Subcutaneous immunoglobulin (SCIg) ‘Getting started’

September 2025

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Australian Red Cross Lifeblood

Blood Matters

Acknowledgement of Country

We acknowledge and pay our respects to the past, present and future Traditional Custodians and Elders of this land and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

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What is subcutaneous immunoglobulin (SCIg)?

Immunoglobulins (also known as antibodies), are glycoprotein molecules produced by plasma cells (white blood cells). They act as a critical part of the immune response by specifically recognising and binding to particular antigens, such as bacteria or viruses, and aiding in their destruction.

- Normal IgG level 7 – 12 g/L (this may vary slightly between laboratories)

- SCIg is a fractionated blood product containing a concentrated mix of antibodies, made from pooled human plasma
- The main immunoglobulin in SCIg is IgG (approx. 98%)
- SCIg has been available in Australia since 2013 and used for immune replacement therapy and immune-mediated conditions
- Alternative treatment to IVIg for eligible patients administered subcutaneously at home post education and training

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Approved indications for SCIg in Australia

SCIg is available under the national blood arrangements for 5 specific medical conditions

- inborn errors of immunity (IEI) with antibody deficiency
- specific antibody deficiency
- acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation
- secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation
- chronic inflammatory demyelinating polyneuropathy (CIDP)

Comparison table between SCIg and IVIg

Issue	SCIg	IVIg
Who can have it?	Meet SCIg criteria	Meet IVIg criteria
Where?	Patient's home – self or carer administered	Hospital – health professional administered
Route	Subcutaneous; abdomen, thigh, upper arm	Intravenous
Lifestyle	Can be administered at a convenient time Allows flexibility and independence Fewer hospital visits	Required to attend hospital Arranged by hospital staff
Education	Required to enable self administration; how to draw up product, insert subcutaneous needle, use pump, document event Report any reactions	Report any reactions
Duration of infusion	Approx. 1 hour per infusion – varies depending on dose, number of sites and product	2 – 5 hours per infusion
Frequency	Daily, weekly, fortnightly – varies depending on dose	1 per month (4 weeks)/as prescribed
Health effect	Consistent, steady Ig levels, no wear off effect	Peaks and troughs, wear off effect can start up to 1 week prior to next infusion
Side effects	Local side effects; site swelling, redness and itching at the injection site(s), Can last 1 – 2 days Lower risk of systemic side effects	Systemic side effects; during and post infusion Headache, nausea, flushing shivers, itch and fatigue Can last up to 3 days post infusion
Travel	Can administer SCIg while travelling	Can be difficult to arrange treatment especially overseas

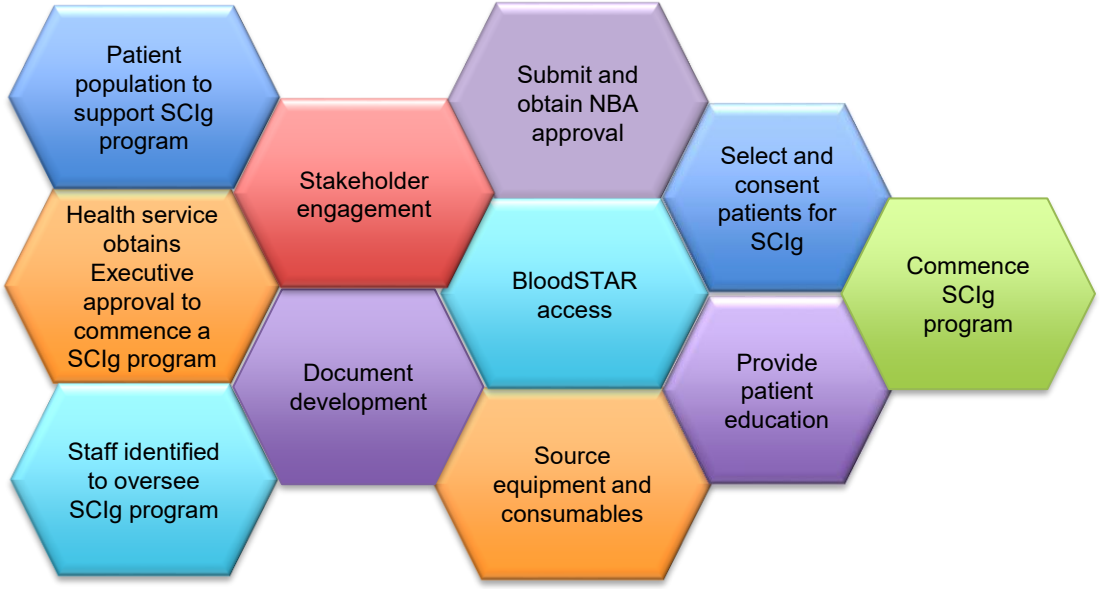
Subcutaneous Immunoglobulin (SCIg) - Australasian Society of Clinical Immunology and Allergy (ASCIA)
https://www.allergy.org.au/hp/papers/scig

Australasian Society of Clinical Immunology and Allergy (ASCIA) SCIg Position Statement

- SCIg treatment for immunodeficiency is efficacious, well tolerated, has a favourable safety profile and should be available to all patients where clinically appropriate, with relevant education and follow up care.
- Studies have demonstrated:
  - Immune Replacement Therapy using SCIg has equivalent efficacy to IVIg in preventing bacterial infections in patients with antibody deficiencies.
  - Results suggest that maintaining higher steady state IgG levels results in fewer infections.
  - Incidence of infection is inversely related to the steady state IgG level and maintaining higher IgG levels are beneficial, although no given level is necessarily adequate for all patients.
  - Studies indicate that SCIg infusions result in more stable serum immunoglobulin concentrations with little fluctuation in IgG levels compared to the peaks and troughs of IgG levels associated with monthly IVIg administration.
  - More stable IgG levels reduce the risk of immediate and systemic adverse effects due to high IgG levels post-infusion and symptoms related to wearing off effects of IgG trough levels.
- SCIg therapy has been shown to be well tolerated with a low risk of systemic side effects.
- Whilst local tissue reactions are frequent with SCIg therapy, they are often mild and tend to improve over time. Provision of adrenaline autoinjectors is not considered to be necessary, given the demonstrated safety of SCIg infusions.

Based on Recommendation 5 ASCIA Position statement - subcutaneous immunoglobulin (SCIg)
Subcutaneous Immunoglobulin (SCIg) - Australasian Society of Clinical Immunology and Allergy (ASCIA)
https://www.allergy.org.au/hp/papers/scig

Putting the SCIg pieces together



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Patient eligibility/criteria

- Patients must meet approved clinical indication as set out in the Criteria for the use of immunoglobulin products
- The patient must be treated by a clinical specialist within a hospital based SCIg program, where the hospital provides access to all resources and takes full accountability for the management and use of the SCIg product, at no additional cost to patients
- Patient-specific SCIg request must be submitted to, and authorised by, the Australian Red Cross Lifeblood (Lifeblood) via BloodSTAR.

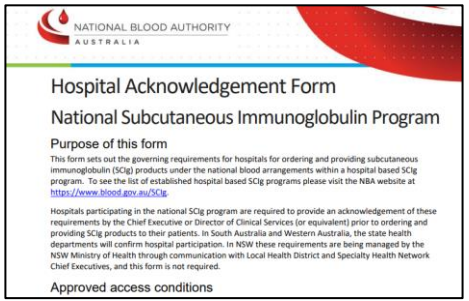
Health service eligibility criteria

The hospital must be approved by the NBA to commence a hospital based SCIg program

The NBA - Hospital Acknowledgement Form National Subcutaneous Immunoglobulin Program must be completed and includes governance requirements for the program.

SCIg-hospital-acknowledgment-form-2021_2.docx
<https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.blood.gov.au%2Fsites%2Fdefault%2Ffiles%2Fdocuments%2F2025-01%2FSCIg-hospital-acknowledgment-form-2021_2.docx&wdOrigin=BROWSELINK>

Completed form must be returned to the to the National Blood Authority
Email: iggovernance@blood.gov.au
Fax: (02) 6151 5235 (Attention: Ig Governance)


NATIONAL BLOOD AUTHORITY
AUSTRALIA

Hospital Acknowledgement Form

National Subcutaneous Immunoglobulin Program

Purpose of this form

This form sets out the governing requirements for hospitals for ordering and providing subcutaneous immunoglobulin (SCIg) products under the national blood arrangements within a hospital based SCIg program. To see the list of established hospital based SCIg programs please visit the NBA website at https://www.blood.gov.au/SCIg.

Hospitals participating in the national SCIg program are required to provide an acknowledgement of these requirements by the Chief Executive or Director of Clinical Services (or equivalent) prior to ordering and providing SCIg products to their patients. In South Australia and Western Australia, the state health departments will confirm hospital participation. In NSW these requirements are being managed by the NSW Ministry of Health through communication with Local Health District and Specialty Health Network Chief Executives, and this form is not required.

Approved access conditions

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Governance – quality assurance & clinical oversight

Quality assurance

- Policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the National Safety and Quality Health Service (NSQHS) Standards.
  - Who will write the policies/procedures?
  - Who will monitor compliance?

Clinical oversight

- A recognised treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist
- Must provide ongoing clinical oversight and support for participating patients
- The responsible clinician must consider patient suitability for the self-management and administration of SCIg to ensure appropriate management and use of SCIg product.

Governance – equipment, facilities, education & training

Equipment and facilities

- Must ensure that patients have access to all necessary equipment and consumables to administer the product, **at no additional cost to patients**
  - What equipment will be used?
  - Where will the patient education take place?
  - Where will the patient get the necessary consumables from?
  - Who will ensure the patient has everything they need?

Education and training

- Must provide education and training for staff and patients to ensure appropriate management and use of SCIg, including transport, storage, use of equipment and infusion techniques
  - Who will provide the staff education?
  - Who will be responsible for patient education?

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Governance – review and product supply

Regular review

- Assessing clinical benefit of treatment for ongoing therapy should be conducted at periods specified by the responsible clinician in line with the Criteria
- Patients should be encouraged to maintain a diary to record SCIg product use and any adverse reactions, as well as collection and management of product as an aid for the clinician at the assessment

Supply of product

- Orders for SCIg for authorised patients must be managed via BloodSTAR
- The amount of SCIg supplied to a patient should not exceed more than is required for treatment for two months
- Supply and dispensing of SCIg product to patients must be in accordance with relevant state/territory legal requirements

SCIg is an S4 medication and must be dispensed by a pharmacist
Requires a medication prescription; must provide a copy to the pharmacy

Governance – reporting unused, discarded, spoilt/broken product

Reporting unused, discarded, spoilt/broken product

- *Patients supplied with SCIg will be expected to report details of unused, discarded or spoilt/broken product to the hospital, to be reported by the hospital through BloodNet*
    - Who will the patient report this to?
    - How will the patient report this?

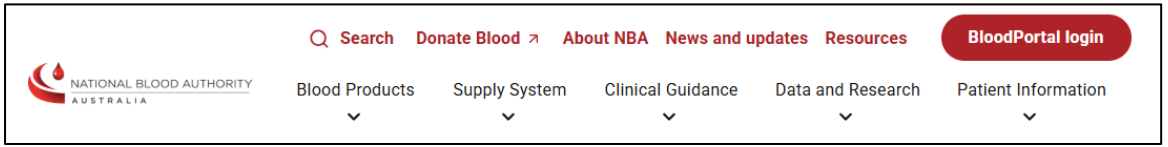
Other considerations

- Cost benefit analysis – business case to support the decision (template available on Blood Matters SCIg program, tools and resources webpage)
  Subcutaneous immunoglobulin (SCIg) program: tools and resources | health.vic.gov.au
  <https://www.health.vic.gov.au/patient-care/subcutaneous-immunoglobulin-scig-program-tools-and-resources>
- Clinical engagement – medical, nursing and pharmacy staff
- Space – is there a suitable ward/location for patient education?
- BloodSTAR and BloodNet registration and education
- Prescription required by pharmacy to dispense product

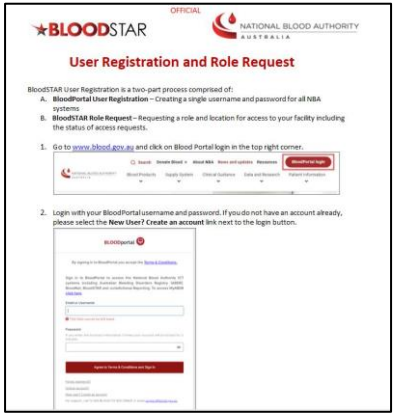
BloodSTAR

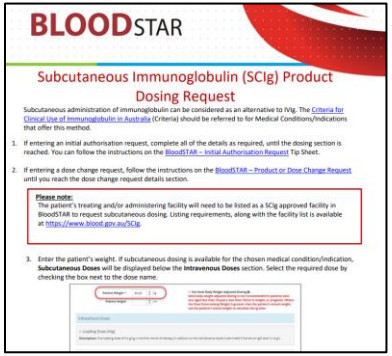
Two-part process

- BloodPortal user registration
  - ➢ create username and password for all NBA systems
- BloodSTAR role request
  - ➢ request a role and location for access to your facility



Home | National Blood Authority <https://www.blood.gov.au/>





BloodSTAR user tips and support materials

BloodSTAR user tips and support materials | National Blood Authority

<https://www.blood.gov.au/bloodstar-user-tips-and-support-materials>

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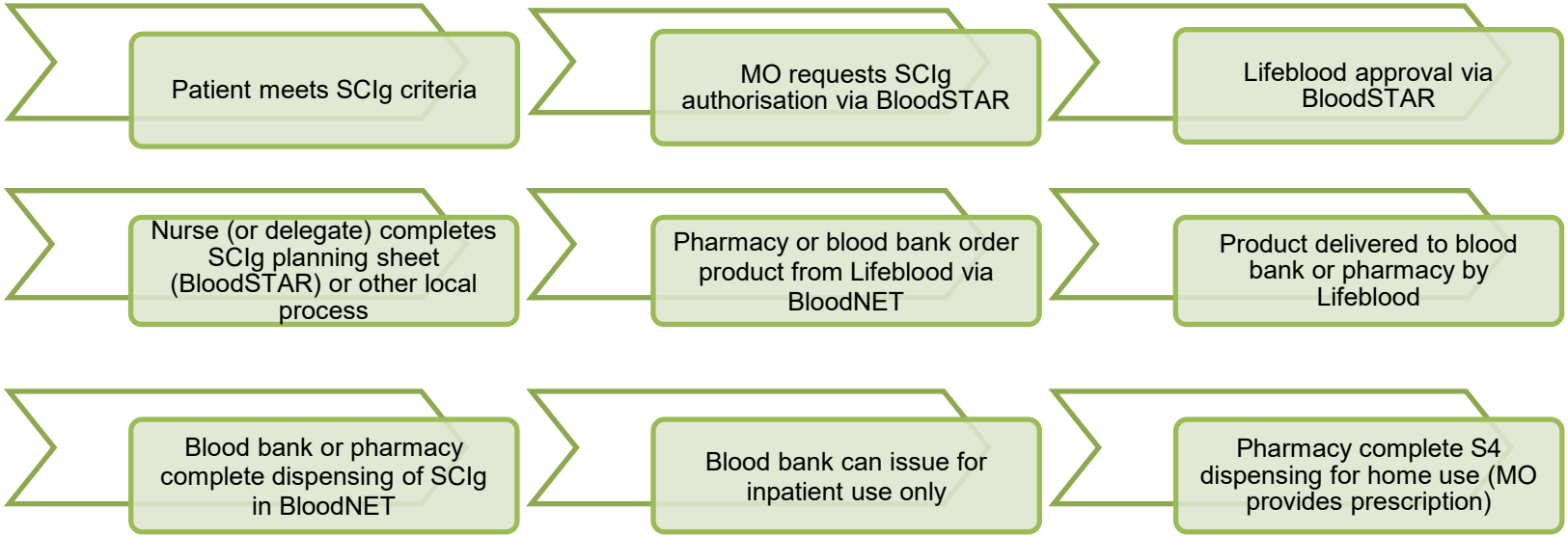
Ordering SCIg flow



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Products, storage, & vials

	Hizentra® AU*	Hizentra®*	Cuvitru®*	Xembify®*
Plasma source	Local	Imported	Imported	Imported
Stabilizer	Proline	Proline	Glycine	Glycine
Concentration	20%	20%	20%	20%
Storage	<25°C (do not freeze, store in outer carton to protect from light, should be room temperature prior to administration)	<25°C (do not freeze, store in outer carton to protect from light, should be room temperature prior to administration)	2 – 8°C (do not freeze, store in outer carton to protect from light, allow to reach room temperature prior to administration)	2 – 8°C (do not freeze, store in outer carton to protect from light, allow to reach room temperature prior to administration) May be stored ≤25°C for up to 6 months any time prior to expiry date
Vial sizes	1g (5mL), 4g (20mL)	1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL)	1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL)	1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL)

- * Refer to Product information for further information

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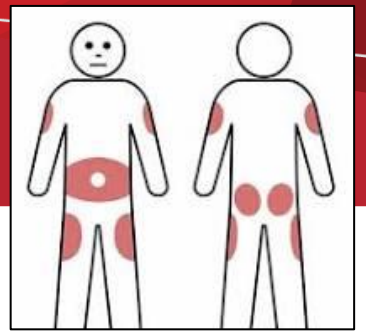
SCIg infusion sites



Administer in the subcutaneous tissue only

Abdomen - (at least 5cm from the umbilicus), thigh, upper arm, lateral hip

If using multiple sites, ensure they are at least 5cm apart

Do not insert the needle where the skin is scarred, bruised, broken or inflamed

Same sites V's rotating sites

Hizentra AU®*	Hizentra®*	Cuvitru®*	Xembify®*
Doses >50mL it is advisable to administer the dose at multiple sites.	Doses >50mL it is advisable to administer the dose at multiple sites.	In adults, doses >30mL may be divided according to patient preference. Paeds 5-15mL/site.	In adults, doses >30mL may be divided according to patient preference. Paeds 5-15mL/site.

- * Refer to Product information for further information

Equipment: pumps & consumables

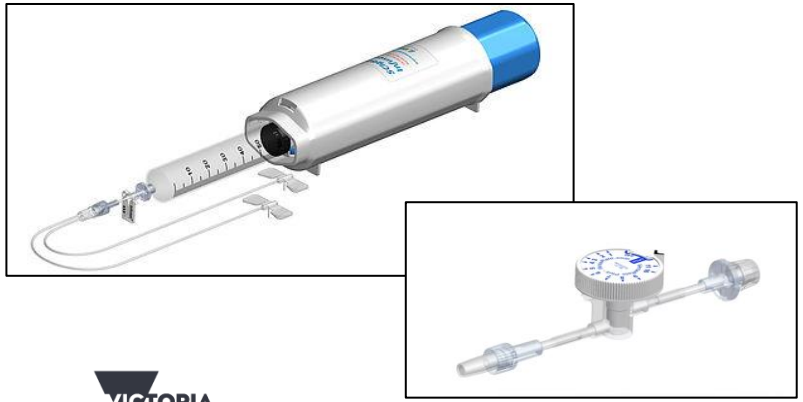
- Cooler bag/esky for transport (ice brick)
- Infusion pump
- Subcutaneous infusion set
- Sharps container
- Antibacterial wipes or soapy water (to clean a work surface or infusion mat)
- Alcohol swabs
- Luer lock syringe(s)
- Drawing up needle(s)/vented dispensing pin
- Adhesive dressing
- Small band aid/gauze/cotton ball
- Infusion diary/Infusion App

Pumps

Emed - SCIg 60 infusion system

Explore Our Infusion Products | EMED Technologies
<https://www.emedtc.com/explore-our-infusion-products>

- Spring driven
- 50/60mL BD syringe
- Rate controller



Springfuser ® syringe infusion pump - 10,30 or 50

Go Medical Industries Pty Ltd - Springfusor & FCT
<https://www.gomedical.com.au/products/infusion/springfusor-fct>

- Spring driven
- 10ml, 30ml or 50ml Syringe (syringe size varies with pump size)
- Flow rate control tubing and syringe (purchased separately)
- Can be used with any needle system

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Subcutaneous infusion sets

Item	EMED SAF-Q	EMED OPTFlow	Neria
Needle gauge	24G & 27G	26G	27G
Needle length	4mm, 6mm, 9mm, 12mm	4mm, 6mm 9mm,12mm,14mm	Steel: 8mm, 10mm, Soft: 9mm
Tubing	36 inch / 91cm	36 inch / 91cm	Single lumen: 80cm Multiple lumens: 90cm Soft cannula: 110cm
Needle sets	1, 2, 3, 4 lumens	1, 2, 3, 4, 5, & 6 lumens	Steel: 1, 2, 4 lumens Soft cannula: single lumen
Wings	Y	Y	Y
Adhesive dressing	Dressing included	Dressing included	Integrated dressing

Patient selection

- Meet SCIg criteria
- Willingness to self-infuse or for carer to infuse
- Patient or carer with the dexterity and ability to administer SCIg
- Ability to store product at required temperature
- Patients with difficult IV access
- Patients who have significant or frequent reactions to IVIg
- Patients who travel a long way to get treatment
- Patients who are time poor for any reason and find it difficult to attend for IVIg
- Patients who may be more compliant with SCIg than IVIg – assess reason for non-compliance
- Patients who do not have severe thrombocytopenia

Contraindications to SCIg*

- Anaphylactic or severe systemic reactions to immunoglobulin (Ig)
- Extensive skin conditions- psoriasis, eczema
- Cognitive impairment
- Poor manual dexterity, decreased hand grip, tremors, poor eyesight
- IgA deficiency – discuss with immunologist
- Severe thrombocytopenia
- Hizentra® AU - patients with known hyperprolinemia (type I or II)
- Hizentra® - patients with known hyperprolinemia (type I or II)
- Cuvitru® - patients with known reactions to glycine and patients with IgA deficiency
- Xembify® - patients with known reactions to glycine and patients with IgA deficiency

* Refer to product information

Patient education

- Clean work area
- Hand washing & aseptic technique
- Pump & consumables
- Injection site selection & care
- Checking of product
- Drawing up product
- Priming infusion set – dry prime
- Skin preparation & needle insertion technique
- Needle placement check
- Infusion rate, commencement & completion
- Documentation – diary/App
- Adverse reaction management
- Ordering & collection of product & consumables
- Transport & storage of product
- Reporting waste
- Manual push method (pump failure)

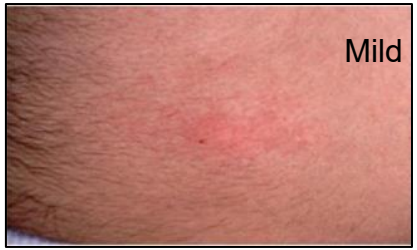
Documentation

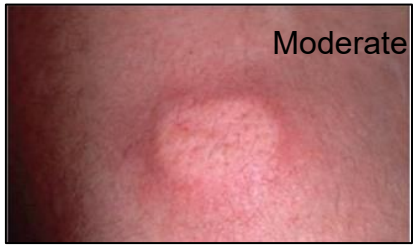
Record in the patient infusion diary/infusion App/medical record:

- Product name
- Batch number & expiry date
- Dose
- Volume
- Infusion commencement time
- Infusion completion time
- Infusion site(s)
- Symptoms/side effects

Adverse reactions*

Frequency	Reaction
Common	Infusion site reaction: redness, itching, swelling, hardness, blanching & discomfort Usually mild and resolves within 24-48 hours Site reactions usually decrease after 8-10 infusions
Uncommon	Headache, fever, nausea, diarrhoea, sore throat, rash, cough, back pain
Rare	Allergic reactions, kidney problems, blood clots & aseptic meningitis





Subcutaneous immunoglobulin (SCIg) therapy - general information - Australasian Society of Clinical Immunology and Allergy (ASCIA)
<https://www.allergy.org.au/patients/immunodeficiencies/scig-therapy-general-information?highlight=WyJzY2lnIiwiZmFxII0=>

Report adverse reactions to relevant product manufacturer or TGA

*Refer to product information for specific adverse reaction information

Management of infusion site reactions

If an infusion site reaction occurs:

- Apply gentle massage and warm or cold pack (according to personal preference) to reduce discomfort. An ice pack should not be applied for four hours post infusion to ensure adequate absorption.
- Do not rub or scratch the infusion site.
- Record site reactions in an infusion diary.

Subcutaneous immunoglobulin (SCIg) therapy - general information - Australasian Society of Clinical Immunology and Allergy (ASCIA)
<https://www.allergy.org.au/patients/immunodeficiencies/scig-therapy-general-information?highlight=WyJzY2lnIiwiZmFxII0=>

ASCIA INFORMATION FOR PATIENTS AND CARERS

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.

Patient support programs

Each SCIg product manufacturer has a patient support program

- CSL Behring Cares
- Takeda Cuvitru at Home
- Grifols Xembify Connex

Accessed via a referral form

Provide SCIg administration education in the patient's home, supply some consumables

Suite of SCIg resources for patients and health care professionals

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Questions to you

- What support/assistance do you need?
- Business case
- Policy/procedure
- Staff education and checklist
- Patient education and checklist

Further information:

Contact: Anne Graham

Blood Matters Nurse Consultant (SCIg)

Phone: 03 9694 0126

Blood Matters Subcutaneous immunoglobulin (SCIg) access & information, tools and resources:

https://www.health.vic.gov.au/patient-care/subcutaneous-immunoglobulin-scig-access-program
<https://www.health.vic.gov.au/patient-care/subcutaneous-immunoglobulin-scig-access-program>

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Acknowledgement

Australian governments fund the Australian Red Cross Lifeblood to provide blood, blood products and services to the Australian community.

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Accessibility

To receive this presentation in another format phone 03 9694 0102, using the National Relay Service 13 36 77 if required, or email Blood Matters <bloodmatters@redcrossblood.org.au>.

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