

Information FOR PATIENTS, CONSUMERS AND CARERS



Subcutaneous Immunoglobulin (SCIg) Therapy General Information

Updated September 2022

Immunoglobulins (commonly known as antibodies) are used to treat adults and children with primary immune deficiencies (PID), also known as inborn errors of immunity, 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.

What is SCIg?

Subcutaneous Immunoglobulin (SCIg) infusions are given by slowly injecting purified immunoglobulin into fatty tissue just underneath the skin. SCIg:

- Requires frequent administration (ranging from 1-3 times per week to once a fortnight) by patients or carers at home.
- Involves slow diffusion of IgG from subcutaneous tissue.
- Is associated with more consistent serum IgG levels due to frequent administration.
- Is administered at multiple injection sites according to personal preference, usually in the lower abdomen. However, the outer edge of the thigh or back of the upper arm can also be used.

How are SCIg infusions given?

SCIg can be given at home using:

- Mechanical infusion pumps spring loaded or battery powered.
- Push method a manual method that does not require a pump, with the infusion pushed by hand through a syringe.

Immunoglobulin products are safe

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.

Manufacturers also include steps in the processing of blood or plasma that inactivate or remove viruses.

This means that there is an extremely low (almost zero) chance of the transmission of blood borne viruses (such as Hepatitis B, Hepatitis C, HIV and Variant Creutzfeldt-Jakob disease (also called "mad cow disease") via SCIg.

What are the risks associated with SCIg?

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.
 - Most itching is resolved by slowing the infusion.

- 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 6 and 7 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. Nurses play a crucial role in educating and supporting people who are being treated with immunoglobulin products.

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.

An ASCIA Transfer Care Plan for patients is available at www.allergy.org.au/hp/papers/ascia-transfer-care-plan-irt

This plan has been developed as a medical document to be completed by an immunology or nurse specialist, when a patient is transitioning from:

- Paediatric to adult medical care.
- · One region to another.
- IVIg to SCIg.
- SCIg to IVIg.

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.

However, multiple (2-3) sites can be used on a rotating basis, according to patient preference.

Rotating the infusion site is preferable for some patients and this may reduce the risk of scar tissue developing.

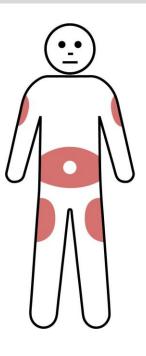
SCIg injection sites are usually in the lower abdomen, but the outer edge of the thigh, buttocks or back of the upper arm can also be used. Avoid bony areas such as the hips.

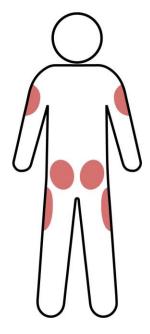
When using the lower abdomen in adults and most children, the needle should be inserted at least 5cm away from the belly button.

If using more than one site at a time, make sure they are at least 5cm apart.

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







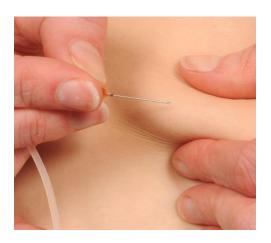
Before infusion it is important to have your equipment ready – see the ASCIA Subcutaneous Immunoglobulin (SCIg) Equipment Checklist www.allergy.org.au/patients/immunodeficiencies/scig-therapy-equipment-checklist

An ASCIA Subcutaneous Immunoglobulin (SCIg) Infusion Checklist is also available at www.allergy.org.au/patients/immunodeficiencies/scig-infusion-checklist

It is recommended to have a cold pack, a non-drowsy antihistamine and an analgesic (pain medication) available in case of a mild reaction.

Examples of SCIg infusions are shown below.





Documenting the SCIg infusion

Patients should record the following details in a SCIg infusion diary, which can be shown to the nurse or medical specialist:

- Brand of SCIg product.
- Batch number/sticker.
- Date and time of infusion.
- Time taken for infusion.
- Dose.
- Reactions to infusion.
- Problems with product (e.g. visible particles not used and returned).
- Unused or wasted product (e.g. spilled/damaged or infusion stopped due to adverse reaction).

Ordering, collection, transport and storage of SCIg

- Use the ASCIA SCIg Treatment Plan, which is available on the ASCIA website www.allergy.org.au/hp/papers/ascia-scig-treatment-plan
- SCIg product needs to be ordered in advance.
- 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.
 - Take SCIg home immediately and place in a sealed container in the central part of the refrigerator.

- Storage temperatures are dependent on product choice (refer to information about each product below).
 Your nurse or medical specialist will advise you how to store the specific SCIg product you are using.
 However, the following principles should be followed for all SCIg products:
 - ✓ Store SCIg in original packaging until needed, and protected from light.
 - ✓ Store SCIg between 2°C and 25°C and avoid extreme temperatures.
 - **Do not** freeze SClg never store below 2°C and do not use SClg that has been frozen.
 - ✗ Do not shake SCIq.

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 the vial is opened, SCIg needs to be used as soon as possible as the product does not contain preservative.
- If an infusion cannot be completed within the recommended time (which varies between 2 and 4 hours for different products), any unused product should be discarded.

ascia www.allergy.org.au	TREATMEN Subcutan Immunog			
Patient Name:				
Plan prepared by:				
Date:				
Note: This plan has been developed a	s a medical document to	completed by an immunology or nurse specialist		
IMMUNOLOGY AND NU	RSE SPECIALIS	T DETAILS		
Immunology Specialist:				
Nurse Specialist:				
Telephone:				
Email:				
After hours contact name:				
Telephone:				
SCIG PRODUCT DETAILS				
Brand:				
Dose:				
1 grams	mls	times/week		
2grams	mls	times/week		
To order SCIg:				
Telephone:				
Email:				
To collect SCIg:				
Telephone:				
EQUIPMENT				
For ordering of consumable equipment supplies (e.g. syringes, needles):				
Telephone:				
Email:				
For servicing of pump (if applicable):				
Telephone:				
Important:				
Allow 7 days when ringing to order SCIg and allow days for ordering consumable equipment supplies				
ASCIA 2017 ASCIA is the peak professional body of clinical immunology and a Disclaimer This document has been adapted with permission from resource reviewed by ASCIA members and is based on exsert opinion and	s developed by Princess Margaret Hospital Im	d dissurancing Department (Department of Health, Western Australia). It has been peer for freine. Information contained in this document is not intended to resize medical		

• All SCIg vials must be disposed of in the sharps container provided by your hospital. These should be returned to the hospital or pharmacy. SCIg vials must not be discarded in your household bin.

SCIg Products

There are currently three different brands of SCIg available in Australia and New Zealand:

- Hizentra® CSL Behring
- Evogam® CSL Behring
- Cuvitru® Takeda

SCIg Product - Hizentra®

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



Normal Immunoglobulin (Human) 20% (20 g/100 mL) - Subcutaneous injection

- Complete Hizentra® infusions within 4 hours of starting infusion.
- For instructions go to https://www.nps.org.au/medicine-finder/hizentra-vial

SCIg Product - Evogam®

- Once removed from the refrigerator, store Evogam® between 2°C and 25°C and use within two weeks.
- Evogam® is a clear, pale-yellow to light brown solution.
- Do not use if the solution is cloudy or contains particles.
- Complete Evogam® infusions within 4 hours of starting the infusion.





Human Normal Immunoglobulin 16% (16 g/100 mL) - Subcutaneous

SCIg Product - Cuvitru®

- Store between 2°C and 8°C, this is a change from below 25°C.
- The shelf life is now 36 months, this is an increase from 24 months.
- Cuvitru® is a clear and colourless to a pale yellow or light brown solution.
- Do not use if the solution is cloudy or contains particles.
- Complete Cuvitru® infusions within 2 hours of starting the infusion.
- For instructions go to https://www.nps.org.au/medicine-finder/cuvitru

Note: The National Blood Authority (NBA) advises that Cuvitru is transitioning to a revised temperature and storage requirement from 12 September 2022 in accordance with product registration changes on the Australian Register of Therapeutic Goods. Future Cuvitru stock will be labelled to specify the revised shelf life and temperature storage requirements.

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.

Use of SCIg when unwell, pregnant or breastfeeding

Contact your doctor or nurse specialist for further advice if you:

- Are unwell with a fever.
- Suspect you are pregnant.
- Are breast feeding.

Your doctor and nurse specialist will work with you to develop a plan to respond to any adverse reaction.



SCIg and vaccinations

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

Travelling with SCIg

People travelling with SCIg should:

- Plan well in advance before travelling.
- Obtain advice from their doctor or nurse specialist before travelling, especially overseas, as an export permit may be required.
- Use the ASCIA SCIg Travel Plan, completed by their nurse or medical specialist Travel Plans are available on the ASCIA website www.allergy.org.au/hp/papers/asciatravel-plan-for-scig-patients
- Take their SClg Travel Plan and Treatment Plan in hand luggage.
- Consider having a dose of Intravenous Immunoglobulin G (IVIg) before travel, which may be a convenient alternative.
- Consider having extra SCIg infusions before and after the trip, for shorter periods of travel.
- Pack SCIg in hand luggage when flying, whilst maintaining the cold chain and remembering to collect it before they leave the plane. SCIg must not be put into checked-in luggage.
- Carry pain medication and a nondrowsy antihistamine in case of adverse reactions.
- Take enough consumable equipment for the time they are away from home.



Patient name (as shown in passport):		
Date of birth:	Passport number:	
Home address:		
Departure date and airline:		
Destination/s and reason for travel:		
Contact details whilst travelling:		
SCIg brand name:	Quantity carried:	
Clinical indication:		
Plan prepared by:	Signed:	
Hospital/clinic:		
Overseas medical contact (if applicable):		
Date:		
☐ This patient is travelling and needs to carry their It must not be placed in checked-in luggage.	r SCIg product with them on the plane in carry-on luggage.	
This therapy is required weekly for the patient's medical condition, and is a registered product in Australia, New Zealand and many other countries. It is for their personal use and represents no risk to others.		
☐ The patient has contacted the airline before the	e flight to notify them that they are carrying SCIg therapy.	
STORAGE REQUIREMENTS		
SCIg must be carried in its original box/es with leakproof packaging, inside a cool box or cooler bag.		
SCIg must be protected from light and never stored below 2°C or above 25°C.		
SCIg vials must not be in direct contact with ice, to avoid possible freezing.		
SCIg must be in carry-on luggage, not in checked-in luggage.		
ATTACHMENTS		
ASCIA SCIg treatment plan		
Copy of passport front page		
Copy of e-ticket/s		
Copy of export license (required by Australian patients travelling overseas)		
© ASCIA 2019 ASCIA is the peak professional body of clinical immunology/allergy specialists in Australia and New Zealand This plan has been developed as a medical document to be completed by an immunology or nurse specialist		

Pack enough SCIg for the trip and store this in original packaging until needed, in a cool box or cooler bag.
 It is important to keep SCIg at an appropriate temperature as specified for the product, at all times. Patients should check product information, and if uncertain, check with their nurse specialist. SCIg should never be stored below 2°C or above 25°C.

Managing side effects of SCIg

Common local reactions at the infusion site include:

- Mild or moderate swelling (egg sized lump).
- Hardness.
- Blanching (whiteness).
- Redness at the infusion site.

These 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.

Most people start to notice a decrease in local reactions after about 8-10 weeks.

Over time, the skin will "get used" to the repeated infusions, and local reactions will lessen.

Images courtesy of Wasserman, R. L. (2008) *Patient Prefer Adherence*. 2,163–166.





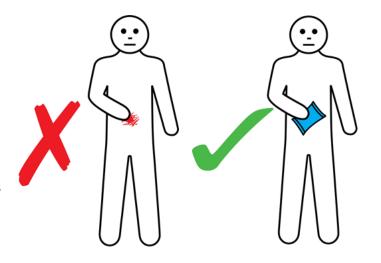
Using the same SCIg infusion site versus rotating sites

Using the same site for SCIg infusions can help to reduce the amount of local swelling and redness that can occur after an infusion. However, rotating the infusion site is preferable for some patients, and may reduce the risk of scar tissue developing.

General steps to take if an infusion site reaction occurs

If an infusion site reaction occurs, you should:

- Apply gentle massage and warm or cold pack (according to your personal preference) to reduce discomfort. An ice pack should not be applied for four hours post infusion to ensure adequate absorption.
- Not rub or scratch the infusion site.
- Record site reactions in an infusion diary.
- Report unusual site reactions, such as extreme pain or discomfort, blistering or spreading redness to your nurse specialist.
- Refer to the table below for different ways to manage reactions or problems at the infusion site.



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 needle may be too short.	 If it does not cause discomfort, do nothing. Warm or cold pack for short periods may help with discomfort. Wrap warm/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. Swelling usually 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 warm/cold packs in a cloth - do not apply directly to the 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 pack in a cloth - do not apply directly to the 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 - wrap pack in a cloth - do not apply directly to the 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) - wrap pack in a cloth - do not apply directly to the skin.
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.

Management guide for other reactions to SCIg

MILD REACTION

If any one of the following symptoms occur:

Headache, flushing, feeling sick, shivering, muscle aches, mild generalised itching, anxiety, dizziness, irritability or other mild symptoms

STOP INFUSION

Take non-drowsy antihistamine and/or pain medication

If symptoms improve or go away, restart infusion

If symptoms **DO NOT** improve, **REMOVE NEEDLE(S)**

Inform your doctor or nurse specialist as soon as practical

MODERATE REACTION

If any one of the following symptoms occur:

Severe generalised itching, widespread skin rash, or any of the mild symptoms are getting worse

STOP INFUSION AND REMOVE NEEDLE(S)

If not taken earlier, take non-drowsy antihistamine and/or pain medication

Inform your doctor or nurse specialist as soon possible

SEVERE REACTION

If any one of the following symptoms occur:

Breathlessness or wheezing, extreme dizziness or fainting, feeling of severe pressure in chest or feeling you are about to collapse, or any of the moderate symptoms continue to get worse

STOP INFUSION AND REMOVE NEEDLE(S)

Dial 000 (AU) or 111 (NZ) to get urgent medical help

Lie down

Inform your doctor or nurse specialist as soon possible

© ASCIA 2022

ASCIA is the peak professional body of clinical immunology and allergy specialists in Australia and New Zealand

Disclaimer

This document has been adapted with permission from resources developed by Perth Children's Hospital Immunology Department (Department of Health, Western Australia), formerly Princess Margaret Hospital. The content has been peer reviewed by ASCIA members and is based on expert opinion and the available published literature at the time of review. Information contained in this document is not intended to replace medical advice and any questions regarding a medical diagnosis or treatment should be directed to a medical practitioner. Development of this document is not influenced by commercial organisations.

Content updated August 2022