

Subcutaneous immunoglobulin (SCIg) therapy

Immunoglobulins (commonly known as antibodies) are used to treat adults and children with primary immune deficiencies (and other medical conditions), who are unable to make enough of their own antibodies, or who have antibodies that don't work properly. Replacing these antibodies helps to protect against infection and can prevent long term damage from ongoing infections (such as chronic lung disease).

Subcutaneous Immunoglobulin (SCIg) infusions are given by slowly injecting purified immunoglobulin into fatty tissue just underneath the skin. SCIg can be given at home, using a mechanical infusion pump (spring loaded or battery powered) or by rapid push (a manual method that does not require a pump - infusion is pushed by hand through a syringe).

What are the risks associated with SCIg?

SCIg is very well tolerated and safe. SCIg is made from plasma (the liquid part of blood), which comes from blood donors who are checked to make sure they are healthy and do not have certain infectious diseases. This means that there is an extremely low (almost zero) chance of blood borne viruses (such as Hepatitis B, Hepatitis C, HIV and Variant Creutzfeldt-Jakob disease (also called "mad cow disease").

Reactions or side effects to SCIg include:

- **Common injection site reactions** such as redness, swelling and itching these are usually mild and go away over a day or two. Reactions are generally worse with the first few infusions and get better over time.
- **Uncommon side effects** such as headache, feeling hot, nausea, diarrhoea, sore throat, rash, increased cough and back pain these are usually mild.
- Extremely rare and serious side effects such as allergic reactions, kidney problems or blood clots.

If a reaction occurs you must inform your nurse specialist or doctor as soon as possible and get advice before having any more infusions. For information about managing reactions see pages 5 and 6 of this document.

What needs to be done before starting SCIg?

Before you start on SCIg, your nurse specialist will provide you with information and training on how to give SCIg at home. You will need to sign a consent form to say that you understand the need for treatment and the chance of reactions that may occur with the treatment.

Choosing a SCIg infusion site

Using the same site for infusions can help reduce the amount of local swelling and redness that can occur after an infusion. Usually the lower abdomen will be used. However, the outer edge of the thigh or back of the upper arm can also be used for SCIg infusions. Avoid bony areas such as the hips.

When using the lower abdomen in adults and most children, the needle should be inserted at least 5cm away from the belly button. If using more than one site at a time, make sure they are at least 5cm apart. Before you infuse, have your equipment ready (see checklist). It is recommended you have a cold pack, a non-drowsy antihistamine and an analgesic (pain medication) available in case of a mild reaction.

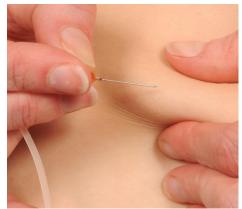
The shaded areas shown below can be used for insertion of the needle:



Note: Do not insert the needle where the skin is scarred, bruised, broken or inflamed (such as eczema). Examples of SCIg infusions:



Boy having SCIg infusion using a pump



Patient inserting needle in the fat under the skin in order to give a SCIg infusion

Documenting the SCIg infusion

The details of each infusion session must be recorded in a SCIg Infusion diary. Your nurse specialist or doctor will give you a SCIg infusion diary and will explain the information you will need to record. Completed diaries must be available for review by your nurse specialist or doctor at each outpatient clinic visit.

Ordering, collection, transport and storage of SCIg

- Make sure you order SCIg product in advance (follow your SCIg treatment plan).
- Your nurse specialist or doctor will explain how and where to collect the SCIg product and this should be included in your SCIg treatment plan.
- SCIg must be kept cool (2-8°C) for the journey home:
 ✓ When collecting SCIg you must provide a cool box or cool bag large enough to transport vials with an icepack. Ensure SCIg vials are not in direct contact with the ice, to avoid possible freezing.
 - \checkmark Take SCIg home immediately and place in a sealed container in the central part of the refrigerator.
 - ✓ Store SCIg so that it is protected from light and extreme temperatures (above 25°C or below 2°C).
 - ✓ Always keep SCIg vials in their individual boxes and protect from light.

- **Do not** freeze and do not use SCIg that has been frozen.
- **Do not** store SCIg in the door or bottom storage unit of the refrigerator
- *> Do not* store SCIg near cold outlet from freezer to refrigerator (combination freezer-refrigerator)
- *** Do not** shake SCIg

If you have a power or refrigerator failure and are unable to keep SCIg refrigerated:

- Contact your nurse specialist as soon as practical for further advice.
- If fridge is still cold, keep your supply in the fridge.
- If the fridge is no longer cold, place SCIg in your transport cool box or cool bag with an ice pack.

Product from a vial is for single use only:

- Once opened, SCIg must be used within 4 hours.
- Any unused portion should be discarded. As SCIg is a blood product, all used vials should be disposed of in the sharps container provided by your hospital. Do not discard SCIg in your household bin.

SCIg Product - Hizentra®

- Once removed from the refrigerator Hizentra® must be stored between 2°C and 25°C and used up until the expiry date.
- Hizentra® is a clear and pale yellow to light brown solution. Do not use if the solution is cloudy or contains particles.

SCIg Product - Evogam®

- Once removed from refrigerator, Evogam® must be stored below 25°C and used within two weeks.
- Evogam is clear, pale-yellow or light brown. Do not use if the solution is cloudy or contains particles.

Checking SCIg vials before an infusion

All SCIg vials should be checked for the following prior to an infusion:

- Expiry date on the vial DO NOT USE if out of date
- Protective cap is in place **DO NOT USE** if seal is broken
- Solution in vial is clear DO NOT USE if solution is cloudy, discoloured or contains particles

Contact your nurse specialist if any of the above happens.

Travelling with SCIg

Travelling with SCIg requires planning well beforehand. A dose of Intravenous Immunoglobulin G (IVIg) before you travel may be a convenient alternative option. For shorter periods of travel, you may give the SCIg doses due as extra SCIg infusions before and after the trip. Speak to your doctor or nurse specialist for advice well before travelling, especially overseas.

When planning a trip:

- Contact your nurse specialist as you may require an export permit if going overseas. For information go to <u>www.blood.gov.au/supply-australians-overseas</u>
- When flying, take SCIg with you on the plane in carry-on luggage. It must not be put into checked-in luggage. For longer flights, ask cabin crew if it can be stored in the refrigerator for the duration of the flight. Don't forget to collect it before you leave the plane.
- Get a letter from your doctor and take this and your treatment plan with you.
- Pack pain medication and a non-drowsy antihistamine in case of adverse reactions.
- Pack enough consumable equipment for the trip.
- Pack enough SCIg for the trip and store this in a cool box or cooler bag in its original box.

If unwell, pregnant or breastfeeding

Contact your doctor or nurse specialist for further advice if:

- If you are unwell with a fever
- If you suspect you are pregnant, or if you are breast feeding.

Your doctor and nurse specialist will work with you to develop a plan for who, how and under what circumstances you will need to contact someone if you or your child have an adverse reaction.

SCIg and vaccinations

Some immunisations may not be required while on SCIg. Discuss this with your doctor.

Managing side effects of SCIg

Common reactions at the injection site include swelling (egg sized lump), "hardness", blanching and redness at the infusion site. These local reactions are normal and short lived (usually gone by the next day). They are more common in people who have just started SCIg, especially in the first few months.

Using the same site for SCIg infusions can help to reduce the amount of local swelling and redness that can occur after an infusion. Over time, the skin will "get used" to the repeated infusions, and local reactions will lessen. Most people start to notice a decrease in local reactions after about 8-10 weeks.

If an injection site reaction occurs:

- Do not rub or scratch the site. Apply gentle massage and warm or cold pack (according to your personal preference) to reduce discomfort. Report unusual site reactions, such as extreme pain or discomfort, blistering or spreading redness to your nurse specialist.
- Record site reactions in the infusion diary.
- Refer to table on the next page for different ways to manage reactions/problems at the infusion site.

Mild infusion site reaction:



Moderate infusion site reaction:



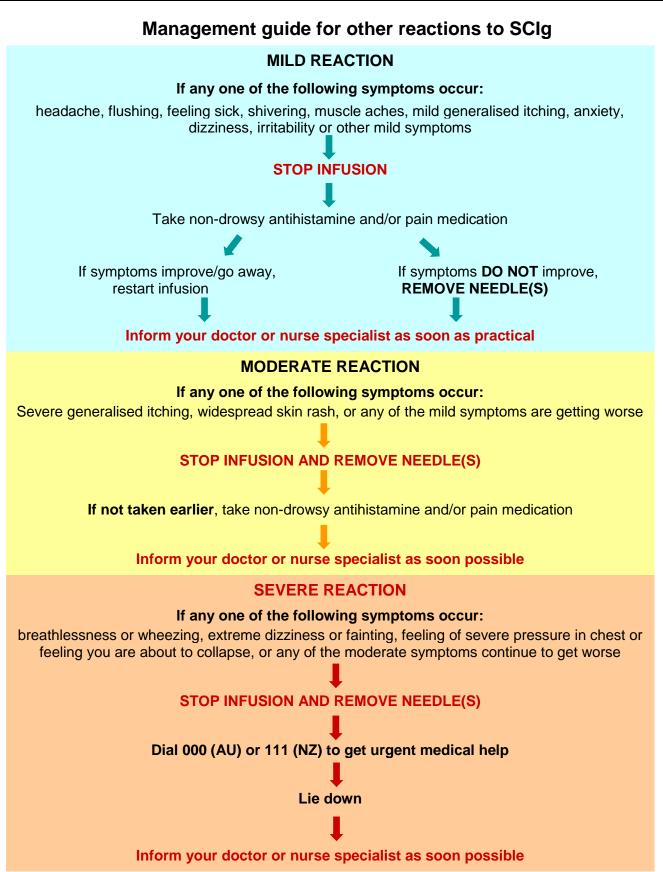
Picture courtesy of Wasserman RL. Patient Prefer Adherence. 2008; 2: 163–166

Attachments:

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Management guide for SCIg infusion site reactions and problems

Site Issue	Possible Cause/s	Management Options
Redness	 Common reaction, which usually settles over 24 hours. If redness is excessive: In some cases it may be due to an allergy or sensitivity to tape. Needle may not have been inserted correctly, or may be too short. 	 If it does not cause discomfort, do nothing. Warm or cold pack for short periods may help with discomfort (wrap cold packs in a cloth, do not apply directly to the skin) Slow the infusion rate if uncomfortable Try using an over the counter non-drowsy antihistamine Check correct needle placement/length with your nurse specialist Consider alternative tapes/dressings to secure needle/s with your nurse specialist
Swelling	 Common reaction, which usually settles over 24 hours. Results from the amount of fluid being infused underneath the skin (amount of swelling should relate to the volume being infused). 	 If it does not cause discomfort, do nothing A warm pack for short periods may help with absorption. A cold pack for short periods may help with discomfort but delays absorption (wrap cold packs in a cloth, do not place directly on skin) Take a walk to help with absorption Check correct needle placement/length with your nurse specialist May need to decrease volume at the site, reduce the rate or change the infusion site. This should be discussed with your nurse specialist
Itching or burning	 Incorrect needle placement Incorrect needle length Irritation from tape Ig at needle tip, causing skin irritation 	 Do not scratch or rub Check needle placement and length Try using an over the counter non-drowsy antihistamine Consider alternative tapes/dressings to secure needle/s Apply cold pack for short periods (wrap cold packs in a cloth, do not place directly on skin) Discuss dry priming with your nurse specialist
Pain with infusions	 Incorrect needle placement Incorrect needle length Infusion going too fast 	 Check needle placement/length Apply cold pack for short periods (do not apply directly to skin) Slow infusion rate Try simple pain medication (such as paracetamol) before starting the infusion Take a walk to provide a distraction Check tape placement for pulling on skin or body hair Discuss with your nurse specialist
Blanching (whiteness)	Normal tightening of tissue that can occur as SCIg infuses into the fatty tissue under the skin.	 Do nothing, usually goes away on its own when the fluid is absorbed Warm pack for short periods (may assist absorption).
Leaking from the infusion site	 Incorrect needle insertion Incorrect needle length Amount of volume infused at the site 	 Check needle insertion May need to consider changes to volume, needle length or rate of infusion. Speak to your nurse specialist or doctor.



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