Patient information - Sculptra®

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Glossary
Anaesthetic – a medication (or "treatment") that reduces pain.
PLLA – poly-L-lactic acid.
Lidocaine – a commonly used local **anaesthetic** to numb the skin, see "**anaesthetic**".

What is Sculptra?

Sculptra is a product used to increase the volume of depressed areas of your facial skin such as skin creases, wrinkles, folds and skin aging. It is also suitable for large volume corrections of signs of facial fat loss. The product is injected into your skin.

Sculptra is a powder that contains poly-L-lactic acid (PLLA) and the excipients sodium carboxymethylcellulose and mannitol. The product should be dissolved by your health care professional before use. Sometimes a lidocaine solution is added to the PLLA suspension to provide pain relief during the injection procedure.

How does Sculptra work?

The Sculptra suspension consists of solid PLLA particles that, when injected into the skin, may stimulate the production of new collagen. Gradually, wrinkles and skin depressions are corrected. In time, the PLLA particles are eliminated by the body.

With Sculptra treatment the results are gradual. This means that changes are subtle, and usually aren't apparent immediately after the first treatment. Your healthcare practitioner should evaluate the results as they develop (no sooner than 4 weeks after treatment) and determine if additional treatment is required.

Users:

- The product shall only be used in persons over 18 years of age.
- You should only be given the product by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

Are there any reasons why I should not use Sculptra?

To ensure a safe procedure, your healthcare professional will talk to you about your medical history to determine if you are an appropriate candidate for treatment. You should not use Sculptra if:

- You are allergic to any substance contained in Sculptra.
- You have severe allergies with a history of severe reactions (anaphylaxis) or multiple severe allergies.
- You have areas with skin sores, pimples, rashes, hives, cysts, or infections. The treatment should be postponed until healing is complete as this could delay healing or make your skin problems worse.

As lidocaine may be added to Sculptra suspension prior to treatment, you should tell your healthcare practitioner if:

- You are allergic to lidocaine or similar anaesthetic agents and medications

If you are not sure about your medical history concerning these allergies or other medical conditions you think might be relevant, please discuss further with your healthcare professional.

Are there other warnings or precautions that I should discuss with my healthcare professional?

Warnings

- One of the risks with using this product is unintentional injection into a blood vessel. The risks of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

- You have had any prior surgery or procedures in the area you intend to be treated with Sculptra.

After having the injection, seek immediate medical attention if:

- you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment.

Precautions

There are several other important precautions to discuss with your healthcare professional to ensure a satisfactory result and to avoid any complications. Please be sure to discuss the following with your healthcare professional if:

- you are breastfeeding or pregnant. The safety of Sculptra for use during pregnancy, in breastfeeding women, has not been studied.

- you are prone to bleeding or have been diagnosed with a bleeding disorder or are taking any medication that can thin your blood or prolong bleeding, such as aspirin and warfarin. As with any injection procedure this may have a higher risk of severe bleeding or bruising.

- you have permanent implants in the intended treatment location in your face as this has not been studied.

- you have a history of herpes infection, this could be reactivated as a result of an injection.

- you have any wound healing disorders or have dark skin. This might increase your risk of developing skin scarring or skin discoloration after treatment.

- you are on any medications to decrease your body's immune response (immunosuppressive therapy).

- you recently had skin therapies such as laser treatment, mechanical or chemical peels. This may lead to increased risk of side effects such as redness, swelling, heat or pain of the skin.

- you have a dental block or are concurrently using another anaesthetic agent, to avoid side effects from too much anaesthetic if lidocaine is added to Sculptra before use.

If you have any additional questions about any topic in this section, please discuss further with your health care professional.

How long does Sculptra last?

The effects of Sculptra are long-lasting and improvement in wrinkle severity may last up to 25 months after treatment. This was demonstrated in a clinical study in which subjects were treated in up to 4 treatment sessions with Sculptra in the lines at the side of the nose to the corners of the mouth (nasolabial folds).

The product effects may vary, depending on individual characteristics, the amount used, and the area being treated.

All residual risks and potential undesirable side-effects listed

As with any medical procedure, there are risks involved with the use of injectable fillers.

Local skin reactions such as transient bleeding from the needle stick, pain, localised redness, bruising or swelling (oedema) are expected and commonly occur at the treatment location after the injection procedure. Usually these reactions do not need any treatment and will go away by themselves within 2–6 days.

Other reported side effects from healthcare professionals and customers using Sculptra include:

- Lumps and bumps (papules/nodules)
- Temporary swelling (oedema)
- Short duration of effect (device ineffective)
- Mass formation/hardening (induration)
- Pain/tenderness
- Bruising/bleeding
- Redness (erythema)
- Small area of inflammation in tissue (granuloma)
- Eye disorders including dry eyes, eye pain, eye swelling, eyelid drooping (eyelid ptosis), increased tear flow (increased lacrimation), blurred vision, and visual disturbance such as blindness, and reduced vision
- Skin reactions at the injection location including burning sensation, dryness, exfoliation, irritation, discomfort, warmth,
- Skin discoloration
- Inflammation
- Facial nerve paralysis, reduced sense of touch (hypoaesthesia), tingling sensation (paraesthesia)
- Infections/pocket of pus (abscesses)
- Itching (pruritus)
- Uneven appearance of the skin (deformity/asymmetry)
- Scarring
- Allergic reaction (hypersensitivity)/rapid swelling (angioedema)
- Rash
- Restricted blood flow/tissue death (ischemia/necrosis) including paleness of skin (pallor),
- Skin irritation (dermatitis)
- Hives (urticaria)
- Muscle twitching and muscular weakness
- Blisters
- Symptoms of reactivation of herpes infection
- Acne
- Implanted gel moving from the site of injection (device dislocation)
- Dilated small blood vessels (telangiectasia)

- Leakage from implant site (discharge)
- Other skin related effects include localised hair loss (alopecia), skin tightness and skin wrinkling
- Other side effects not associated with the treatment location include anxiety, pain in joint (arthralgia), chills, depression, diarrhoea, dizziness, shortness of breath (dyspnoea), emotional distress, tiredness (fatigue), headache, flu like illness, trouble falling asleep (insomnia), feeling sick (malaise), nausea, fever (pyrexia), sinusitis, and vomiting

Lumps and bumps (papules/nodules) can occur several months after injection, starting from 1-2 months up to 14 months after last administration of Sculptra. In some cases, the lumps and bumps go away on their own or after medical treatment, whilst other lumps and bumps could last up to 2 years. In rare cases surgery is required to remove the lumps and bumps. Post treatment massage may reduce this risk (see 'What should I do after receiving treatment?').

The healthcare professional performing the treatment may accidentally inject the product into a blood vessel, which can cause injury to the blood supply. The risk of this is very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include death of tissue (skin necrosis) with temporary scabs or permanent scarring of the skin, and in rare cases temporary or permanent vision changes, including blindness or, stroke.

When and how to report undesirable side effects

If you have any questions concerning possible side effects, please discuss further with your healthcare professional. You should always tell your healthcare professional if you experience anything unusual after the treatment.
If you believe that you have experienced a serious side effect related to your treatment with Sculptra this should also be reported to the Australian Government Therapeutic Goods Administration through their website at:
www.tga.gov.au and to the product sponsor (see contact information above)

After procedure information

What should I do after receiving treatment?

- After the injection session, ice (in a suitable cloth, avoiding any direct contact with the skin) should be applied to the treatment area in order to reduce swelling and/or bruising.
- It is important to thoroughly massage the treated area(s) to evenly distribute the product (use of an appropriate cream may help to reduce the friction on the skin surface during massaging). Periodically massage the treated areas for five minutes, five times per day for five days after the treatment to ensure a natural-looking correction.
- For the first 24 hours, you should avoid or minimise hard (strenuous) exercise. You should also avoid or minimise exposure to extensive sun, UV lamps and extreme temperatures until any swelling and redness has resolved. Exposure to any of these may cause the area where you

were treated to temporarily become red, swell and/or itch. If you experience any of these problems, an ice pack can be applied for a short period for relief.
- Avoid touching or shaving the treated area and not to apply any creams or cosmetics in the treated area before the skin has healed completely in order to prevent infections or other local skin reactions.

When should I call my doctor? What should I call my doctor about after the treatment?

You should call your doctor immediately or seek immediate medical attention if you have:
- Changes in your vision.
- Signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion).
- White appearance of the skin.
- Unusual pain during or shortly after treatment.

The above symptoms may indicate inadvertent injection of Sculptra into a blood vessel (refer to 'Residual Risks and Side Effects' for further information).

Be sure to call your doctor if you have:
- Persistent skin reactions at the treatment location beyond 14 days after the injection, as any early skin reactions such as bruising, swelling, pain, tenderness, redness, and itching will usually go away by itself within one week.
- Bumps (papules) on the skin or lumps (nodules) under the skin at the injection site. Massaging the treatment area may minimise the appearance of such bumps or lumps.
- Blisters or skin sores that recur, which may signal the presence of a herpes infection.
- Any signs of infection such as fever, or redness that spreads to surrounding areas of your skin, drainage of pus, increasing tenderness or increasing pain from the treatment location that does not go away. If you develop an infection you may need antibiotics. If it gets worse, you may need other treatments, such as surgery.
- Significant pain away from the treatment location.

If you have any additional questions, please ask your healthcare professional.

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