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GALDERMA

SCULPTRA®

Poly-L-lactic acid

en PATIENT INFORMATION

Manufacturer name

Q-Med AB, Seminariegatan 21, SE-752 28
Uppsala, Sweden

www.galderma.com/library

Sponsor name, address:

Galderma Australia Pty Ltd
Level 18, 1 Denison Street
North Sydney NSW 2060
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Australia Health authority name, address and website:
Therapeutic Goods Administration PO Box 100
Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653
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https://www.tga.gov.au

Glossary

Anaesthetic – a medication that reduces pain.

PLLA – poly-L-lactic acid.

Lidocaine – a commonly used local **anaesthetic** to numb the skin.

What is Sculptra?

Sculptra is a powder that contains plant-based poly-L-lactic acid (PLLA) sodium carboxymethylcellulose and mannitol. Before use, your healthcare professional will prepare the product by using sterile water for injection. While PLLA is the main ingredient, sodium carboxymethylcellulose and mannitol are needed to stabilize the product during manufacturing and to give the resulting suspension the right properties for injection. Your healthcare professional will inject the product into your skin. The healthcare professional may add a lidocaine solution to the product for pain relief while administrating the injection.

Content in each vial of dry powder

Poly-L-lactic acid	150 mg
Sodium carboxymethylcellulose	90 mg
Mannitol	127.5 mg

How does Sculptra work?

When Sculptra is injected into or under your skin, it provides a gradual filling of skin depressions and your skin will become thicker, over the course of a few weeks. This occurs because the body may produce new collagen and elastin fibers where Sculptra was injected. The product gradually breaks down and disappears within 18 months or more. PLLA particles have been visible 28 months after injection. Thus, side effects (e.g. lumps, bumps or inflammation) may occur with a late onset, see Section **“What are the potential side-effects?”**

The product can be used for:

- increasing the volume of depressed areas of your skin such as skin creases, wrinkles, folds, cellulites and for skin quality improvements.
- large volume corrections of signs of facial fat loss.

The product can be used in the skin in the following areas:

- the lines from your nose to the corners of your mouth (nasolabial folds),
- cheeks,
- the lines from the corner of your mouth downwards (sad mouth or marionette lines),
- temples,
- the horizontal crease that forms between the bottom lip and chin (chin crease),
- chest area (décolletage),
- buttocks,
- back of thighs,
- upper arms

Your healthcare professional will evaluate the results (no sooner than 4 weeks after treatment) as they develop and determine if you need additional treatment. You may need several treatment sessions to achieve optimal aesthetic correction.

Are there any reasons why I should not use the Sculptra?

Talk to your healthcare professional about your medical history to determine if you are a good candidate for treatment.

- You must be at least 18 years of age to use this product.
- Do not use the product if you are pregnant or breastfeeding, as the safety has not been established.

Treatment with the product may result in an allergic reaction or cause a worsening of an ongoing skin problem. Do not use the product if:

- You are allergic to any substance contained in Sculptra.
- You have multiple severe allergies or a history of severe allergic reactions (anaphylaxis).
- You have areas with skin sores, pimples, rashes, hives, cysts, tumor or infections. Postpone your treatment until these areas have healed. The treatment could make your skin problems worse.

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

- You are allergic to the anesthetic lidocaine.

Please discuss further with your healthcare professional if:

- You are not sure about your medical history concerning allergies and skin problems, or
- You have an active disease or other medical conditions you think might be relevant.

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

Warnings

Before having the injection, tell your healthcare professional if:

- You are prone to bleeding, have been diagnosed with a bleeding disorder or are taking any medications that can thin your blood or prolong bleeding (such as aspirin and warfarin). You may be at higher risk of severe bleeding or bruising.
- You have had any prior surgery or trauma to the area you intend to treat.

There is a risk that your healthcare professional may accidentally inject the product into a blood vessel. The risk of this happening is very small, but the complications can be serious and may be permanent. These rare complications can include temporary scabs, permanent scarring of the skin, temporary or permanent vision changes, blockage of blood flow in part of your lung (lung emboli), blindness, or stroke.

After having the injection, seek immediate medical attention if:

- You have changes in your vision.
- You have signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, drooping face, severe headache, dizziness, or confusion).
- You have signs of a lung emboli (including sudden shortness of breath and sharp chest pains that get worse if you exert yourself or take a deep breath)
- Your skin appears white in the treatment area, or
- You have unusual pain shortly after treatment.

Precautions

You should only be given the product by trained and qualified healthcare professionals in a medical office environment.

Talk to your healthcare professional about precautions to avoid any complications. Before your injection, talk to your healthcare professional if:

- You have an autoimmune disease or are on any medications to decrease your body's immune response (immunosuppressive therapy). This may increase the risk of side effects related to your disease.
- You have any wound-healing disorders or have dark skin. This may increase your risk of developing skin scarring or skin discoloration after treatment.
- You have a history of herpes infection. This could be reactivated by the injection.
- You have prior implants (other than Sculptra) in the area where the product will be injected. This may increase your risk of side effects or result in a poor aesthetic outcome.
- You have recently had skin therapies such as laser treatment or chemical peels. This may increase your risk of side effects such as redness, swelling, burning sensation or pain at the treatment site.
- You have a dental block or are using topical lidocaine at the same time as your injection, to avoid side effects from too much anesthetic if lidocaine is added to Sculptra before use.

After the injection, Sculptra may be visible on diagnostic imaging (such as an ultrasound, MRI, CT and standard plain radiography). If you have a diagnostic imaging of the area injected with Sculptra, inform your healthcare professional that you have injected Sculptra in the area.

If you have any additional questions about any of the topics in this section, please discuss these further with your healthcare professional.

What effects can I expect from Sculptra and how long does the effect last?

Sculptra was tested in several clinical studies for different facial and non-facial treatment areas. The patients were followed for up to 5 years. Studies have shown a long-lasting 2 years or more aesthetic improvement and high patient and investigator satisfaction.

What are the potential side-effects?

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

Side effects reported in clinical studies, literature and from healthcare professionals and customers using the product include:

Most common side effects:

Local skin reactions such as bruising/bleeding, pain or tenderness, swelling, redness (erythema) and itching (pruritus) might occur at the treatment location immediately or shortly after the injection procedure. Usually, these reactions do not need treatment and will go away by themselves within one week after the injection.

Small lumps and bumps (papules/nodules) can occur several weeks up to 1 year or longer after last administration. These could be invisible, but felt under the skin, or visible and appear as an unevenness or bumpiness of the skin, and often painless. In some cases, the lumps and bumps go away on their own or after treatment with corticosteroid injections; other lumps and bumps last up to 2 years. In some 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 to minimize risk of side effects?').

Temporary swelling (edema) may occur up to several weeks or months after treatment. These events could be related with a local inflammatory reaction and sometimes with a bacterial infection, including pocket of pus (abscess), bump with pus (pustule), bacterial infection of your skin (cellulitis) and discharge that oozes from a wound (purulent discharge), and sometimes with an uneven appearance of the skin (asymmetry or deformity). Serious events are rare and could occur up to a year or more, after the injection. The swelling or infection may be reduced by using a short course of anti-inflammatory drugs (corticosteroids) or antibiotics. If the inflammatory symptoms or infections persist for a longer period, the product could be removed by a surgical procedure. Severe inflammatory reactions and infections might result in thin skin (skin atrophy) and scarring.

Less common side effects:

Larger lumps (mass formation), skin hardening (induration) and foreign body reactions (granuloma) could occur from a month and up to a year or longer after treatment. Troublesome lumps or granuloma could require treatment with corticosteroid injections or a surgical removal.

Allergic reactions with symptoms of redness, skin irritation (dermatitis), hives (urticaria), rash, blisters/vesicles, rapid swelling (angioedema), could occur immediately or within a few days following treatment. These events would usually be treatable with topical or oral drugs to relieve allergy symptoms.

Skin discoloration/pigmentation changes could occur following treatment and often resolve spontaneously. People with dark skin or with wound-healing disorders are more likely to develop persistent skin pigmentation changes and skin scarring (keloid and hypertrophic scarring) after treatment.

Other temporary local skin reactions at the treatment area include skin burning sensation, skin exfoliation, dryness, irritation, eyelid edema, discomfort, warmth and needle track marks.

Neurological symptoms could occur in case of a temporary compression of a nerve by the implant or an injury to the nerve. These symptoms could include reduced sense of touch (hypoesthesia), tingling sensation (paresthesia) and paralysis of the facial nerve. Use of anti-inflammatory drugs could improve these symptoms. Severe injuries could give persistent symptoms.

Eye disorders after treatment and which usually are temporary include dry eyes, double vision, eye irritation, eye pain, eye swelling, eyelid drooping, increased tear flow and blurred vision.

Other rarely reported adverse events:

Acne, implanted gel moving from injection site, leakage from implant site, swelling or bleeding in muscle (compartment pressure symptoms), muscle twitching, muscular weakness and muscle tightness, reactivation of herpes infection, small dilated blood vessels (telangiectasia), skin laceration, worsening of skin condition that causes blushing or flushing and visible blood vessels in your face (rosacea), other local side effects including localized hair loss, thickening or scarring of the tissue (fibrosis), fat lump (lipoma), skin disorders, skin tightness and skin wrinkling, other side effects not associated with the treatment location including anxiety/emotional distress, worsening of autoimmune reaction, joint pain, difficulty swallowing, breathing difficulty, tiredness, headache, influenza-like symptoms, insomnia, swollen lymph nodes (lymphadenopathy), nasal congestion, nausea, oral disorder, swelling and inflammation/infection of the salivary glands, fever, feeling of fainting, runny nose, sinusitis and tinnitus.

There is a risk that your healthcare professional may accidentally inject the product into a blood vessel. This may cause restricted blood flow (ischemia) and tissue death (skin necrosis) at the injection site, surrounding skin areas or in other areas further away such as the eyes, lungs or brain. The risk of this happening is very small, but the complications can be serious and may be permanent. These complications can include skin discoloration, temporary scabs, formation of wounds and scarring of the skin, temporary or permanent vision changes, blindness, lung damage or stroke. Treatments for these events include massage, warm compress or drugs that widen blood vessels. It is important to receive prompt medical treatment by a specialist healthcare professional if this should occur (see section below on symptoms and when to contact your healthcare professional after the treatment).

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

How do I report undesirable side effects?

If you have any questions concerning possible side effects, please discuss further with your healthcare professional. Always tell your healthcare professional if you experience anything unusual at the treatment area. You may also report this to your local Galderma representative. If you experience a side effect that is serious, i.e., it requires professional medical care, causes permanent injury or a life-threatening condition, then this should also be reported to your local competent authority.

For Australia this should 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)

Post-procedure information

What should I do after receiving treatment to minimize risk of side effects?

- Gently massage the treated areas for a couple of minutes over the next days to promote a natural-looking correction.
- For the first 24 hours, you should avoid or minimize hard (strenuous) exercise, or long-term sitting if the buttocks or posterior thighs are treated.
- Avoid or minimize exposure to sun, UV lamps or extreme temperatures until any swelling and redness has resolved. These may cause the treatment area 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, shaving, applying creams/cosmetics or other aesthetic procedures to the treated area until the skin has healed completely. This will help prevent infections or other local skin reactions.

When should I call my healthcare professional after the treatment?

Call your healthcare professional immediately if:

- You have changes in your vision.
- You have signs of stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, drooping face, severe headache, dizziness, or confusion).
- You have signs of a lung emboli (including sudden shortness of breath and sharp chest pains that get worse if you exert yourself or take a deep breath)
- Your skin appears white in the treatment area.
- You have unusual pain shortly after treatment.

It is normal to experience side effects such as bruising, swelling, pain, tenderness, redness and itching that resolve within one week. Call your healthcare professional if you have:

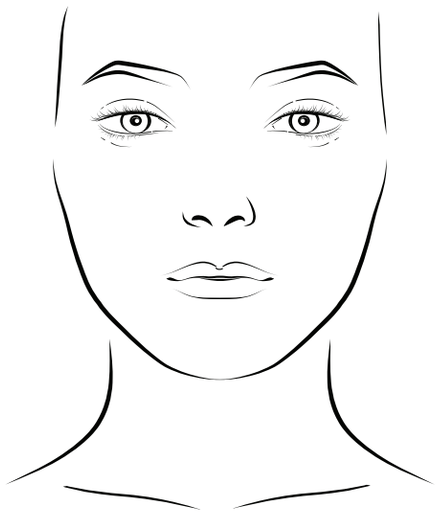
- Persistent skin reactions at the treatment location beyond 14 days after the injection.
- Bumps (papules) on the skin or lumps (nodules) under the skin at the injection site. Massaging the treatment area may minimize the appearance of such bumps or lumps.
- Blisters or skin sores that recur, which may signal the presence of a herpes infection.
- Significant pain in an area other than the treatment location.
- Any signs of infection, such as:
  - fever,
  - redness that spreads to surrounding areas of your skin,
  - drainage of pus from the injection location, or
  - increasing tenderness or increasing pain from the treatment location that does not go away.

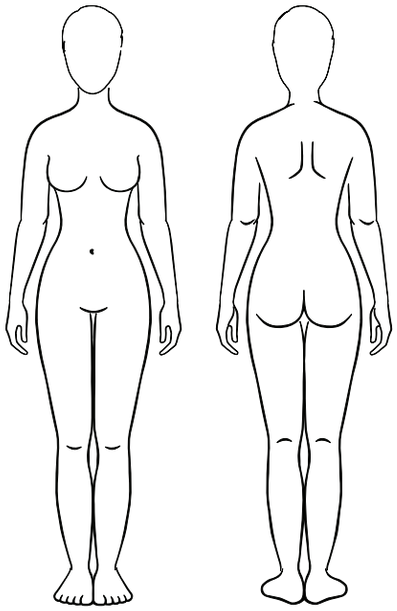
If you develop an infection, you may need antibiotics. If it gets worse, you may need other treatments, such as surgery.

TREATMENT RECORD

FOR THE HEALTHCARE PROFESSIONAL:

Fill in the Treatment Record according to instructions in the Instructions for use. Provide the Patient Information to the patient.





Number of vials used:

Preparation volume per vial:

Treatment area(s):

Injected volume per treatment area:

	Patient name/patient ID
	Date of treatment
	Name and address of Health care center or doctor
	Name and address of the manufacturer
	Information website for patient
UDI	Unique device identifier
LOT	Batch code

CE 0344

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EN 556-2, EN ISO 10993-1, EN ISO 11137-1, EN ISO 11137-2, EN ISO 13408-1, EN ISO 13408-2, EN ISO 13408-3, EN ISO 13408-4, EN ISO 13408-5, EN ISO 13408-6, EN ISO 13485, EN ISO 14155, EN ISO 14630, EN ISO 14971, EN ISO 15223-1, EN ISO 17665-1, EN ISO 20417, EN 62366-1, (EU) 2022/2346.