

Subcutaneous Immunoglobulin (SCIg) Therapy

Frequently Asked Questions

This document has been developed by [ASCIA](http://www.allergy.org.au), the peak professional body of clinical immunology/allergy specialists in Australia and New Zealand. ASCIA information is based on published literature and expert review, is not influenced by commercial organisations and is not intended to replace medical advice. For patient or carer support contact [AusPIPS](http://www.auspipe.com.au), [IDFA](http://www.idfa.org.au), or [IDFNZ](http://www.idfnz.org.nz).

Q 1: What is SCIg?

Immunoglobulins (commonly known as antibodies) are used to treat adults and children with some inborn errors of immunity (IEI), including primary immunodeficiencies (PID), 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:

- 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.

Q 2: 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.

Q 3: Are immunoglobulin products 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.

Q 4: 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 9 and 10 of this document.

Q 5: 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.

The ASCIA Treatment Summary 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 transferring/transitioning from:

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

ascia AUSTRALIAN SOCIETY OF CLINICAL IMMUNOLOGY AND ALLERGY www.allergy.org.au		TREATMENT SUMMARY FOR PATIENTS on Immunoglobulin Therapy	
Patient name:	UR/MRN/NHI:		
Date of birth:			
Contact details (phone and email):			
Plan prepared by (date):			
Nurse Specialist:			
Immunology Specialist:			
Clinical indication:			
Next of kin (name and contact number/s):			
Relationship to patient:			
CURRENT <input type="checkbox"/> IVIG OR <input type="checkbox"/> SCIG			
IVIg or SCIg product name:			
Dose:	Frequency:		
Patient weight (date):	Trough IgG levels (date):		
Current problems and comments:			
SCIG DELIVERY METHOD: <input type="checkbox"/> RAPID PUSH OR <input type="checkbox"/> PUMP			
Giving set/needle type:	Needle gauge:	Needle length (mm):	
Number of sites per infusion:	Infusion site/s:		
Pump brand (if applicable):			
Date SCIg technique last assessed and comments:			
ATTACHMENTS			
<input type="checkbox"/> IVIg: Product/s used:			
Side effects, reasons for change, comments:			
<input type="checkbox"/> SCIg: Product/s used:			
Side effects, reasons for change, comments:			
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Q 6: How are SCIg infusion sites chosen?

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.

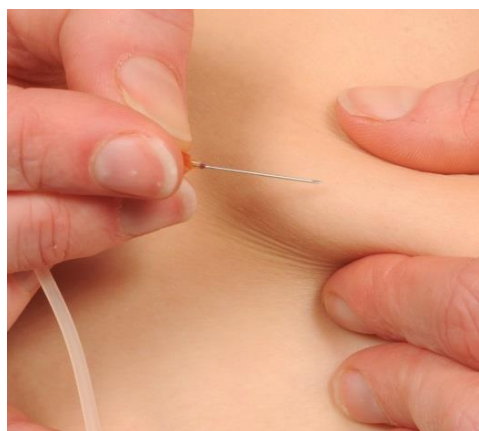
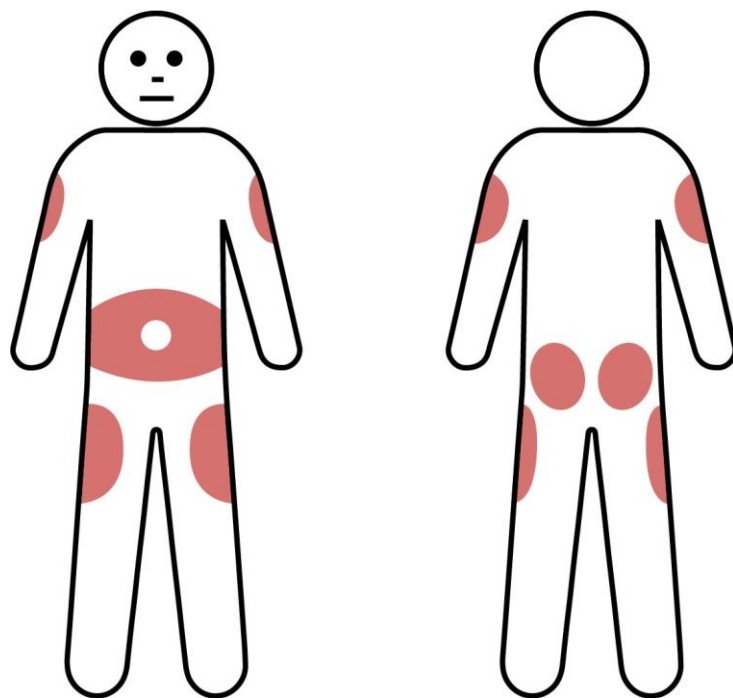
Note: Do not insert the needle where the skin is scarred, bruised, broken or inflamed (such as eczema).

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

The ASCIA Subcutaneous Immunoglobulin (SCIg) Infusion Checklist for the process of infusion is also useful. 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.



Q 7: How should SCIg infusions be documented?

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).

Q 8: How is SCIg ordered, collected, transported and stored?


- Use the ASCIA SCIg Treatment Plan, which is available on the ASCIA website www.allergy.org.au/hp/papers/ascia-sci-g-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 SCIg - never store below 2°C and do not use SCIg that has been frozen.**

*** 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.



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**TREATMENT PLAN FOR
Subcutaneous Immunoglobulin
(SCIg)**

Patient name: _____

Plan prepared by: _____

Date: _____

IMMUNOLOGY AND NURSE SPECIALIST DETAILS

Immunology Specialist: _____

Nurse Specialist: _____

Telephone: _____

Email: _____

After hours contact name: _____

Telephone: _____

SCIG PRODUCT DETAILS

Brand: _____

Dose: _____

1. _____ grams _____ mls _____ times/week

2. _____ grams _____ 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 up to 14 days when ringing to order SCIg and allow _____ days for ordering consumable equipment supplies

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This plan has been developed as a medical document to be completed by an immunology or nurse specialist

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.
- 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.

Q 9: What SCIg products are available in Australia and New Zealand?

The following brands of SCIg are available in Australia and New Zealand:

- Hizentra® AU - CSL Behring
- Hizentra® NZ - CSL Behring
- Hizentra® - CSL Behring
- Cuvitru® - Takeda
- Xembify® - Grifols

The following information has been adapted from the Lifeblood website:

www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/SCIg

SCIg Product - Hizentra® AU and Hizentra® NZ

Hizentra® AU and Hizentra® NZ are SCIg products supplied by CSL Behring and available as a 20% solution (20 g/100 mL) in vial sizes: 1 g/5 mL and 4 g/20mL.

[Hizentra® AU and Hizentra® NZ product information and educational materials](#)

This link takes you to CSL Behring's web information about Hizentra® AU and Hizentra® NZ where you can download the product information (PI) sheet for these products.

The PI details the pharmacology, indications, contraindications, precautions, adverse effects, use in pregnancy and lactation, dosage and administration of Hizentra® AU and Hizentra® NZ.

Lifeblood has sent a letter to all Approved Health Providers regarding the introduction of Hizentra® AU and a copy can be found [here](#).

SCIg Product - Hizentra®

Hizentra® is an imported SCIg product, supplied by CSL Behring and available as a 20% solution in vial sizes: 1 g/5 mL, 2 g/10mL, 4 g/20mL and 10 g/50mL.

[Hizentra® product information and educational materials](#)

This link takes you to CSL Behring's web information about Hizentra® where you can download the product information (PI) sheet for this product.

The PI details the pharmacology, indications, contraindications, precautions, adverse effects, use in pregnancy and lactation, dosage and administration of Hizentra®.

SCIg Product – Cuvitru®

Cuvitru® is an imported SCIg product, supplied by Takeda and available as a 20% solution in vial sizes: 1 g/5 mL, 2 g/10mL, 4 g/20mL and 8 g/40mL.

[Cuvitru® product information](#)

This link takes you to Takeda's web information about Cuvitru® where you can download the product information (PI) sheet for this product.

The PI details the pharmacology, indications, contraindications, precautions, adverse effects, use in pregnancy and lactation, dosage and administration of Cuvitru®.

SCIg Product - Xembify®

Xembify® is an imported SCIg product, supplied by Grifols and available as a 20% solution (20 g/100 mL) in vial sizes: 1 g/5 mL, 2 g/10 mL, 4 g/20mL and 10 g/50 mL.

[Xembify® product information](#)

This link takes you to Therapeutic Goods Administration (TGA) website where you can download the product information (PI) sheet for Xembify®.

The PI details the pharmacology, indications, contraindications, precautions, adverse effects, use in pregnancy and lactation, dosage, and administration of Xembify®.

To assist with developing hospital (or treating facility) administration protocols for Xembify®, [Consumer Medicine Information](#) is also available on the TGA website.

Lifeblood has sent a letter to all Approved Health Providers regarding the introduction of Xembify® and a copy can be found [here](#).

Q 10: What needs to be checked on 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.

Q 11: How should SCIg be used 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.


Q 12: How does SCIg affect vaccinations?

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

Q 13: What documents are required when 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/ascia-travel-plan-for-sci-g-patients
- Take their SCIg 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 non-drowsy antihistamine in case of adverse reactions.
- Take enough consumable equipment for the time they are away from home.
- 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.



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**TRAVEL PLAN FOR PATIENTS
on Subcutaneous
Immunoglobulin (SCIg) Therapy**



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 SCIg product with them on the plane in carry-on luggage. It must not be placed in checked-in 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 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)

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Q 14: How can side effects of SCIg be managed?

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.

Mild



Moderate



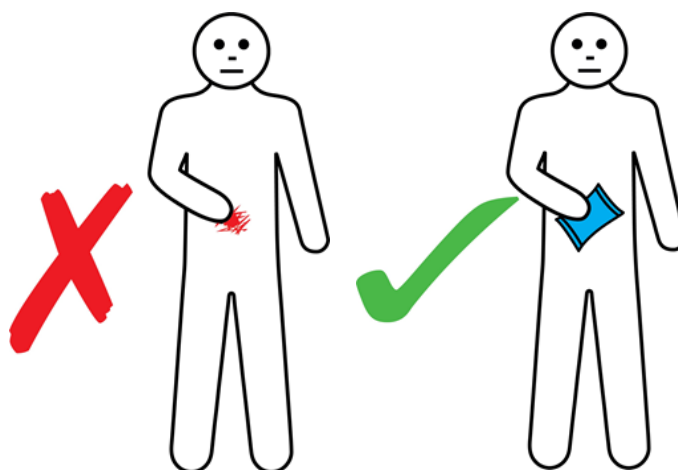
Q 15: Should the same SCIg infusion site be used instead of rotating sites?

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.

Q 16: What general steps should be taken 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 information on the following pages for different ways to manage reactions or problems at the infusion site.



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For more information go to www.allergy.org.au/patients/immunodeficiencies

To support allergy and immunology research go to www.allergyimmunology.org.au/donate

Management guide for SCIg infusion site reactions and problems

Site Issue	Possible Cause/s	Management Options
Redness	<p>Common reaction, which usually settles over 24 hours.</p> <p>If redness is excessive:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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	<p>Common reaction, which usually settles over 24 hours.</p> <p>Swelling usually results from the amount of fluid being infused underneath the skin (amount of swelling should relate to the volume being infused).</p>	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Incorrect needle placement. Incorrect needle length. Irritation from tape. Ig at needle tip, causing skin irritation. 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Incorrect needle placement. Incorrect needle length. Infusion going too fast. 	<ul style="list-style-type: none"> 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)	<p>Normal tightening of tissue that can occur as SCIg infuses into the fatty tissue under the skin.</p>	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Incorrect needle insertion. Incorrect needle length. Amount of volume infused at the site. 	<ul style="list-style-type: none"> 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