weeks after treatment) may be minimized by adhering to proper dilution and injection technique (e.g., avoiding superficial injections or over-correction). In addition, massaging the treatment area to ensure proper distribution of the product may also minimize the appearance of nodules.

Delayed occurrence of subcutaneous nodules at the injection site, mostly occurred several months post-injection (within 1 to 14 months), with sometimes a prolonged duration of up to 2 years. In some cases, they resolved spontaneously or following treatment with intralesional corticosteroids. Surgical excision of the nodules was sometimes required when they were larger in size, occurring in difficult anatomical regions (e.g. lower eyelid) or persisting after other treatments.

For nodule areas or granuloma formation, the treatment may include multiple intralesional injections of corticosteroids or elective excision.

Other rarely reported adverse events include injection site abscess, injection site infection including cellulites (facial), staphylococcal infection, local infection, granuloma formation, allergic reaction, injection site urticaria, injection site swelling, skin hypertrophy and injection site atrophy, hypersensitivity, angioedema, telangiectasis, skin sarcoidosis.

Scarring and skin discoloration have also been reported.

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1. Sculptra® (poly-L-lactic acid). Instructions for use. September 19, 2012.

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