

Subcutaneous Immune Globulin Home Infusion Program

Patient Handbook



IH SCIG Program Patient Handbook

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1. Introduction to Subcutaneous Immune Globulin (SCIG)

1.1 Description of Subcutaneous Immune Globulin (SCIG or sub-q)

- A blood product used to treat adults and children who need antibody replacement therapy due to primary immune deficiency (PID) or secondary immune deficiency (SID).
- Primary immune deficiency is a condition in which a person's natural defence or immune system, does not function properly and is unable to produce antibodies, leaving them more vulnerable to infections.
- SCIG replaces these antibodies, making people with PID/SID less likely to develop an infection.
- It is a sterile liquid that is injected under the skin into the subcutaneous (fatty) tissue.

1.2 When you should not use SCIG

- If you have a history of severe allergic reactions to immunoglobulin treatment.
- If you have a selective IgA deficiency.
- Check with your doctor if you have a platelet disorder or other bleeding tendency.
- The safety and effectiveness of SCIG has not been studied in patients less than two years old.
- Clinical studies with pregnant women have not been conducted. If you are pregnant or think you may be pregnant or if you are nursing, discuss with your doctor whether SCIG is necessary.

1.3 Warnings and Precautions

As you adjust to receiving SCIG

- You may be at risk for developing reactions including fever, chills, nausea and vomiting.
- On rare occasions these reactions may lead to shock. You will be monitored by an IH SCIG Program nurse or doctor the first few times you receive SCIG. You may be at risk if:
 - this is the first time you are receiving immune globulin therapy
 - you are switching from another brand of immune globulin (such as IVIG)
 - you have not received immune globulin therapy for at least eight weeks.
- As part of training, your IH SCIG Program nurse will monitor you the first two times you get SCIG and will continue to be available for questions by phone.

Common Side Effects

- Headache, fever, rash and nausea

Local Reactions

- Local reactions at the infusion site, including redness, swelling and itching, are common. These usually disappear within four days and become less frequent as your body gets used to getting SCIG.

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Adverse Reactions

- More rarely, immune globulin products have been reported to be associated with the following serious events. Inform the IH SCIG Program nurse **and see your physician**.
 - allergic reactions including the possibility of anaphylactic shock
 - aseptic meningitis syndrome
 - thrombo-embolism
 - renal impairment or kidney dysfunction
 - hemolysis/hemolytic anemia
 - transfusion related acute lung injury.

Blood Product Safety

Although considered one of the safer blood products with a low risk of spreading disease, SCIG – like other immune globulin replacement therapies – is made from human plasma and may contain infectious agents such as hepatitis viruses, the human immunodeficiency virus (HIV) and theoretically, the variant Creutzfeldt-Jakob Disease agent.

Vaccines

SCIG can interfere with some vaccines, such as measles, mumps and rubella (MMR). Let your doctor know you are receiving SCIG so appropriate precautions can be taken.

See Section 6 Managing Adverse Reactions in this handbook for more detailed information.

1.4 Educational resources

- Brochure: Subcutaneous Immune Globulin (SCIG) Home Infusion: Information for Patients and Caregivers
- Canadian Immunodeficiency Patient Organization <http://www.cipo.ca>
- Immune Deficiency Foundation (IDF) <http://www.primaryimmune.org>
- There may be manufacturer videos and materials available, please refer to the individual websites.

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2 Equipment Needed

Equipment	Comment
SCIG vial(s)	Check expiry date and visually inspect to ensure no vial damage, cloudiness or particles
Subcutaneous (sub-q) infusion set	<p>Subcutaneous needle(s) with micro-bore tubing (either multiple lead for multiple infusion sites or single lead or butterfly for single infusion site).</p> <ul style="list-style-type: none"> • Diameter: Suggest using 23-25 gauge needles. • Length: Suggest using 6 mm long needles for children and thin adults and 9 -12 mm long needles for average weight adults. <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Choosing the right needle length is important to ensure the product is injected into the subcutaneous tissue and not the muscle (which can happen if the needle is too long) or into the skin (which can happen if the needle is too short).</p> </div>
Infusion pump, if using	For controlling administration of the SCIG
Transparent dressing	For anchoring tubing and needles to infusion sites (included in the tubing packaging)
Alcohol swabs	For vial stopper cleansing and skin cleansing
Chlorhexidine swab	(if sensitive to alcohol swab) for skin cleansing
Syringes	Selection of syringe size will depend on the volume of SCIG to be injected and the ease of manipulation of the syringe.
BD Blunt fill needle - 18 gauge X 1.5"	For drawing up the SCIG
Sterile 2" X 2" gauze	For applying pressure on infusion site after removal of subcutaneous needle
Hypo-allergenic adhesive tape	To secure sterile 2X2 gauze
Sharps disposal container	To discard all needles and connected tubing, vials and syringes
Infusion log	To document infusion and any adverse reactions
Epinephrine auto-injector (Epi-Pen®)	If recommended - used as treatment for anaphylactic reaction
Antihistamines/ Analgesics	See Section 6 Managing Adverse Reactions for suggested over the counter medications

3 Preparing for the Infusion

3.1 Keeping out germs

- Germs that can cause infections are everywhere. Skin provides a barrier against these germs. When SCIG is administered, the needle breaks the skin barrier. Be careful not to accidentally contaminate or touch something that must remain sterile (without germs) with something that may have germs on it.
- Do not use equipment that has fallen on the floor.
- Check that the packaging of sterile equipment is intact prior to use.
- If a SCIG vial becomes contaminated during the infusion process, such that the contents cannot be infused, report it as wasted on the infusion log and discard the vial in the sharps container.

3.2 Handwashing

Wash your hands before gathering your supplies and before starting your infusion. Thoroughly wash and dry hands as follows:

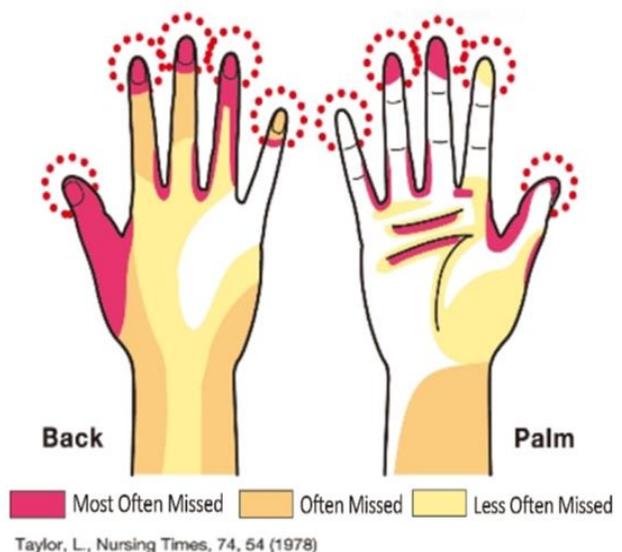
- Remove jewelry
- Wet hands with warm running water
- Distribute soap thoroughly over hands (disinfectant soap not recommended)
- Massage entire hands and lower wrists vigorously for 15-20 seconds (sing “Happy Birthday” twice)
- Remember to scrub around the fingertips and nails and between the fingers
- Rinse under running water
- Dry with a disposable paper towel or a clean unused cloth towel
- Use paper towel to turn off the tap

Six stage handwashing technique



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Areas Most Missed During Handwashing



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3.3 Gathering Supplies

Gather all supplies and place on a clean, dry flat surface.

SCIG Vials - removal and inspection

1. Assemble the required number of SCIG vials and remove from the packaging
 - If you are storing your SCIG in the refrigerator, remove the vials 30-60 minutes before infusion to allow it to reach room temperature (20° to 25° C, 68° to 77° F) naturally.
 - **Do not** put them in the microwave or warm water.
2. Check the product expiry date.
3. To prevent product waste, the vial(s) with the earliest expiry date should be used first. If the vial has expired, do not use. Record as expired product on the Infusion Log and discard the vial in a sharps container and leave a message on the IH SCIG Program phone line.
4. Look carefully at the vials – gently rotate the vial -do not shake
Do Not use if:
 - there are cracks or other damage
 - the protective cap loose or absent
 - the liquid is cloudy or contains particles
5. Record as wasted product on the infusion log and return the vial to the hospital transfusion service. If the vial is leaking, dispose of it in a sharps container. Leave a message on the IH SCIG Program phone line.

If you have any doubt about the safety of a vial, phone the hospital transfusion service to ask what to do.

Phone Number to call:

Other supplies

- Subcutaneous (sub-q) infusion set
- Alcohol swabs
- Syringes
- Blunt fill needle - 18 gauge X 1.5” (red ones)
- 2” X 2” gauze
- Hypo-allergenic adhesive tape
- Sharps disposal container
- Infusion log
- Infusion pump (if using)
- Mini-Spike dispensing pin (if using)
- Fluid dispensing connector (if using)
- Transparent dressing (for pump method only)
- Chlorhexidine swab (if sensitive to alcohol swabs)
- Epinephrine auto-injector (Epi-Pen®) (if prescribed by your physician)

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3.4 Filling syringes

1. Remove product lot# label from the vial(s) attach to the log sheet.
2. Remove the protective cap from the vial(s) to expose the central portion of the rubber stopper.
3. Clean the rubber stopper with an alcohol wipe, allow it to dry. Do not shake the vial.
4. Attach the blunt needle to the syringe tip, taking care not to touch any surface that must remain sterile. If you accidentally touch something that needs to stay sterile, throw it away and start over.
5. Remove the second blunt needle (venting needle) from package.
6. Insert the venting needle on a 45° angle into the side of the rubber stopper so needle tip is into an air pocket.
7. Insert syringe needle into center of rubber stopper at a 90 degree angle. Tilt vial up and ensure syringe needle tip is in the SCIG product.
8. Pull on the syringe plunger to draw the SCIG product into the syringe.
9. Remove all of the SCIG product from the vial.
10. Remove the syringe needle from vial and recap needle.
11. Hold syringe with the needle pointing up and push plunger to remove air.
12. Repeat steps 6-11 for additional vials.

3.5 Priming the infusion set

1. Remove the subcutaneous (sub-q) infusion set from the package.

Do not remove the cap of the sub-q needle attached to the tubing.

2. Remove the protective cover from the syringe end of the sub-q infusion set. Do not touch this end.
3. Remove the needle from filled syringe by grasping the needle cap and twisting it in a counter-clockwise direction. Do not touch the tip of the syringe. Discard the needle in a sharps disposal container.
4. Attach the syringe tip to the syringe end of the sub-q infusion set.
5. Tighten the connection by rotating the syringe clockwise.
6. Prime the tubing up to 4 inches before the needle.

If using an infusion pump, follow manufacturer's instructions for filling the infusion pump reservoir and priming the tubing.

4 Infusing SCIG

4.1 Select and prepare the infusion site(s)

1. Select the subcutaneous infusion site(s). The lower abdomen or the upper inner thighs are most commonly used, but the back of the upper arms, flanks and upper buttocks may be used as well (see fig. 1).
 - Select sites that are 5-10 cm (2-4 inches) from the umbilicus (“tummy button”)
 - Avoid all bony prominences, such as hips and ribs
 - Avoid the upper abdomen as the skin can be tighter than the lower abdomen
 - Avoid the waistline or area where your pant/skirt waistband normally sits, to prevent irritation from the waistband rubbing against the infusion site
 - Avoid any area that is scarred, bruised or has a large blood vessel under the skin
 - Reusing the same infusion sites on a weekly basis is acceptable as long as the sites have recovered from the previous infusion.
 - Reusing the same site for infusion sessions may reduce site reactions. If you are going to reuse a site, make sure it is free of redness, swelling, tenderness, bruising and/or unusually firm or hard tissue.
 - If using multiple sites, make sure they are at least 5-10 cm (2-4 inches) apart.
2. Clean the site vigorously with an alcohol swab (use chlorhexidine swab if skin is sensitive to alcohol). Use a circular motion, starting from the centre of the site and working outward. Let the site dry completely before proceeding to the next step.

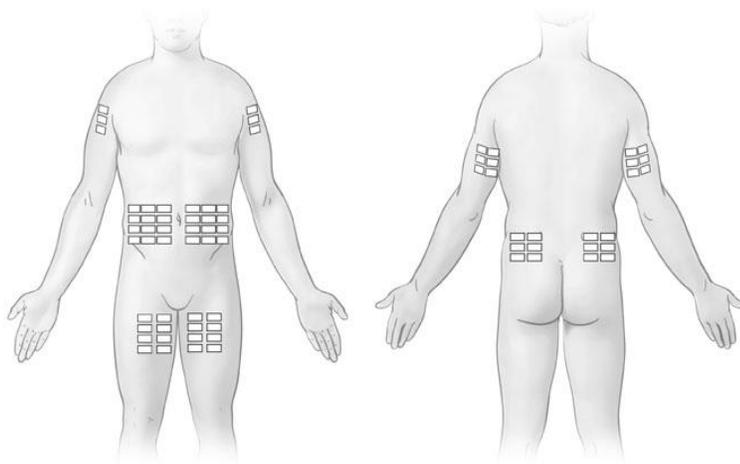
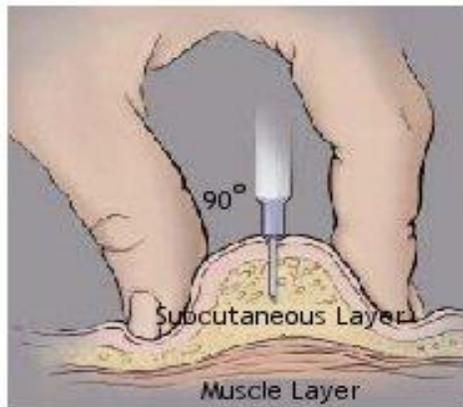


Fig. 1

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4.2 Insert needle

1. Remove the clip holding the wings of needle. (multiple/single lead sets)
2. Grasp the wings in an upright position with your dominant hand (if you are right-handed your right hand is your dominant hand).
3. Remove and discard the needle cap. Do not touch the needle.
4. If there is a drop of SCIG on the end of the needle, gently wipe the end of the needle with alcohol swab (let dry) prior to the infusion. This reduces the chance of skin reactions to the SCIG.
5. Using the thumb and index finger of your non-dominant hand, grasp the skin around the infusion site. (fig.2)
6. Insert the needle straight down (90° angle to skin) into subcutaneous (fatty) tissue using a darting motion. (fig.3)
7. Use a 45° degree insertion only if instructed by your SCIG program nurse. (fig.3)
8. Check to see if the needle is level with the skin, then release the skin slowly, keeping one finger on the wings to prevent the needle from accidentally coming out.
9. Secure the needle by applying sterile gauze or transparent dressing over the site and tape in place.
10. If using an infusion pump, secure the administration tubing to the infusion pump according to the manufacturer's instructions.



A subcutaneous injection into the fatty layer of tissue under the skin.

Fig. 2

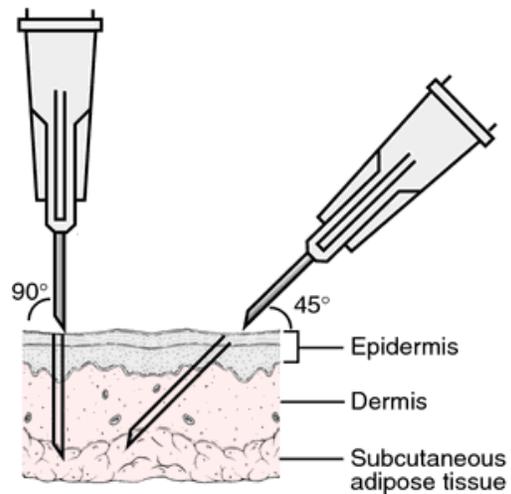


Fig. 3

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4.3 Start infusion

Slowly begin to infuse SCIG. If using an infusion pump, set the rate of infusion and turn on the pump.

- The maximum volume for Cuvitru is 60 mL/ site.
 - Maximum infusion rate: 60 mL/hour per site
- The average volume for Gamunex is 34 mL/ site (17-69 mL).
 - Maximum infusion rate: 20 mL/hour per site.
- The maximum volume for Hizentra is 20 to 50 mL/ site.
 - Maximum infusion rate: 20 to 50 mL/hour per site

4.4 Discontinuing infusion

1. Once the infusion is complete, wait about 5 minutes before removing the needle
2. Remove the transparent dressing or tape holding the needle in place.
3. Grasp the wings of the needle(s) and pull straight out.
4. Place a 2x2 gauze over the infusion site and gently tape in place. A few drops of fluid may appear at the site – this is normal. Avoid applying excessive pressure, as this will push product out of the site.
5. Keep the site clean and dry for at least one hour.
6. Stick the vial lot number sticker on the log sheet
7. Discard equipment that has touched the SCIG product in a sharps container.
8. Put unused supplies in a safe place.
9. If using an infusion pump, follow the manufacturer's instructions regarding care of the pump after each use.
10. Check that you have enough supplies for your next infusion.

5 Safe Waste Disposal

5.1 What is a sharps container?

- Must be made of puncture-resistant, hard material that is not glass or thin plastic
- Must have screw cap or tightly secured lid
- Must be wide-mouthed and leak-proof
- Must be clearly labeled “HAZARDOUS MATERIALS”

5.2 What goes in a sharps container

- Needles and connected tubing
- Vials
- Syringes

**DO NOT place needles, syringes or vials in the garbage or recycle bins.
Keep the sharps container nearby when doing your infusion.**

5.3 Sharps container safety

- Do not fill above the “fill line” or above $\frac{3}{4}$ the size of the container.
- Do not puncture the container
- Ensure the container is not leaking
- Do not store the container near food
- Store the container out of reach of children

5.4 How to dispose of a full sharps container

- Ensure the lid is snapped closed
- **DO NOT** dispose of a sharps container in regular garbage or recycling bins
- Your IH Transfusion Medicine Laboratory will take the full sharps container if the container is not overfilled and the lid is snapped closed.

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6 Managing Adverse Reactions

6.1 Before you infuse

1. The IH SCIG Program nurse will work with you to develop a plan in the event you experience an adverse reaction.
2. Make sure you have the name and phone number of the IH SCIG Program nurse.
See Section 11 for IH SCIG Program Contact Information
3. You should have a non-drowsy antihistamine and an analgesic (pain medication) on hand at home prior to starting an infusion. Options are listed in the table below.

Non-drowsy Antihistamines	Analgesics (pain medication)
ceterizine (Reactine®)	acetaminophen (Tylenol®)
loratidine (Claritin®)	ibuprofen (Advil®, Motrin®)
desloratidine (Aerius®)	
fexofenadine (Allegra®)	

6.2 Managing infusion site reactions

1. Infusion site reactions are common. They can happen during or after the infusion. Reactions should diminish over 24-48 hours as the SCIG is absorbed, although they may take up to 4 days to completely resolve.
 - Puffiness or swelling where the SCIG is infused can be expected
 - Redness or blanching and itching may also be expected.
2. Reusing the same infusion sites on a weekly basis may reduce site reactions. If a site is going to be reused, make sure it is free of redness, swelling, tenderness, and bruising and/or unusually firm or hard tissue.
3. No site should be used more than once per week.
4. See the management options on the following table.
5. Report unusual site reactions, such as extreme pain or discomfort, blistering or spreading redness to the IH SCIG Program nurse.
6. Record site reactions in the infusion log.

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Managing SCIG Infusion Site Reactions*		
Site Issue	Possible Cause	Management Options
Redness	<ul style="list-style-type: none"> • Histamine release, which is a normal response when a protein (IgG) is introduced into subcutaneous tissue • Potentially an allergy or sensitivity to tape 	<ul style="list-style-type: none"> • If it does not cause discomfort, do nothing • Cool compresses for short periods (10-15 minutes) may help with discomfort (do not place directly on skin) • Slow the infusion rate if uncomfortable • If redness does not diminish or worsens, contact physician immediately • Try using an over the counter non-drowsy antihistamine
Swelling	<ul style="list-style-type: none"> • Normal response due to the volume being delivered to the subcutaneous tissue. • Size of swelling should be consistent with the volume being infused. 	<ul style="list-style-type: none"> • If it does not cause discomfort, do nothing • Warm compresses for short periods may help with absorption (do not place directly on the skin) • Cool compresses for short periods may help with discomfort but delay absorption (do not place directly on skin) • Take a walk to help with absorption and provide a distraction • Assess needle length, may be too short
Itching	<ul style="list-style-type: none"> • Histamine release, which is a normal response when a protein (IgG) is introduced into the subcutaneous tissue 	<ul style="list-style-type: none"> • Do not scratch or rub • Try using an over the counter non-drowsy antihistamine • Assess needle length: may be too short • Consider tape allergy/sensitivity
Rash at the site	<ul style="list-style-type: none"> • Histamine release 	<ul style="list-style-type: none"> • Consider tape allergy/sensitivity • Check with physician regarding using an over the counter non-drowsy antihistamine • If rash is generalized (covers body), STOP the infusion and seek medical advice to see if infusion can continue.
Leaking at site	<ul style="list-style-type: none"> • Needle dislodged • Infusion rate too fast • Too much volume per site or • Too short a needle 	<ul style="list-style-type: none"> • Is the needle securely taped to skin? • Is the needle inserted at correct angle (90° or 45°)? • Is the needle in an area that moves too much? • Consider the needle length: Is it too short? <p><u>Management:</u></p> <ul style="list-style-type: none"> • Call the IH SCIG Program nurse • If single-lead infusion set, remove and start again • If multi-lead set, reduce the infusion rate and clamp off tubing to the leaking site • Consider slowing infusion; increasing infusion days per week or the number of sites

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Managing SCIG Infusion Site Reactions*		
Site Issue	Possible Cause	Management Options
Discomfort / burning	<ul style="list-style-type: none"> • Needle length too long causing irritation to the muscle wall 	<ul style="list-style-type: none"> • Consult with the IH SCIG Program nurse about using a shorter needle • Slow infusion rate • Check tape placement for pulling on skin or body hair <p style="margin-left: 20px;">After Care- (once needle is out)</p> <ul style="list-style-type: none"> • Apply Warm/cool compresses for short periods (do not apply directly to skin)
Blanching (whiteness)	<ul style="list-style-type: none"> • Normal, due to volume of IgG at the site 	<ul style="list-style-type: none"> • Do nothing, usually goes away as IgG is absorbed • Warm compresses for short periods (do not place directly on skin) • Taking a walk increases absorption
Hard fat nodule under the skin	<ul style="list-style-type: none"> • Over use of site • Scar tissue formation 	<ul style="list-style-type: none"> • Keep infusions at least 5 cm (2 inches) away from the hard area until resolved • Talk to your IH SCIG Program nurse about rotating infusion sites

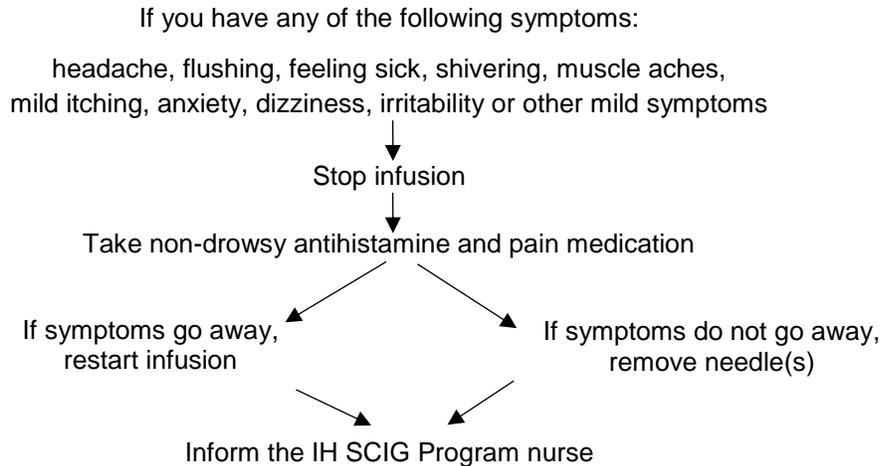
6.3 Managing other adverse reactions to SCIG

1. Other than local site reactions, adverse reactions to SCIG are rare.
2. See the following table Managing **Adverse Reactions to SCIG** for symptoms and management of potential adverse reactions.

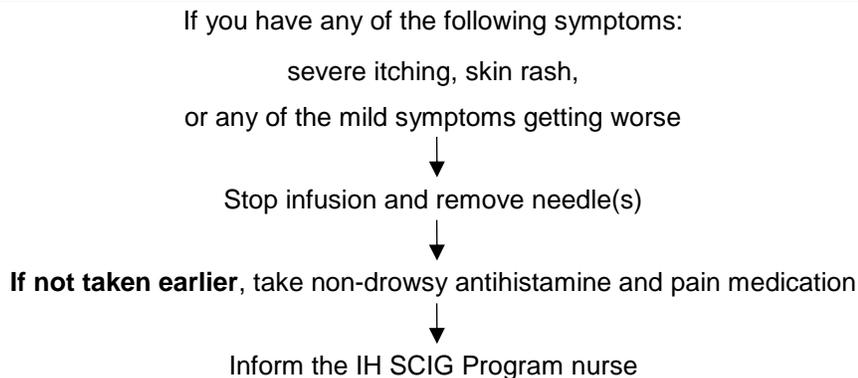
Reaction	Person to Contact	Contact Information

Managing Adverse Reactions to SCIG

Mild Reaction



Moderate Reaction



Severe Reaction

*If you have **any** of the following symptoms:*
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 getting worse



7 Documenting the Infusion

1. Record the details of each infusion on the IH SCIG Infusion Log. The instructions are on the log sheet.
2. **Submission of completed infusion logs is a requirement of Health Canada** as identified in the Participation Agreement. Interior Health is required to report the usage of all blood products.
3. Mail or fax your completed Infusion Logs to the IH SCIG Program nurse each time you re-order. (Every 3 months or more frequently)

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8 Obtaining and Storing SCIG

1. The Transfusion Service will issue some SCIG for your training. Afterwards, the IH SCIG Program nurse will work with you to determine the amount of product you can pick-up for home infusion.
2. Phone the IH SCIG Program nurse when you have 2 to 3 weeks of product left. The IH SCIG Program nurse will contact you to discuss your next product request. The maximum supply is 3 months.
3. Photo identification is required by the Transfusion Service to pick up your product. Anyone picking up on your behalf must show their own photo identification and the Letter of Authorization for Pick-up.
4. Bring an insulated container large enough to transport the vials when picking up the SCIG from the lab. Take the SCIG home immediately after picking it up.
5. SCIG should be protected from getting too hot or too cold. DO NOT FREEZE. Do not use product that has been frozen. Protect from light. Do not shake.
6. See table below for storage temperature for your product

Shire Cuvitru™, Subcutaneous Immune Globulin (Human)
<ul style="list-style-type: none">• Can be stored either in the refrigerator or at room temperature• Store between +2°C to +25°C (+35°F to +77°F)
CSL Behring Hizentra™, Subcutaneous Immune Globulin (Human)
<ul style="list-style-type: none">• Can be stored either in the refrigerator or at room temperature• Store between +2°C to +25°C (+35°F to +77°F)
Grifols Gamunex® (Human)
<ul style="list-style-type: none">• Shelf-life is up to 36 months if stored in the refrigerator at +2° to + 8°C (35°F to 46°F)• Gamunex® may be stored at room temperature (not to exceed 25°C / +77°F). Gamunex® expires 6 months from the date it is moved from refrigerator storage to room temperature storage. Change the expiry date on the box.• Once Gamunex® is moved to room temperature storage it cannot be returned to the refrigerator.

7. If SCIG is stored in the refrigerator, avoid spots that are too cold. You should purchase a fridge thermometer, put it on the shelf where the SCIG is stored and check regularly to ensure the temperature remains in the +2° to + 8°C range. If the refrigerator temperature goes out of range, contact the IH SCIG Program nurse or local transfusion service for instructions.

9 Travelling with SCIG

When planning a trip:

1. The maximum amount of SCIG issued to a patient in British Columbia is a 3 month supply.
2. Check and confirm before travel:
 - Restrictions on traveling with liquids at points of departure
 - Customs requirements
 - Airline requirements
 - Availability of a fridge at destination
3. Get a travel letter from the IH SCIG Program nurse.
4. Always carry an extra week of SCIG and all supplies in case of unexpected delays.
5. Pack your supplies, including pain medication and a non-drowsy antihistamine, in your carry-on luggage.
6. Purchase a travel-size sharps container from your pharmacy and pack in your checked luggage.
7. Pack the SCIG in carry-on luggage:
 - Use a collapsible cooler
 - Keep the product in its original box
 - Place the travel label, provided by the IH SCIG Program nurse, onto each box
 - Consider using an ice pack to keep the SCIG cool during transport
 - SCIG should not be in direct contact with the ice pack to avoid freezing
 - Put SCIG in zippered plastic storage bags to keep it dry
8. If you cannot safely discard the sealed sharps container at your destination, bring it home in your checked luggage.

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10 Troubleshooting

Problem	Action
Leaking at site	<ul style="list-style-type: none"> • Assess needle: Is it securely taped to skin? • Assess placement: Is the needle in an area that moves too much? • Assess needle length: Is it too short? Discuss the needle length alternatives with IH SCIG Program nurse. • If using a single-lead infusion set or butterfly, remove and start over. • If using a multi-lead infusion set, clamp off the leaking lead and continue infusion.
Needle or other sterile equipment contaminated by touching, dropping, etc.	<ul style="list-style-type: none"> • Discard contaminated equipment in sharps container and continue with new infusion set
Someone is injured by used needle	<ul style="list-style-type: none"> • Wash the area with soap and water • Call the IH SCIG program nurse and seek medical advice
Discomfort from needle during infusion	<ul style="list-style-type: none"> • Assess needle length: Is it too long and irritating the abdominal wall? Discuss needle length alternatives with IH SCIG Program nurse. • Ask IH SCIG Program nurse about using a numbing anesthetic cream at the site before insertion • Warm/cool compresses for short periods may help (do not apply directly to skin) • Gentle massage • Slow infusion rate • Check tape placement for pulling on skin or body hair

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11 IH SCIG Program Contact Information

Phone

250-469-7070 Extension 12105

The SCIG office phone is answered 2 days/week, please leave a message.

Email

If you prefer to email please send to this address.

Please note that we are governed by Interior Health's email policy which prevents us from transmitting confidential information to external email systems.

Location and Mailing Address

SCIG Program
505 Doyle Avenue
Kelowna, BC
V1Y 0C5