

Sculptra[®]

Poly-L-lactic acid

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Sculptra.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet handy.

You may need to read it again.

What Sculptra is used for

Sculptra is a sterile powder containing poly-L-lactic acid which is reconstituted with sterile water for injections to form a suspension.

Sculptra works to smooth out areas of depressed skin such as skin creases, wrinkles, folds, scars and skin aging. It also assists in the restoration and/or correction of the signs of facial fat loss including HIV or AIDS patients treated with antiretroviral drugs (medicines used to treat HIV).

Your doctor, however, may prescribe Sculptra for another purpose.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you are given it

When you must not be given it

Do not have Sculptra if you have:

- acute or chronic skin disease (infection or inflammation) near the area to be treated
- a known history of or susceptibility to keloid formation or scarring

Do not have Sculptra if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Sculptra should not be given to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Do not have Sculptra if you are pregnant or intend to become pregnant.

The safety of Sculptra for use in pregnancy has not been established.

Do not have Sculptra if you are breastfeeding or planning to breastfeed.

The safety of Sculptra for use in breastfeeding has not been established.

Sculptra should not be used after the expiry date (EXP) printed on the vial.

If it is used after the expiry date has passed, it may not work as well.

Sculptra should not be used if the packaging is torn/damaged or shows signs of tampering.

Before you are given it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if:

- you are susceptible to keloid formation & scarring

Tell your doctor if you are pregnant or intend to become pregnant.

If there is a need to consider using Sculptra during your pregnancy, your doctor will discuss the risks and benefits of having it.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Your doctor will discuss the risks and benefits of using Sculptra if you are breastfeeding or planning to breastfeed.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell him/her before you are given Sculptra.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

No studies of interactions of Sculptra with other drugs or other substances or implants have been done. However, as with all injections, patients treated with anti-coagulants (medicines used to prevent blood clots) may run the risk of a haematoma (bruise) or localised bleeding at the injection site.

How it is given

How much is given

The volume to be used should be limited to 0.1mL – 0.2mL per individual injection.

The volume of the product injected per treatment area will vary depending on the surface area to be treated.

Treatment of entire cheek:

One vial per cheek per injection session. Multiple injections may be required to cover targeted area.

Treatment of naso labial fold:

This may require multiple injections of 0.1mL – 0.2mL up to half a vial per side per injection session.

Additional sessions may be needed to achieve full effect. This will be determined by your doctor.

How it is given

Sculptra should only be administered by a doctor who is trained in the required technique. It is given as an injection below the surface of the skin.

Sculptra is intended for single patient use only.

If you receive too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have swallowed or accidentally injected Sculptra.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are being given Sculptra.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given Sculptra.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.

Things to be careful of

Avoid exposure or minimise exposure of the treated area to excessive sun or UV lamp until any initial swelling and redness has resolved.

Be careful driving or operating machinery until you know how Sculptra affects you.

Sculptra should not normally interfere with your ability to drive or operate machinery.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor as soon as possible if you do not feel well while you are being given Sculptra.

Tell your doctor or pharmacist as soon as possible if you notice any of the following and they worry you:

- local reaction around the injection site such as bleeding, pain or discomfort, swelling, redness
- erythema (flushing & redness of the skin)
- urticaria (pinkish, itchy swellings on the skin, also called hives or nettle rash)
- bruising
- localised blood clotting
- abscess or infection at the injection site
- lumps or hard lumps including at the injection site
- scarring

- skin discolouration

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- **swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing.**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Sculptra. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Ask your doctor or pharmacist to answer any questions you may have.

After you are given it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

After the injection session, apply an ice pack to the treatment area in order to reduce swelling and/or bruising. Avoid direct contact of the ice to the skin.

Important to massage the treatment area to evenly distribute the product.

Periodically massage the treatment area for 5 minutes, 5 times a day for 5 days after the treatment.

Storage

Sculptra is usually stored in the doctor's surgery or clinic. However, if you need to store Sculptra:

- **Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- **Keep it in a cool, dry place where the temperature stays below 30°C.**

Reconstituted Sculptra can be stored up to 72 hours at room temperature.

- **Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.**
- **Do not leave it in the car.**
Heat and damp can destroy some medicines.

Product description

What it looks like

Sculptra is a sterile freeze-dried powder in a clear glass vial.

Ingredients

Active Ingredient:

- 150mg Poly-L-lactic acid per vial

Other Ingredients:

- 90mg Sodium Carboxymethylcellulose
- 127.5 mg Mannitol

Sponsor

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Sculptra is supplied in New Zealand by:

sanofi –aventis new zealand limited
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