

Subcutaneous immunoglobulin (SCIg)  
clinical practice guidance template

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| OFFICIAL |

**Contents**

[General information 3](#_Toc139528044)

[Purpose 3](#_Toc139528045)

[Approved access conditions for SCIg 3](#_Toc139528046)

[Governance requirements for a hospital based SCIg program 4](#_Toc139528047)

[Quality assurance 4](#_Toc139528048)

[Clinical oversight 4](#_Toc139528049)

[Equipment and facilities 4](#_Toc139528050)

[Education and training 4](#_Toc139528051)

[Regular review 4](#_Toc139528052)

[Supply of product 5](#_Toc139528053)

[Reporting unused, discarded, spoilt/broken product 5](#_Toc139528054)

[Considerations for a successful SCIg program 5](#_Toc139528055)

[BloodSTAR 5](#_Toc139528056)

[SCIg approval/dispensing process 6](#_Toc139528057)

[Options for SCIg dispensing 6](#_Toc139528058)

[Patient selection criteria 7](#_Toc139528059)

[SCIg product comparison\* 7](#_Toc139528060)

[Presentation 7](#_Toc139528061)

[Storage 8](#_Toc139528062)

[Stabiliser 8](#_Toc139528063)

[Approved therapeutic indications and product dosing guide 8](#_Toc139528064)

[Infusion rate 10](#_Toc139528065)

[IgA level 10](#_Toc139528066)

[Contraindications 10](#_Toc139528067)

[Precautions 11](#_Toc139528068)

[Pathogen safety and infection control 12](#_Toc139528069)

[Drug interactions 12](#_Toc139528070)

[Use in pregnancy 12](#_Toc139528071)

[Use in lactation 13](#_Toc139528072)

[Effects on fertility 13](#_Toc139528073)

[Paediatric use 13](#_Toc139528074)

[Use in the elderly 13](#_Toc139528075)

[Genotoxicity and carcinogenicity 13](#_Toc139528076)

[Product information References: 13](#_Toc139528077)

[Equipment and consumables for SCIg administration 14](#_Toc139528078)

[Types of pumps and infusion sets 14](#_Toc139528079)

[Infusion site selection 17](#_Toc139528080)

[Product administration procedure 17](#_Toc139528081)

[Infusion process: in the health service 17](#_Toc139528082)

[Observations: in the health service 18](#_Toc139528083)

[Administration instructions 18](#_Toc139528084)

[Completion of infusion 19](#_Toc139528085)

[Adverse effects and management 19](#_Toc139528086)

[Troubleshooting 20](#_Toc139528087)

[Adverse effect reporting 21](#_Toc139528088)

[Nurse competency 21](#_Toc139528089)

[Patient education 22](#_Toc139528090)

[Home treatment: patient education requirements 22](#_Toc139528091)

[Examples of patient training checklists and templates 22](#_Toc139528092)

[Documentation 23](#_Toc139528093)

[Product and consumable order and collection 23](#_Toc139528094)

[Follow up/review 23](#_Toc139528095)

[Transport recommendations 24](#_Toc139528096)

[Wastage 24](#_Toc139528097)

[Appendix A: Example of a patient education competency template 25](#_Toc139528098)

[Appendix B: Recommended consumable supply list template 27](#_Toc139528099)

[Appendix C: Patient treatment record template 28](#_Toc139528100)

[Reference list/recommended reading 29](#_Toc139528101)

[Journal Articles 31](#_Toc139528102)

[Acknowledgements 32](#_Toc139528103)

## General information

Immunoglobulins (Ig), also known as antibodies, are a critical part of the body’s immune defence system. They are produced by a particular type of white blood cell known as a plasma cell. Igs recognise and bind to toxins or other foreign substances (antigens) produced by pathogens (bacteria, viruses or other microorganism that can cause disease), thereby aiding in the pathogen’s destruction.

Ig products are fractionated blood products made from pooled human plasma.

Subcutaneous immunoglobulin (SCIg) is a treatment that is administered under the skin (subcutaneously) and is generally used for:

* replacement therapy - providing additional Ig to patients who do not make enough of their own to aid in maintaining a healthy immune system. This is generally because of a genetic disorder, disease, or as a side effect of disease treatment; and
* immunomodulation therapy – supporting patients with a range of auto-immune disorders by modulating their immune system (to prevent it attacking its own body).

## Purpose

To provide health services with the necessary information to implement a SCIg program.

To assist health services in the development of the necessary governance documents that will facilitate safe administration of SCIg according to the manufacturers’ instructions (product information).

This information is a guide only.

Health service policy/procedures based on this information should be implemented, and monitored for compliance with best practice, safety guidelines and all other requirements specific to the products and the National Safety and Quality Health Service (NSQHS) Standards.

All health service policies/procedures should be developed in accordance with local governance requirements and approval processes.

## Approved access conditions for SCIg

The National Blood Authority (NBA) sets out the access conditions for patients to be approved to receive SCIg. They must fulfil the eligibility requirements of the Criteria for the Clinical Use of Immunoglobulin in Australia (the Criteria) Version 3 (22 October 2018). This is only available online in BloodSTAR and at: [www.criteria.blood.gov.au](http://www.criteria.blood.gov.au)

SCIg is only available under national blood supply arrangements for patients with a medical condition:

1. Where there is support for use cited in the Criteria, namely:

* Primary immunodeficiency diseases with antibody deficiency
* Specific antibody deficiency
* Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
* Secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)
* Chronic inflammatory demyelinating polyneuropathy (CIDP), (including IgG and IgA paraproteinaemic demyelinating neuropathies)

1. Being treated by a clinical specialist within a hospital based SCIg program (see below), 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, and
2. Following a patient specific SCIg request submitted and approved in BloodSTAR.

## Governance requirements for a hospital based SCIg program

Prior to commencing a SCIg program the health service Chief Executive or Director of Clinical Services (or equivalent) must provide a signed acknowledgement of compliance with the governing requirements to the NBA.

The following information is outlined in the National Blood Authority Hospital Acknowledgement Form National Subcutaneous Immunoglobulin Program. To access the acknowledgement form, go to: <https://www.blood.gov.au/SCIg>

The governance requirements are as follows:

#### Quality assurance

The health service must have in place policies and procedures that provide quality assurance and monitor compliance for the management and use of SCIg in line with the NSQHS standards, the Clinical Governance Standard (1) and the Blood Management Standard (7).

#### Clinical oversight

The health service must have a recognised treatment program for the management and use of immunoglobulin for the relevant indications, including an appropriate supervising specialist.

The health service based SCIg program must provide ongoing clinical oversight and support for participating patients. This may include community nursing, hospital in the home or contact persons for both routine and emergency support as required.

The responsible clinician must consider patient suitability for the self-management and administration of SCIg, to ensure appropriate management and use of SCIg product.

#### Equipment and facilities

The health service based SCIg program must ensure that patients have access to all necessary equipment and consumables to administer the product, at no additional cost to patients.

#### Education and training

The health service based SCIg program must provide education and training for staff and patients to ensure the appropriate management and use of SCIg, including for transport, storage, use of equipment and infusion techniques.

#### Regular review

Regular review to assess 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 the product, to aid the clinician at the assessment.

#### Supply of product

Requests for SCIg for authorised patients must be managed via BloodSTAR, or alternative arrangements if necessary. 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 and the [National Policy: Access to Government-Funded Immunoglobulin Products in Australia](https://www.blood.gov.au/national-policy-to-ig).

#### 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 recorded in-turn by the hospital through BloodNet or alternative arrangement if necessary. This, and other information relevant for authorisation of requests collected by BloodSTAR will be reported to the NBA to assist with supply reconciliation and planning.

## Considerations for a successful SCIg program

Successful SCIg therapy depends on the participant’s commitment to therapy and the education and support they receive. Participants should have input into what best suits their lifestyle/work commitments to establish a regimen that ensures maximum compliance.

The success of a SCIg program is dependent on appropriate resourcing which may include:

* Dedicated registered nurse specialist/s who are usually responsible for the overall program administrative tasks as well as patient education/care.
* Consultant medical specialist/s to refer patients to the program, conduct medical reviews and consent, prescribe the product and complete BloodSTAR requirements.
* SCIg is a Schedule 4 (S4) medication and as such must be dispensed by a pharmacist for home administration.
* Laboratory/blood bank scientists (or pharmacist) usually order the product from Australian Red Cross Lifeblood (Lifeblood) and maintain traceability.
* Specialised equipment and consumables need to be provided for the patient.
* Availability of patient education and support resources.
* Available location for patient education and SCIg program administration.
* BloodSTAR requirements for participating clinicians.

## BloodSTAR

BloodSTAR is an online system used across Australia to manage access to government funded immunoglobulin products.

To register and create a BloodSTAR account go to [www.blood.gov.au](http://www.blood.gov.au) select the Blood Portal tab, select New user? Create an account (Figure 1). Tip sheets for creating an account are located: <https://www.blood.gov.au/bloodportal>

Figure 1: NBA BLOODportal login

A screenshot of a the National Blood Authority BLOODportal login.
This asks the user to set up a BLOODportal account.



#### SCIg approval/dispensing process

All SCIg approved health services will have an allocated BloodSTAR facility administrator. The facility administrator will ensure all staff (medical, nursing; laboratory/pharmacy) have access to the relevant health service patients via BloodSTAR. Relevant staff are responsible for creating their own BloodSTAR log in account via the Blood Portal. Once created the facility administrator can then approve access.

Once the patient has been assessed by a relevant medical specialist and confirmed to meet criteria for SCIg therapy the following process applies:

* Request for SCIg is created electronically by Treating Medical Specialist (TMS) or delegated Medical Officer (MO) via BloodSTAR. The NBA [Subcutaneous Immunoglobulin (SCIg) Product Dosing Request tip sheet](https://www.blood.gov.au/system/files/FINAL-BloodSTAR-Requesting-SCIg-tipsheet.pdf) can assist.
* Once request has been submitted via BloodSTAR, Lifeblood will review the request and if all the criteria are met the request is then approved.
* The requesting treating MO and TMS, are notified electronically via BloodSTAR and the affiliated laboratory/pharmacy who issue/dispense the SCIg are notified electronically via BloodSTAR to BloodNet.
* SCIg dose is then requested by the laboratory/pharmacy from Lifeblood and delivered to the requesting laboratory/pharmacy.

**NB:** AsSCIg is a S4 medication it must be prescribed by an authorised practitioner (e.g. a medical practitioner) and dispensed by a pharmacist for home administration.

Further information regarding the [regulatory requirements for health practitioners](https://www.health.vic.gov.au/drugs-and-poisons/health-practitioners)

All [blood and blood products have traceability requirements](https://www.health.vic.gov.au/traceability-requirements-of-blood-and-blood-products)

#### Options for SCIg dispensing

1. The transfusion laboratory (pathology service) orders SCIg in BloodNet and it is traced via the laboratory inventory system (LIS). Lifeblood delivers SCIg to the laboratory and it is then transferred to the pharmacy for dispensing and collection by the patient.
2. The pharmacy orders SCIg in BloodNet and it is traced via the pharmacy system. Lifeblood delivers SCIg to the pharmacy for dispensing and collection by the patient.
3. Regional patients once competent to infuse at home may collect SCIg from a local pharmacy if required/more convenient. The NBA, Lifeblood customer service and Blood Matters Project Nurse (SCIg) can assist setting up this process if the pharmacy is new to the dispensing of SCIg.

## Patient selection criteria

Patients who are eligible for SCIg (or their carer) must be physically and psychologically able to:

* Draw up and administer the SCIg as per patient competency (see appendix A).
* Understand the importance of correct storage, handling, and transport of SCIg.
* Understand safe disposal of medical waste.
* Be compliant with self-administration, documentation and attending for review.
* Understand the importance of reporting adverse effects or any concerns related to treatment.

SCIg may not be appropriate for patients with:

* Extensive skin conditions - psoriasis, eczema
* Cognitive impairment
* Poor manual dexterity, decreased hand grip, tremors, poor eyesight.

## SCIg product comparison\*

#### \*This information has been summarised using the manufacturer’s product information (PI) and has not been subject to manufacturer endorsement. When considering these products, review of the full PI is encouraged.

Note: Xembify® (Grifols) 20% Ig solution will be available January 2024.

#### Presentation

All SCIg products are clear and colourless to a pale yellow or light brown solution. Do not use if particulate matter and/or discoloration is observed.

None of the SCIg products require reconstitution.

|  |  |  |  |
| --- | --- | --- | --- |
| Hizentra® AU (CSL Behring)  20% Ig solution | Hizentra® (CSL Behring)  20% Ig solution | Cuvitru® (Takeda)  20% Ig solution | Xembify® (Grifols)  20% Ig solution |
| Domestic plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL) vials | Imported plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials | Imported plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL) vials | Imported plasma source  Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials |

#### 

#### Storage

Do not freeze, do not use if the solution has been frozen, protect from light, do not use after expiry date.

|  |  |  |  |
| --- | --- | --- | --- |
| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| Store below 25°C. | Store below 25°C. | Refrigerate at 2-8oC. | Refrigerate at 2-8oC.  May be stored ≤25°C for up to 6 months any time prior to expiry date |

#### Stabiliser

|  |  |  |  |
| --- | --- | --- | --- |
| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| Proline | Proline | Glycine | Glycine |

#### Approved therapeutic indications and product dosing guide

The treating medical specialist will determine the SCIg dose for each patient. The dose will be rounded to prevent product waste.

Dosing varies based on indication. Check the manufacturers’ PI for specific dosing. As an example, patients may receive a total dose of 0.4g/kg every 4 weeks. This dose can be divided into 4 weekly doses of 0.1g/kg. Variations in dose and frequency can by individualised by the clinician with the patient. (Younger 2013, NBA criteria 2018).

Example patient weight = 80kgs, 0.4g/kg = 32g, weekly dose of 0.1g/kg = 8g

Patients may require a loading dose of IVIg 1-2 weeks prior to the commencement of SCIg to ensure adequate trough serum IgG level. Different patients will require different IgG levels to remain clinically well and free from infections and different dosing regimens to achieve and maintain appropriate trough IgG levels (Jolles 2014).

It is recommended that patient dosing is individualised per patient and per product and is based on serum IgG trough levels (for replacement therapy) and clinical response. Dosing for patients switching from other subcutaneous or intravenous immunoglobulin treatments to Cuvitru® and Xembify® is outlined in Table 1.

**Product dosing guide**

| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| --- | --- | --- | --- |
| **Replacement therapy** in adults and children in: Primary Immunodeficiency Disease (PID) and Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.  **Dosage guideline:**  A loading dose of at least 0.2-0.5g/kg of body weight may be required.  Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of 0.4 – 0.8g/kg of body weight.  **Immunomodulatory therapy** in patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) as maintenance therapy after stabilisation with IVIg.  **Dosage guideline:**  The recommended subcutaneous dose is 0.2 to 0.4g/kg of body weight per week. The dose may need to be adapted to achieve the desired clinical response. | **Replacement therapy** in adults and children in: Primary Immunodeficiency Disease (PID) and Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.  **Dosage guideline:**  A loading dose of at least 0.2-0.5g/kg of body weight may be required.  Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of 0.4 – 0.8g/kg of body weight.  **Immunomodulatory therapy** in patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) as maintenance therapy after stabilisation with IVIg.  **Dosage guideline:**  The recommended subcutaneous dose is 0.2 to 0.4g/kg of body weight per week. The dose may need to be adapted to achieve the desired clinical response. | **Replacement therapy** in adult and paediatric patients for: Primary immunodeficiency diseases (PID) and Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.  **Dosage guideline:**  A loading dose of at least 0.2-0.5g/kg of body weight may be required.  Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of 0.3 – 1.0g/kg of body weight.  See PI for further information regarding dosing. | **Replacement therapy** in adult and paediatric patients for: Primary immunodeficiency diseases (PID) and Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.  **Dosage guideline:**  A loading dose of at least 0.2-0.5g/kg of body weight may be required.  Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of 0.4 – 0.8g/kg of body weight.  See PI for further information regarding dosing. |

Table 1: Cuvitru® and Xembify® dosing for patients switching from other subcutaneous or intravenous immunoglobulin treatments

|  | Weekly | Biweekly (fortnightly) | Frequent dosing (2-7 times per week) |
| --- | --- | --- | --- |
| For patients switching from immunoglobulin subcutaneous (human) treatment (SCIg): | The weekly dose of Cuvitru® or Xembify® (in grams) is recommended to be the same as the weekly dose of prior SCIg treatment (in grams)# | Biweekly dosing: Multiply the calculated weekly dose by 2 | Divide the calculated weekly dose by the desired number of times per week |
| For patients switching from immunoglobulin intravenous (human) treatment (IVIg)+ | To calculate the initial weekly dose, divide the previous IVIg dose in grams by the number of weeks between intravenous doses | Biweekly dosing: Multiply the calculated weekly dose by 2 | Divide the calculated weekly dose by the desired number of times per week |

#To convert the dose (in grams) to millilitres (mL), multiply the calculated dose (in grams) by 5.

+Begin treatment with Cuvitru or Xembify® one week after the patient’s last IVIg.

#### Infusion rate

| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| --- | --- | --- | --- |
| Infusion device/pump - initial infusion rate should not exceed 20mL/hr/site. If well tolerated infusion rate can be gradually increased to 35mL/hr/site for the subsequent two infusions. Thereafter, the infusion rate can be further increased as per the patient’s tolerability.  If larger doses are given >50mLs /site administration via multiple sites is recommended.  Manual push - the recommended initial infusion rate should not exceed 0.5 mL/min (30 mL/hour/site).  If well tolerated, the infusion rate can be increased up to 2.0 mL/min/site (120 mL/hour/site), based on the healthcare professional’s judgement and patient’s individual tolerability. | Infusion device/pump - initial infusion rate should not exceed 20mL/hr/site. If well tolerated infusion rate can be gradually increased to 35mL/hr/site for the subsequent two infusions. Thereafter, the infusion rate can be further increased as per the patient’s tolerability.  If larger doses are given >50mLs /site administration via multiple sites is recommended.  Manual push - the recommended initial infusion rate should not exceed 0.5 mL/min (30 mL/hour/site).  If well tolerated, the infusion rate can be increased up to 2.0 mL/min/site (120 mL/hour/site), based on the healthcare professional’s judgement and patient’s individual tolerability. | Recommended initial infusion rate is 10mL/hr/site gradually increased to 20mL/hr/site as tolerated for the initial two infusions. Subsequent infusion rate and volume/site based on patient tolerability. | Recommended infusion rate for first two infusions should not exceed 25mL/hr/site.  Subsequent infusions – gradually increase to 35mL/hr/site based on patient comfort & tolerability. |

#### IgA level

For IgA deficient patients, product with the lowest IgA level should be selected. The treating clinician should discuss IgA deficiency with the patient.

| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| --- | --- | --- | --- |
| ≤ 0.05mg/mL (normally below 0.005mg/mL) | ≤ 0.05mg/mL (normally below 0.005mg/mL) | Average IgA concentration is 0.08 mg/mL | <0.16mg/mL1 |

#### 1email communication from Grifols

#### Contraindications

* Patients who have had a true anaphylactic reaction to the active substance or to the product stabiliser.
* Hizentra® AU and Hizentra® are contraindicated in patients with hyperprolinemia type I or II.
* Patients with severe IgA deficiency and a history of hypersensitivity to human immunoglobulin treatment.

#### Precautions

For **subcutaneous** administration only and **must not** be administered intravenously.

If inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be implemented.

**Aseptic Meningitis Syndrome (AMS)**

* AMS has been reported to occur in association with SCIg treatment. Discontinuation of SCIg treatment may result in remission of AMS within several days without sequelae.

**Thromboembolism**

* There is clinical evidence of an association between immunoglobulin administration and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thromboses.
* Caution should be exercised in patients with pre-existing risk factors for thrombotic events and with obese patients. Risks such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilia disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, and patients with diseases which increase blood viscosity.
* Patients should be sufficiently hydrated prior to the use of immunoglobulins.
* Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.
* For patients at risk of thrombosis, minimum dose and infusion rate should be considered.
* See PI for further information.

**Severe renal adverse reactions**

* Reports of renal dysfunction and acute renal failure in patients receiving immunoglobulin products. Patients at increased risk are those with pre-existing renal insufficiency, diabetes mellitus, age greater than 65 years, volume depletion, sepsis, hyperviscosity and paraproteinaemia, and those taking concomitant nephrotoxic drugs.
* Caution using products containing sucrose, current formulations available in Australia do not contain sucrose.
* SCIg should be administered at the minimum rate of infusion and dose practicable in patients at risk of acute renal failure.
* Although the majority of renal adverse events have occurred with sucrose containing IVIg products, caution is also advised during administration of any SCIg product.
* See PI for further information.

**Hypersensitivity**

| Hizentra® AU | Hizentra® | Cuvitru® | Xembify® |
| --- | --- | --- | --- |
| Hypersensitivity reactions may occur even in patients who had tolerated previous treatment with human normal immunoglobulin. Severe hypersensitivity or anaphylactic reactions up to shock can particularly occur in patients with known anti-IgA antibodies. | Hypersensitivity reactions may occur even in patients who had tolerated previous treatment with human normal immunoglobulin. Severe hypersensitivity or anaphylactic reactions up to shock can particularly occur in patients with known anti-IgA antibodies. | True hypersensitivity reactions may occur. They can particularly occur in cases of IgA deficiency with anti-IgA antibodies and these patients should be treated with caution. Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. | True allergic reactions are rare.  They can particularly occur in patients with anti-IgA antibodies and these patients should be treated with caution. Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. |

#### Pathogen safety and infection control

See PI for specific pathogen safety steps.

SCIg products do not contain antimicrobial preservative. Therefore, they must be used immediately after opening/spiking the bottle. Use in one patient on one occasion only. Any unused portion should be discarded appropriately.

#### Drug interactions

Immunoglobulin administration may impair for a period of at least six weeks and up to three months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. After administration of SCIg an interval of three months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to one year. Therefore, patients receiving measles vaccine should have their antibody status checked.

See PI for further information.

#### Use in pregnancy

The safety of SCIg products for use in human pregnancy has not been established in controlled clinical trials and therefore it should only be given with caution to pregnant women. Immunoglobulin products have been shown to cross the placenta, increasingly during the third trimester.

Clinical experience with immunoglobulins suggests that no harmful effects on the pregnancy course or foetus/ neonate are to be expected.

#### Use in lactation

During breast-feeding immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate.

Physicians should balance the potential risks and only prescribe SCIg if clearly needed.

#### Effects on fertility

No reproductive toxicity studies have been conducted. Based on clinical experience with immunoglobulins it is suggested that no harmful effects on fertility are to be expected.

#### Paediatric use

Clinical trials with all SCIg products showed a similar safety profile in paediatric and adult patients. Hizentra®, Cuvitru® and Xembify® has not been formally studied in paediatric patients under two years of age. Note – no studies have been conducted with Hizentra® AU. All studies quoted in the Hizentra® AU PI relate to Hizentra®.

#### Use in the elderly

Limited information available in clinical trials showed no elderly specific dose requirements necessary to achieve the desired serum IgG levels. When administering Cuvitru monitor patients who are at an increased risk for developing renal failure or thrombotic events. Do not exceed the recommended dose and infuse at the minimum infusion rate practicable.

#### Genotoxicity and carcinogenicity

No genotoxicity or carcinogenicity studies have been conducted.

#### Product information references:

[Hizentra AU](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2020-PI-01937-1&d=20231015172310101)

[Hizentra](https://labeling.cslbehring.com/PI/AU/Hizentra/EN/Hizentra-Product-Information.pdf)

[Cuvitru](https://www.guildlink.com.au/gc/ws/tk/pi.cfm?product=tkpcuvit11220)

[Xembify](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01660-1)

## Equipment and consumables for SCIg administration

SCIg administration can require specific equipment and consumables (see appendix B)

* Infusion pump,
* Subcutaneous needles and tubing,
* Luer lock syringes(s) (must fit pump if used),
* Drawing up needles or vented dispensing pins,
* Alcohol swabs or skin prep,
* Surgical tape/dressing,
* Small band aid or gauze,
* Sharps container,
* Transport bag and ice brick if required (Evogam® and Cuvitru® are stored at 2-8°C),
* Patient treatment record/Infusion diary/product App,
* Antibacterial wipes or soapy water (to clean SCIg preparation area/placemat).

#### Types of pumps and infusion sets

The information below is an example of equipment and consumables available. Blood Matters do not endorse the use of any particular equipment/resources. Health services should clarify the information with the suppliers independently and source equipment available and purchase equipment appropriate to their patient needs.

**EMED Technologies**

**SCIg 60 infusion system** – pump, rate control dial and needles (24 & 27 gauge – 1, 2, 3, 4 lumens – 4, 6, 9 & 12mm length). The 24-gauge needles are the most appropriate for ‘push’ administration as it allows the viscous SCIg to be administered with less force by the patient. The smaller the lumen the more difficult it is to push. The multiple lumens allow for faster total administration. If patients’ dose is greater than 25mL in volume, it is advisable to administer in multiple sites. This pump is an option for patients who have dexterity issues, as it does not require force to operate, and the rate control dial allows the patient to easily control the rate of administration.

**Contact details:**  (02) 9450 2400 Website: <https://www.emedtc.com/products>

**Go Medical Industries**

**Springfuser® syringe infusion pump** – 10, 30 & 50 **Flow Control Tubing** – (FCT) constant subcutaneous (SC) infusions in either a 10mL, 30mL or 50mL configuration at a variety of pre-set flow rates. Tubing sets include syringe. Needles are required to be purchased from other suppliers. The FCT has been tested with fluid less viscous than SCIg and as such, flow rates may vary.

NB: the Springfuser® is not validated specifically for SCIg use, which may lead to issues with procurement of this device for SCIg infusion.

**Contact details:** (08) 9388 1700 [info@gomedical.com.au](mailto:info@gomedical.com.au) Website: [Go Medical Industries Pty Ltd - Home](http://www.gomedical.com.au/)

**Clinect**

**Neria needles** Neria (steel cannula) - 27gauge needle – 1, 2 and 4 lumen (8mm and 10mm cannula length) Neria (soft cannula) – 27gauge needle – 1 lumen (9mm) Health Purchasing Victoria (HPV) approved – the Neria range is approved and listed on the HPV tender. The 27G cannulas are small and therefore better to be used with pumps rather than the ‘push method’. Neria has a luer-lock connection and is compatible with all pumps.

**Contact details:**

Please contact Clinect on the email or phone number below for product support including insertion instruction videos and patient brochures. (03) 9918 5555 [info@clinect.com.au](mailto:info@clinect.com.au) Website: [www.clinect.com.au](http://www.clinect.com.au)

**REM systems**

Suppliers of BD BodyGuard™T syringe driver. **BD BodyGuard™T** - Can hold syringes 2-50 mL – the maximum volume of the syringe is dependent on the syringe brand.

Table 2: Maximum syringe volume when using BD BodyGuard™T syringe driver

|  |  |  |  |
| --- | --- | --- | --- |
| Syringe brand | 20mL | 30mL | 50mL |
| Monoject | 18.7mL | NA | NA |
| Braun Omniflix | 20mL | 24.4mL | 37.7mL |
| BD Plastipak | 18mL | 23.5mL | 34.9mL |
| Terumo | 18.6mL | 24.5mL | 38.0mL |
| Codan | 20mL | 22.5mL | 35.9mL |

REM systems has available both online and face to face training to ensure you are confident in the use of the BD BodyGuard™ T.

**Contact details:**

1800 737 222 [customerservice@REMsystems.com.au](mailto:customerservice@REMsystems.com.au) Website: [www.remsystems.com.au](http://www.remsystems.com.au)

**Medical devices**

Suppliers ofSCIg validated infusion devices and needles.

**HigH-Flo needles™** -available in 24 and 26 gauge with a variety of needle lengths (4-14mm depending on gauge) and configurations from single to four needle sets for 24 gauge and single to six for 26 gauge.Use of multiple configurations with a Y-connector could increase the number of sites. **FREEDOM60® syringe infusion system** (60mL syringe) **FreedomEdge® syringe infusion system** (20-30mL syringes)

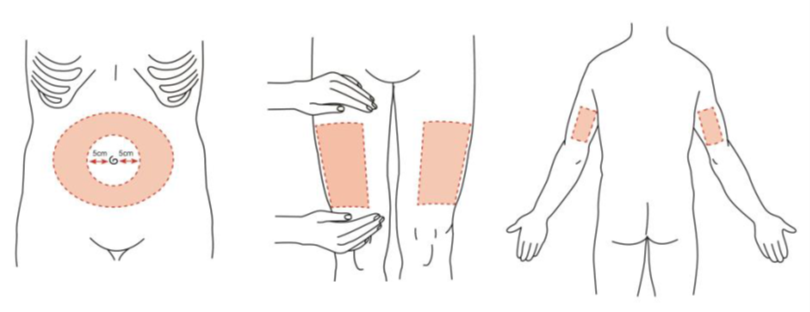
**Contact details:**

1800 77 51 51 [support@medicaldevices.com.au](mailto:support@medicaldevices.com.au) Website: <http://medicaldevices.com.au/syringe-infusion-systems/>

## Infusion site selection

SCIg is administered subcutaneously. Usually, the lower abdomen will be used. Ensure selected site is at least 5cms from umbilicus ‘belly button’. The outer edge of the thigh or back of the upper arm can also be used. The shaded areas in Figure 2 can be used for insertion of the needle. <https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2017.pdf>

Figure 2: Infusion sites



## Product administration procedure

#### Infusion process: in the health service

**Prior to commencing the infusion check:**

* The patient has consented to receive SCIg as per health service requirements.
* SCIg has been prescribed (product, dose, rate, route, and frequency).
* The correct SCIg product has been issued.
* SCIg has reached room temperature prior to infusion.
* The correct corresponding infusion protocol for the patient has been identified (manual push or via infusion device/pump). The choice of administration technique and equipment is at the discretion of the treating healthcare professional and the patient, based on availability of devices and personal preference.
* Baseline observations have been taken and recorded.
* Any pre-infusion symptom which may be confused with an adverse reaction has been noted.
* The patient is well hydrated.

**Checking the patient, product and prescription:**

* Check patient identity following usual health service protocol.
* Check you have the right product as prescribed for this patient.
* Check you have the right dose for this patient.
* Check you have the right date/time the infusion is due.
* Check the expiry date of the product – do not use if expired.
* Check that the product meets the visual inspection criteria.
* Document pre administration checks as per health service protocol.
* Check you have the right rate of infusion. Different SCIg products are given according to different infusion schedules and patient clinical need.
* Please be aware that infusion volumes per site/per infusion vary between products(refer to PI).
* Products/preparations are not interchangeable. Change only occurs if there is a clinical reason for change and a new authorisation and prescription has been obtained.

#### Observations: in the health service

Perform and document the patient’s temperature, pulse, respiration rate and blood pressure at the following points as a minimum:

* prior to commencing
* on completion
* post infusion observation – patients naïve to human normal immunoglobulin, patients switched from an alternative product or when there has been a long interval since the previous infusion should be monitored for the first hour after the first infusion. All other patients should be observed for at least 20 minutes post completion.
* Additional observations may be required based on patient’s clinical condition eg adverse event.
* Please be aware that local policies may require more frequent observations.

#### Administration instructions

* Wash hands and set out equipment and consumables on a clean surface.
* Remove the protective cap from the vial and wipe the rubber stopper with alcohol.
* Draw SCIg into infusion syringe using drawing up needle or vented dispensing pin.
* Slowly inject air into the air in the vial that is equivalent to the amount of SCIg to be withdrawn. Then withdraw the SCIg from the vial. If multiple vials are required to achieve the desired amount of SCIg, repeat this step.
* Once required dose is withdrawn into the syringe attach the infusion set with the required number of needles.
* Prime the infusion set with the SCIg leaving approximately 2-5cm of air at the needle end.
* Clean the injection site/s with antiseptic solution.
* Grasp the skin between two fingers and insert the needle/s into the subcutaneous tissue.
* SCIg must not be injected into a blood vessel. To test the needle/s are not located in a blood vessel, gently pull back on the syringe plunger and look to see if any blood is flowing back into the tubing. If you see any blood, remove and discard the needle and tubing. Repeat priming and needle insertion steps using a new infusion set and a new infusion site.
* Secure the needle/s with tape or transparent dressing.
* Infuse SCIg slowly by push or pump at the specified administration rate.
* Infusion rate and site/s may be changed if required.
* Multiple injection sites can be used simultaneously. Injection sites should be at least 5cm apart and 5cm from the umbilicus.
* Remove the peel-off label from the SCIg vial and insert into the patient treatment record or diary or scan barcode into the product App.

#### Completion of infusion

* At completion of the infusion leave the syringe attached to the infusion set.
* Remove the dressing and pull the needle/s out of the skin.
* Cover injection site/s with band aid/gauze and apply light pressure to the injection site/s.
* Human immunoglobulins are a biohazard – equipment and vials cannot be disposed of in general household waste.
* The needle/s, infusion set, syringes and empty vials must be discarded in a sharps container.
* Once the sharps container is full return it to the health service for disposal.

## Adverse effects and management

Adverse effects most commonly tend to be infusion site related. Figure 3 shows a typical mild and moderate injection site reaction.

Figure 3: Mild and moderate injection site reactions

Mild injection site reaction Moderate injection site reaction

Table 3 and 4 outline possible adverse effects and management for SCIg related products. Please refer to individual PI for specific risk profiles.

Slower rate of infusion and increased monitoring may be considered for patients who receive SCIg:

* for the first time,
* when switched from an alternative product,
* when there has been a long interval since the previous infusion (8 weeks).

Table 3: Possible adverse effects for SCIg products

| Very common | Common | Rare |
| --- | --- | --- |
| Infusion site related  Headache  Fever  Nausea  Vomiting  Diarrhoea | Chills  Back pain  Arthralgia  Hypotension  Dizziness | Allergic reactions  Anaphylactic shock  Thromboembolism  Renal complications  Haemolysis  Transmissible agents  Urticaria  Aseptic meningitis |

Table 4: Adverse effect management at home (Ensure to record all adverse effects in patient diary)

| Reaction | Action 1 | Action 2 |
| --- | --- | --- |
| Mild: (common skin reaction) Swelling and redness at insertion site | Apply cold pack to the area | Take paracetamol or antihistamine if instructed/ordered. Swelling should resolve over next 24-48hrs |
| Moderate: Headache, flushing, nausea, shivering, itching, muscle aches, anxiety, dizziness, irritability | STOP infusion for 30 minutes | Restart when symptoms have gone. Take paracetamol/ antihistamine if instructed/ordered |
| Severe: Chest pain, wheezing, severe itching or any mild or moderate symptoms as above become worse | STOP infusion  Call 000 for urgent medical assistance  Lie or sit down as comfortable | Inform your doctor or nurse specialist as soon as able |

#### Troubleshooting

Table 5 outlines potential issues during SCIg administration and the related actions.

Table 5: Troubleshooting issues and actions

|  |  |
| --- | --- |
| Issues | Actions |
| Injection site reactions  Blanching  Redness/rash  Itching  Discomfort  Swelling | Assess for tape allergy – change to paper/ hypoallergenic tape.  Assess needle size – choose needle that is consistent with volume to be infused.  Assess length of needle – may be too short and infusing into the intradermal layer.  Assess site location – may be too close to muscle layer.  Decrease rate of infusion or volume per site.  Avoid tracking of Ig through the intradermal layer check needle tip is dry prior to insertion.  Consider appropriateness of rotating infusion site.  Consider use of topical anaesthetic cream. |
| Leaking at insertion site | Assess needle – ensure fully inserted and fixed securely.  Assess placement – is it in area of movement, consider alternative site.  Assess length of needle – may be too short, change to longer needle.  Assess infusion volume – decrease amount per site.  Assess rate of infusion – slowing rate may help. |
| Extreme discomfort with needle | Assess needle length ensure not too long and irritating abdominal wall.  Assess needle is being inserted ‘dry’ to prevent tracking through intradermal layer.  Consider using needleless indwelling subcutaneous catheter device.  Consider using ice or topical anaesthetic cream prior to insertion. |
| Long infusion time | Ensure SCIg ready to use at room temperature.  Assess volume per site, rate of infusion, number of sites or adjust infusion regimen.  Check equipment for clamps/kinks, correct selection of needle size, tubing.  If using a pump check function, battery power is not low. |
| Blood return observed | Remove and discard needle with blood return and reinsert with new insertion needle and site. |

<https://www.slideshare.net/DallasAllergyImmunology/immunoglobulin-replacement-therapy>

#### Adverse effect reporting

Adverse effects should be reported using an in-house quality management system and to the relevant product manufacturer.

Adverse event forms are available directly from the product manufacturer:

CSL Behring email: [medicalinformation@cslbehring.com.au](mailto:medicalinformation@cslbehring.com.au)

Takeda email: [medinfoapac@takeda.com](mailto:medinfoapac@takeda.com)

Grifols email: [australia\_medinfo@grifols.com](mailto:australia_medinfo@grifols.com)

Or contact the Lifeblood transfusion nurses (TN) in your state/territory who will forward a copy. Lifeblood Victorian/Tasmanian TN email: [vtatn@redcrossblood.org.au](mailto:vtatn@redcrossblood.org.au)

Where a change of product is required, this is done via BloodSTAR using a dose/product change authorisation request by the treating Medical Officer. NBA has a tipsheet to assist [BloodSTAR-Requesting a Product and Dose Change or an Additional Dose\_0.pdf](https://www.blood.gov.au/sites/default/files/BloodSTAR-Requesting%20a%20Product%20and%20Dose%20Change%20or%20an%20Additional%20Dose_0.pdf)

There is an option to create an alert in BloodSTAR to prevent further dispensing the offending product. The alert can be added by the treating Medical Officer. The NBA has a tip sheet to assist [BloodSTAR - Do Not Prescribe function - tip sheet.PDF](https://www.blood.gov.au/sites/default/files/BloodSTAR%20-%20Do%20Not%20Prescribe%20function%20-%20tip%20sheet.PDF)

## Nurse competency

The nurse providing education to patients receiving SCIg should demonstrate an understanding and competency in regard to the following:

* Patient assessment to ensure appropriate selection
* Contraindications of SCIg therapy
* Health service policy and procedure documents
* Understanding of what immunoglobulins are, and why replacement is necessary
* SCIg product types
* SCIg and the criteria for use
* Documentation of SCIg batch number, expiry date, infusion site/s, dose given, volume per infusion site
* Product preparation
* Infusion techniques
* Infusion sites
* Equipment
* Storage, handling, and transporting SCIg
* Patient monitoring including required pathology tests and frequency
* Adverse effect management and reporting
* Correct disposal of equipment
* Ordering and dispensing of SCIg and where dispensed
* BloodSTAR – login, planning, monitoring and troubleshooting
* Patient education requirements and resources available.

(Ozerovitch 2013, Younger et. al. 2015)

## Patient education

Education should be tailored to each individual’s ability to learn. The time involved and the number of training sessions required for the individual to perform the procedure, feel comfortable and competent to self-administer at home will vary and needs to be considered when commencing training. A range of education materials should be utilised to meet individual needs. Early and frequent reassessment during the first few months of therapy may be required to achieve this (Younger et. al. 2015).

Education may be undertaken in the health service by a SCIg Coordinator/Nurse, or through the CSL Cares, Cuvitru at Home or Grifols Connex patient support programs or other approved nursing service in the patient’s home.

#### Home treatment: patient education requirements

Participants must receive appropriate training and education prior to home self-administration. They must:

* Understand transport and storage requirements of the product prescribed.
* Be able to select appropriate infusion sites and care for the site.
* Describe equipment and consumables necessary to complete procedure.
* Describe SCIg administration procedure and safe removal and disposal of needle, infusion set and vials.
* Understand how to use infusion device/pump, and what to do when not working or if alarm sounds.
* Understand ‘push’ method as an alternative if required.
* Understand how to check and prepare product.
* Demonstrate ability to prepare infusion site and draw up single or multiple vials and prime infusion set.
* Demonstrate insertion of subcutaneous needle/catheter.
* Check for blood and discuss actions to take if blood is present.
* Demonstrate appropriate aseptic technique.
* Understand potential adverse events/reactions that could result from the infusion and their management.
* Understand ordering and collection of product and consumables.
* Understand how to report wastage and return unused product.
* Document/record treatment in patient treatment record/diary/App.
* Document and report wastage.

#### Examples of patient training checklists and templates

* Appendix A for patient education template
* Example [Training Checklist for Home Administered Subcutaneous Immunoglobulin (SCIg) Infusion Treatment](https://www.blood.gov.au/system/files/documents/scig-training-checklist-for-patients.pdf) – NBA

CSL Behring, Takeda and Grifols have a large range of information, treatment record diaries and other resources available for both patients and health care providers:

* Contact CSL Behring at: [customerservice@cslbehring.com.au](mailto:customerservice@cslbehring.com.au) or for customer service enquiries for plasma-derived therapies within Australia phone: 1800 063 892
* Contact Takeda at: [medinfoapac@takeda.com](mailto:medinfoapac@takeda.com) or go to the [Takeda website](https://www.takeda.com/en-au/what-we-do/our-products/) for detailed instructions for administration
* Go to [Grifols Gateway](https://www.gatewayhcpportal.com.au/en/login) to access educational resources, patient brochures and product information
* Patient information brochures located on the [NBA website](https://www.blood.gov.au/system/files/documents/scig-trifold-patient-information-brochure20160307.pdf)
* Australian Primary Immunodeficiency Patient Support (AusPIPS) information brochure located on the [AusPIPS website](https://www.auspips.org.au/about-immunoglobulin-ig-brochure)

## Documentation

The patient is required to record their treatment. This can be done using a patient treatment record (see appendix C), or product providers treatment diary or App.

Information required:

* Product name
* Batch number
* Dose
* Volume
* Infusion time
* Infusion site
* Infusion rate
* Symptoms/side effects.

## Product and consumable order and collection

Patients should liaise with the SCIg Coordinator/Nurse regarding product and consumable requirements.

* A maximum of two months’ supply of SCIg product can be dispensed.
* The equipment checklist (see Appendix B) can be used as an aid to ensure the patient has a sufficient supply of consumables.

## Follow up/review

Patients should be medically reviewed on a six-monthly basis. The review information is entered into BloodSTAR.

The SCIg Coordinator/Nurse should review the patient regularly. This can be at the discretion of the treating team and SCIg Coordinator based on patient need. The purpose is to review the patient treatment record (Appendix C) and discuss any adverse events or issues.

## Transport recommendations

* All products need to be taken directly home and stored as directed (don’t stop to shop on the way home).
* Cuvitru® and Xembify® 2-8°C.
* Hizentra® AU and Hizentra® < 25°C.
* Don’t put products in the car boot for travel (too hot, too easily forgotten); it must be in the car body.
* If travelling by plane the product should be taken as carry-on luggage and stored as directed, never in checked luggage.

## Wastage

* Expired or unused SCIg product vials must be returned to the health service/pharmacy and not discarded in household waste.
* Record all waste/unused SCIg product vials on the patient treatment record/treatment diary/App.
* The NBA has a tip sheet to assist [Managing-broken-vials.pdf (blood.gov.au)](https://www.blood.gov.au/system/files/Managing-broken-vials.pdf)

## Appendix A: Example of a patient education competency template

Affix Patient identification label here

Insert health service details……………………………………..

The person administering the SCIg must be assessed as competent by the clinician prior to transitioning to home-based self-administration.

The number of training sessions required are individualised for each patient.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Session 1**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 2**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: | **Session 3**  Date:\_\_/\_\_/\_\_  Clinician Name:  Signature: |
| Competent (C)/Not yet competent (NYC) | **C/NYC** | **C/NYC** | **C/NYC** |
| Describes transportation & storage of SCIg |  |  |  |
| Describes SCIg administration & infusion site/s |  |  |  |
| Demonstrates infusion sites and appropriate selection |  |  |  |
| Understands equipment required |  |  |  |
| Understands us of infusion device/pump (*if infusion device/pump used)* |  |  |  |
| Demonstrates “push” method (patient must be aware even if infusion device pump is used) |  |  |  |
| Demonstrates SCIg product checking – type, dose, expiry, discolouration |  |  |  |
| Demonstrates drawing up SCIg from single or multiple vials (aseptic technique) |  |  |  |
| Demonstrates priming the giving set and pump set up (where pump used) |  |  |  |
| Demonstrates infusion site skin preparation |  |  |  |
| Demonstrates subcutaneous needle/catheter insertion - no touch (aseptic) technique |  |  |  |
| Demonstrates needle/catheter taping |  |  |  |
| Checks for blood return and understands process if blood is present |  |  |  |
| Demonstrates ability to remove and safely discard needle/s |  |  |  |
| Demonstrates ability to accurately record treatment in patient treatment record/diary/app |  |  |  |
| Understands how to report waste and return unused SCIg |  |  |  |
| Understandings adverse effects and how to manage them |  |  |  |

Created using NBA, Sunshine Health Service documents, Younger et. Al. 2015

## Appendix B: Recommended consumable supply list template

Affix Patient identification label here

Insert hospital details……………………………………..

A guide to equipment required by patient

|  |  |
| --- | --- |
| Consumable | Amount required |
| Small coolers – ice bricks if required. Cuvitru®/Xembify® stored 2-8OC  Utilise cooler in cases of extreme heat and long travel distance for Hizentra® AU and Hizentra® to ensure product remains below 25OC. | Provided by patient/ CSL Behring /Takeda/Grifols |
| Plastic container to store SCIg in refrigerator | Provided by patient |
| Infusion device/pump enter details of equipment selected if using this infusion method |  |
| Luer lock syringe 10mL, 20mL ,30mL, 50mL, other size if required |  |
| Drawing up needle 19 gauge or vented dispensing pin |  |
| Subcutaneous infusion set - add details of choice |  |
| Infusion extension set if required |  |
| Transparent film dressing if required |  |
| Alcohol prep swabs |  |
| Antibacterial surface cleaner wipes |  |
| Surgical tape |  |
| Cotton wool balls |  |
| Band-aids |  |
| Sharps container (exchange when full) |  |
| Patient treatment record/diary/App |  |
| Topical anaesthetic cream if required e.g. EMLA cream |  |

Created using Sunshine Health Service, Duff et. al. 2013, Younger et. al. 2013.

## Appendix C: Patient treatment record template

*Affix Patient identification label here*

Insert hospital details…………………………………….

**Healthcare team contact details**

Hospital /Clinic name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Specialist name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ email: (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Nurse name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ email: (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

General Practitioner name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Product: (circle) Hizentra® AU, Hizentra®, Cuvitru®, Xembify®, Dose:\_\_\_\_\_\_\_g / \_\_\_\_\_\_\_\_\_mL Frequency:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Infusion Record**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Date/time |  |  |  |  |  |  |  |  |
| Volume |  |  |  |  |  |  |  |  |
| Site/s used |  |  |  |  |  |  |  |  |
| Infusion time |  |  |  |  |  |  |  |  |
| Infusion rate |  |  |  |  |  |  |  |  |
| Adverse event |  |  |  |  |  |  |  |  |
| Medications used |  |  |  |  |  |  |  |  |
| Batch numbers (affix label/s) |  |  |  |  |  |  |  |  |
| Notes |  |  |  |  |  |  |  |  |

**Next appointment date:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Created using CSL Behring ‘Hizentra®’, Sunshine Health Service, Duff et. al. 2015, Younger et.al. 2013. NB: CSL Behring have patient record booklets available for Hizentra® AU and Hizentra®. Takeda have a patient record booklet available for Cuvitru®. Grifols have a patient record booklet available for Xembify®.

## Reference list/recommended reading

### National Blood Authority

<http://www.blood.gov.au/Ig-governance> Ig governance document

<https://www.blood.gov.au/system/files/documents/Governing%20requirements%20for%20a%20hospital%20based%20SCIg%20program.pdf> Governing requirements for a health service based SCIg program

<https://www.blood.gov.au/system/files/BloodSTAR-Tip-Sheet-SCIg-Nurses.pdf> SCIg planning tip sheet for Dispensing via BloodSTAR

<https://www.blood.gov.au/system/files/documents/p5.1_scig_poster_0.pdf>

[Ig Governance - Decision Support Home Page (blood.gov.au)](https://www.criteria.blood.gov.au/)

### Australian Red Cross Lifeblood

[Resource library | Lifeblood](https://www.lifeblood.com.au/health-professionals/learn/resource-library?query=comparison%20of%20sub&category=All&filetype=All&sort_bef_combine=changed_1_DESC) IVIg comparison table

[Resource library | Lifeblood](https://www.lifeblood.com.au/health-professionals/learn/resource-library?query=comparison%20of%20sub&category=All&filetype=All&sort_bef_combine=changed_1_DESC) SCIg comparison table

**Transfusion.com.au**

[WI-00635\_v9.pdf (lifeblood.com.au)](https://www.lifeblood.com.au/sites/default/files/resource-library/2021-12/2._WI-00635_v9.pdf) Shipper info

[Subcutaneous (SCIg) | Lifeblood](https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/SCIg) SCIg fact sheet

### CSL Behring

[Hizentra AU consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2023-CMI-01369-1)

[Hizentra AU product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-01937-1&d=20231015172310101)

[Hizentra consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-CMI-01958-1)

[Hizentra product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2014-PI-03180-1)

### Takeda

[Cuvitru consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-CMI-02577-1)

[Cuvitru product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01104-1)

### Grifols

[Xembify consumer medicine information (CMI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-CMI-01658-1&d=20231015172310101)

[Xembify product information (PI)](https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-PI-01660-1)

### Other websites

Australasian Society of Clinical Immunology and allergy (ASCIA) <https://www.allergy.org.au>

[ASCIA\_HP\_Position\_Statement\_SCIg\_2018.pdf (allergy.org.au)](https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Position_Statement_SCIg_2018.pdf)

<https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Clinical_Update_PID_2017.pdf>

[ASCIA PID Clinical Update (allergy.org.au)](https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_IRT_PID_Position_Statement_2022.pdf)

[Patient Support - IDFA](https://www.idfa.org.au/patient-support/)

[AusPIPS – Advocacy and support for people with PID](https://www.auspips.org.au/)

[2001377\_AusPips Brochure\_English\_A4\_v6.5.pdf](https://www.auspips.org.au/files/2001377_AusPips%20Brochure_English_A4_v6.5.pdf)

## Journal Articles

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Other examples are available at [Blood Matters website](https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/speciality-diagnostics-therapeutics/blood-matters) and are available for use with appropriate acknowledgments /permission

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