Procedure

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Administration and Management of Immunoglobulin

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Purpose and Objective

Human immunoglobulin products are human plasma derived blood products, registered for use in Australia for the treatment of a range of neurological, immunological, haematological and other conditions where immune replacement or immune modulation therapy is indicated.

Immunoglobulin (Ig) is a precious blood product, however, due to the high cost of Ig and the demand for its use in Australia, eligibility for access to government-funded Ig is managed through strong governance arrangements.

Under the National Ig Governance Program , the National Blood Authority (NBA) contracts the Australian Red Cross Lifeblood (Blood Service) to provide clinical advice, access and authorisation of requests to those involved in the management, distribution and use of Ig in accordance with the Criteria for the clinical use of immunoglobulin in Australia. When prescribing and managing the use of government-funded Ig products, health professionals must comply with the National Policy.

This procedure outlines the administration and management of immunoglobulin products within the SCHHS in alignment within the relevant legislation, National Blood Authority Policy and National Safety and Quality Health Service Standards.

Sunshine Coast Hospital and Health Service (SCHHS) staff (permanent, temporary, and casual) and undergraduate students (Medical, Nursing and Midwifery) on placement within SCHHS who are involved with the collection, storage and transfusion of blood and blood products and provides guidance in areas central to the provision of transfusion therapy.

The scope of this document includes intravenous and subcutaneous Immunoglobulins supplied by the Blood Service via Pathology Queensland and Private Pathology providers: Intragam®, Privigen®, Gamunex, Flebogamma®, Octagam, Evogam®, Hizentra® and Cuvitru®.

Paediatric Patients

Paediatric patients within SCHHS are to be administered IVIg and SCIg aligning with the Children's Health Hospital and Health Service's Blood and Blood Products Intravenous Immunoglobulin IVIg procedure and Subcutaneous Immunoglobulin procedure.

Requisite training

It is a requisite that all staff members involved in the transfusion process complete the Clinical Transfusion Practice module bi-annually available on the Blood Safe eLearning Australia platform , Additionally, Blood Safe eLearning Immunoglobulin courses are available to staff dependent upon their role and responsibilities in their speciality area.

Administration and Management of Intravenous Immunoglobulin (IVIg)

Background

IVIg is a solution of human plasma proteins and IgG antibodies with a broad spectrum of antibody activity. IVIg is prepared from large pools of human plasma collected from several thousand donors and contains the typical IgG antibodies forum in the normal population and administered intravenously for patients who need replacement of antibodies and for autoimmune disorders.

Purpose

This procedure describes the processes for the safe prescription, administration, and management of adverse reactions of IV Ig to adult patients.

All staff must adhere to the procedures, frameworks and guidelines which support this procedure. This procedure supports Blood Product Administration procedure and Blood Product Information Manual the National Safety and Quality Health Service (NSQHS) Standard 7 Blood Management Standard.

Patient Selection for IVIg

To establish if a patient is eligible for access to government funded IVIg, a patient's clinical diagnosis is considered in conjunction with eligibility requirements and indications for Ig use as set out in the Criteria. Considerations include:

- The purpose for which therapy would be considered, to prevent or manage a particular manifestation of the disease
- Qualifying criteria – patient selection, particular disease characteristics, disease severity, requirements for other treatments to have been demonstrably unsuccessful before IVIg is considered
- Exclusion criteria – specific indications and circumstances where IVIg should not be used.
- Dose and frequency – specific to the indications and circumstances to aim for the minimum dose to achieve optimum clinical outcome for the patient.

Contraindications

- Hypersensitivity to the active substance or to the excipient
- Hypersensitivity to homologous immunoglobulins, especially in the very rare cases of IgA deficiency when the patient has antibodies against IgA
- Patients with hyperprolinaemia (Privigen only)
- Patients with known hypersensitivity to the excipient glycine (Gamunex)
- Fructose intolerance (Flebogamma only).

Precautions

- In all patients, Intravenous immunoglobulin (IVIg) administration requires:
- Adequate hydration prior to the initiation of the infusion of IVIg
- Monitoring of urine output
- Monitoring of serum creatinine levels
- Avoidance of concomitant use of loop diuretics
- Monitoring during infusion and for at least 20 minutes after infusion
- Certain adverse reactions may occur more frequently in:
- Cases of high rate of infusion
- Patients with hypogammaglobulinaemia or agammaglobulinaemia with or without IgA deficiency
- Patients who receive IVIg for the first time or, in rare cases, when the human normal immunoglobulin product is switched or when there has been a long interval since the previous infusion

Patients at risk of hypersensitivity events, haemolytic anaemia, thromboembolism, or acute renal failure, see precautions in the specific product information.

Use in specific populations such as pregnancy, lactation and paediatric, refer to the specific product information

Process

Ordering Immunoglobulins

BloodSTAR is a web-based system that facilitates authorisation for access and management of Ig products for the treatment of medical conditions identified in the Criteria. The Australian Red Cross Lifeblood (ARCLB)

continue in their role as the authorisers of Ig products. BloodSTAR user support is available through the SCHHS Blood Management Intranet and the National Blood Authority BloodSTAR Support Material.

BloodSTAR access is required for Prescribers of Ig and Nurses managing Ig Electronic Planning Sheets via BloodSTAR.

Regular clinical review to assess clinical benefit of treatment for ongoing therapy should be conducted at periods specified within the Criteria.

At review, clinical factors and patient's response to therapy are required to be assessed to inform whether to:

- continue therapy – clinical benefit is evident and demonstrable
- cease therapy – clinical benefit is not evident or demonstrable
- alter dose – increase or decrease dosage for improved efficacy, and/or
- change dosage frequency

Authorisation for continuing access and supply of government-funded Ig product will be ceased, in any of the following cases:

- The authorisation end date has been reached and a review has not been recorded within 8 weeks of that date
- Clinical benefit defined in the patient treatment review criteria is not achieved (not evident or demonstrable)
- A Treating Medical Specialist advises that immunoglobulin is no longer required.

Prescribers of IVIg products through BloodSTAR must manage authorisation requests and review outcomes for Ig products.

Patient Consent

Documented consent is not required in Queensland for immunoglobulin, coagulation products or albumin as per Guide to Informed Decision-Making in Healthcare - Queensland Health

As part of the authorisation request for SCIg, patients must consent to their personal details being stored on the BloodSTAR database.

The privacy consent identifies the patient has provided consent either written or oral to:

- Treatment with immunoglobulin products, in accordance with National Safety and Quality Health Service (NSQHS) Standard 7 Blood Management.
- The collection, retention and use of their personal sensitive data for the purpose of authorisation for access to government funded Ig products, in accordance with the Australian Privacy Principles.

This consent is valid for a 12-month period.

An approved competent interpreter must be used when the patient is non-fluent in English.

Prescription

IVIg orders occur either on ieMR, CHARM or on the SCHHS Blood and blood products prescription form depending on the treating area.

IVIg products will be supplied from ARCLB to the hospital blood bank or pathology.

Nursing staff are to collect the blood product from pathology.

Dosing & Frequency

Regular blood tests are required to ensure an adequate circulating level of Ig is maintained. Physiological normal levels of serum IgG should be within normal range. Trough levels should be measured and assessed in conjunction with the patient's clinical response (e.g., infection rates) and adjusted as required by the treating medical officer.

Doses are scheduled to achieve an IgG trough level of at least the lower limit of the age-specific serum IgG reference range.

IVIg Administration

Administration

Individual IVIg products recommend different weight-based rates of infusion. To avoid confusion, the Australasian Society of Immunology and Allergy (ASCIA) has developed standardised infusion rates for both 5% and 10% IVIg solutions regardless of product ASCIA Guidelines -Standardised infusion rate for IVIg replacement therapy. The SCHHS follows these guidelines. IVIg is to be administered as per the SCHHS Blood Product Administration Manual

Adverse reactions

Mild reactions

Mild reactions include flushing, headache, mild changes in HR or blood pressure

These types of reaction may be rate dependent and may respond to a reduction in the rate of infusion. Closely observe the patient and reduce the rate of infusion.

Moderate to severe reactions

Patients should be advised to inform their nurse or medical officer immediately if they experience:

- Signs of allergy such as rash or hives on the skin, swelling of the face, lips, tongue or other part of the body.
- Other reported side effects which occur infrequently, though should be reported to the treating consultant include fatigue, fever, nausea / vomiting, skin rash, stomach pain, headache and jaundice.

Adverse reactions can be related to the rate of the Ig infusion and often resolve with stopping or slowing the infusion rate. However, a medical officer should be informed of all infusion reactions as patients may require review before re-starting the infusion to rule out other pathologies.

All adverse event in should be documented in the patient notes, the incident management system (RISKMAN) and reported to the product supplier.

Consumer information and education

Patients should be provided with education and relevant consumer information before commencing treatment.

Post infusion it is necessary to inform the patient and carer of the delayed symptoms of adverse events prior to discharge. The most common reactions or side effects to Ig products are:

- Severe headache
- Neck rigidity
- Drowsiness
- Fever
- Photophobia
- Nausea and vomiting – This can occur within seven hours to two days following IVIg administration and may indicate an aseptic meningitis syndrome (AMS)

Patients should be instructed to report symptoms to their doctor immediately, or present to their nearest Emergency Department if symptoms are severe. Patients should also be instructed to inform nursing staff of their adverse reaction the next time they present for their infusion.

Administration and Management of Subcutaneous Immunoglobulin (SCIg)

Background

SCIg is used in the treatment of immunodeficiency for those requiring immunoglobulin replacement therapy and for the treatment of autoimmune Chronic demyelinating polyneuropathy (CIDP). The majority of immunoglobulin therapy in Australia is still given intravenously for inpatients or those patients attending an ambulatory day clinic. Subcutaneous Immunoglobulin (SCIg) provides an alternative delivery mode of immunoglobulin therapy for patients with immunodeficiency and CIDP and can have improved quality of life benefits for patients.

Studies have shown that SCIg is effective in maintaining a steady state of Ig levels, and reducing clinical issues associated with peaks and troughs as seen in a monthly regime of intravenous immunoglobulin (IVIg) administration. Other benefits of SCIg include no requirement for intravenous (IV) access, a favourable safety profile, option to deliver treatment at home or work, and a reduced risk of IVIg -related systemic and local reactions.

The National Blood Authority (NBA) has approved the use of SCIg for patients with medical conditions where there is support for use cited in the Criteria for the Clinical Use of Immunoglobulin in Australia 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 HSCT
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (including IgG and IgA paraproteinaemic demyelinating neuropathies).

Purpose

This document outlines the governance surrounding the Sunshine Hospital and Health Service, SCIg Therapy Program, the requirements of training and education for patients and their family/carers to administer SCIg outside the hospital environment, and management of adverse reactions to SCIg products.

All staff must adhere to the procedures, frameworks and guidelines which support this procedure. This procedure supports Blood Product Administration procedure and Blood Product Information Manual the National Safety and Quality Health Service (NSQHS) Standard 7 Blood Management Standard.

Patient Selection for SCIg Program

The treating clinician must approve if a patient is suitable for the self-management and administration of SCIg or have a carer/family member able and willing to do so to ensure appropriate management and use of the SCIg product. For current conditions, please refer to BloodSTAR.

Contraindications

- History of severe allergic reactions to immunoglobulin treatment.
- Patients with a selective immunoglobulin (IgA) deficiency who have a known antibody against IgA.
- Caution should be used in patients with platelet disorders or other bleeding tendencies.
- Clinical studies with pregnant women have not been conducted. If the patient is pregnant or thinks they may be pregnant or if they are breast feeding, discuss with physician whether SCIg is clearly indicated.

Process

Referral Process

All patients require formal referral from treating consultant. The Consultant will then forward the referral to the relevant SCHHS unit and nurse/s to organise the patients SCIg care plan. Patients transferring SCIg care from another HHS to SCHHS require a formal referral from the current treating consultant. The formal referral letter will be sent to the relevant SCHHS Specialist Consultant. Once the referral is approved by receiving SCHHS Specialist Consultant, the Clinician will then provide a referral to the relevant SCHHS unit and nurse/s to organise the patients SCIg care plan. BloodSTAR authorisation will be updated by the SCHHS Specialist Consultant to reflect the new dispensing location.

Ordering Subcutaneous Immunoglobulin

A request for authorisation for a patient is required by the treating clinician through BloodSTAR

- The patient's weight and 'Subcutaneous' as the Infusion Method should be chosen
- The weekly dose, not the monthly dose is required.

See: BloodSTAR Tip Sheet for SCIg Prescribers and SCIg Dosing

The treating clinician must be registered in the system as an approved prescriber and initiate a request by entering relevant patient and diagnosis details and supporting substantiation, as prompted by the BloodSTAR system, to enable an assessment of eligibility to be made against the Criteria.

This includes information to allow a substantiated assessment to be made against requirements such as: Indication for use

- Qualifying criteria
- Exclusion criteria
- Dose and frequency.

The following requirements must be met for the supply of SCIg:

- Submission of Authorisation Request
- ARCL approval for authorisation
- Patient Review: outcomes must be provided on BloodSTAR as requested, within one month of the patient review date, for continued access to SCIg. Patient weight will need to be provided to support requested dosage.

Patient Consent

Documented consent is not required in Queensland for immunoglobulin, coagulation products or albumin as per Guide to Informed Decision-Making in Healthcare - Queensland Health

As part of the authorisation request for SCIg, patients must consent to their personal details being stored on the BloodSTAR database.

The privacy consent identifies the patient has provided consent either written or oral to:

- Treatment with immunoglobulin products, in accordance with National Safety and Quality Health Service (NSQHS) Standard 7 Blood Management.
- The collection, retention and use of their personal sensitive data for the purpose of authorisation for access to government funded Ig products, in accordance with the Australian Privacy Principles.

This consent is valid for a 12-month period.

An approved competent interpreter must be used when the patient is non-fluent in English.

Prescription

SCIg orders occur either on ieMR, CHARM or on the Subcutaneous Immunoglobulin (SCIg) Prescription/Order depending on the treating area.

The ongoing treatment plan for the patient can be accessed via BloodSTAR Dispense Requesting for Subcutaneous Immunoglobulin (SCIg) Product.

The following information is available from the National Blood Authority Website:

- BloodSTAR Tip Sheet for Nurses Dispense Requesting for Subcutaneous Immunoglobulin

Once approval has been given, nursing staff will order multiple doses from BloodSTAR.

- BloodSTAR Tip Sheet Creating and submitting a planning sheet

Inform Blood Bank that an electronic planning sheet has been submitted.

Once a patient is assessed as stable (nil adverse reactions, and after 3 months treatment) ordering and collection of SCIg can occur on a 2-monthly basis.

SCIg products will be supplied from ARCL to the hospital blood bank or pathology.

Nursing staff are to collect the blood product from blood bank or pathology.

Dosing & Frequency

Regular blood tests are required to ensure an adequate circulating level of Ig is maintained. Physiological normal levels of serum IgG should be within normal range. Trough levels should be measured and assessed in conjunction with the patient's clinical response (e.g., infection rates) and adjusted as required by the treating medical officer.

Doses are scheduled to achieve an IgG trough level of at least the lower limit of the age-specific serum IgG reference range.

Although maintenance dosing is the same, the frequency of SCIg is different from Intravenous immunoglobulin (IVIg). SCIg doses may be administered daily, weekly, or biweekly fortnightly as per product information, patient tolerance and choice. Administration of SCIg on a consistent basis (i.e., weekly) results in steady state pharmacokinetics with little fluctuation in IgG levels.

Dosage is to be individualised for each patient and is dependent on the ongoing clinical response and serum IgG trough levels. Dose is formulated by body weight and adjusted to clinical outcome as required.

The first dose of SCIg should be scheduled approximately 2 weeks after the last IVIg or as required by the treating medical officer.

Transport and storage

- Staff will collect the SCIg from the Blood Bank or pathology.
- Ensure SCIg products are transported correctly, and patients are provided with education regarding this requirement.
- The following storage and handling of SCIg must be maintained to ensure the cold chain integrity of the product.

SCIg product	Storage conditions
Evogam® (to be discontinued 2023 and replaced with Hizentra®**AU** 16% Normal immunoglobulin (Human) Plasma-derived - domestic	Refrigerate at 2-8 degrees C for up to 2 years. Do not freeze. Once removed from refrigeration, store below 25 degrees C and use within 2 weeks. Protect from light. In the event of a power failure, place the Evogam® in an esky with ice bricks. Locate a working refrigerator as soon as possible.
Hizentra®AU (Replacement for Evogam) 20% Normal Immunoglobulin (Human) Plasma-derived - domestic	Store below 25^{0}C for up to 30 months. Do not freeze. Protect from light Do not use after the expiry date.
Hizentra® 20% Normal Immunoglobulin (Human) Plasma-derived - imported	Store below 25 degrees C for up to 30 months. Do not freeze. Protect from light. Do not use after expiry date
Cuvitru®. (Change to storage requirements 2022) 20% Normal immunoglobulin (Human) Plasma-derived- imported	Refrigerate 2-8 degrees C for up to 36 months Do not freeze. Protect from light. Do not use after expiry date

SCIg Administration

SCIg solutions are clear and colourless, pale yellow or light brown. If the solution appears turbid or contains sediment, it must not be used, and the bottle returned to blood bank or pathology during training in the clinical setting. SCIg products do not contain an antimicrobial preservative therefore they must be used immediately after opening the vial and infusion completed within 4 hours.

They should be used for one patient on one occasion only. During training in the clinic setting, any unused portion should be returned to blood bank or pathology and recorded in the patient's notes.

Evogam® Hizentra AU®, Hizentra® and Cuvitru®. should be brought to room temperature before use. Evogam®, Hizentra AU®, Hizentra® and Cuvitru®. should only be administered **SUBCUTANEOUSLY – DO NOT ADMINISTER INTRAVENOUSLY.** Recommended subcutaneous sites are: thighs, abdomen, upper arms and lateral hip. If large doses are required, multiple sites can be used, at least 5 cm apart.

Collection

Patient collects the product monthly from the treatment area for the first three months of treatment after completing training. Once the patient is deemed confident with the storage and administration of SCIg up to two months' supply may be given with approval from ARCL. Nursing staff will undertake a patient assessment at each collection which will be documented in ieMR or the Patient Assessment form. Any identified issues will be addressed and if required discussed with a medical officer.

1-3 months	4 months onwards or when patient is stable
Four (4) weekly supply*	Eight (8) weekly supply*
SCIg Program Patient Assessment and Consumables Collection completed at each collection.	SCIg Program Patient Assessment and Consumables Collection completed at each collection.
SCIg product to be collected from Blood Bank or pathology by nursing staff	SCIg product to be collected from Blood Bank or pathology by nursing staff
SCIg dispensed to the patient and checked with the RN against the batch product issue report, Prescription checked against ieMR, or written prescription form. Consumables checked by patient and collected at each appointment	*SCIg* dispensed to the patient and checked with the RN against the batch product issue report Prescription checked against iMR, or written prescription form. Consumables checked by patient and collected at each appointment

**standard supply, can be adjusted dependant on prescriber discretion*

Education and training

Nursing staff undertaking training of patients in the self-administration of SCIg should be trained by a specialised SCIg nurse and complete the Nurses Training Competency and Immunoglobulin: Administration - BloodSafe eLearning Australia module to ensure understanding of appropriate management and use of SCIg. The training competency may be signed off by Blood Management CNC or any other trained SCIg nurse. Education will address how to manage an adverse event, transport, storage, use of equipment, infusion devices, patient education, information and resources/consumables required

Patients can be referred to the relevant products external SCIg training program for training and assessment with approval of the treating consultant

Patient Assessment

Patient education and assessment will be conducted in the relevant unit for at least the first two training sessions. Further onsite training will be based on the clinical judgement of the nurse and needs of the patient. The Subcutaneous Immunoglobulin (SCIg) Program Nurse Training checklist will be utilised for training purposes and Patient/Carer Training Competency form will be used to determine competency.

Adverse reactions

Patients should be advised to present to the emergency department and inform their nurse or medical officer immediately if they experience:

- Signs of allergy such as rash or hives on the skin, swelling of the face, lips, tongue or other part of the body
- Shortness of breath, wheeze or trouble breathing
- Severe dizziness, light headedness, or fainting

Patient should also be advised to inform their nurse or medical officer if they experience local site reactions such as redness, pruritus and swelling. This is a common reported side effect from SCIg and can decrease with every subsequent infusion or adjustment to infusion regime.

Other reported side effects which occur infrequently, though should be reported to the treating consultant include fatigue, fever, nausea/vomiting, skin rash, stomach pain, headache and jaundice.

All adverse event in should be Documented in the patient notes, the incident management system (RISKMAN) and reported to the product supplier.

Consumer Information

Patients/carers considering commencing on SCIg should be provided with consumer information to ensure that they understand their involvement and responsibilities prior to committing to this mode of treatment.

Patients will be provided with the tools and resources to manage their SCIg at home and record details of used, discarded or broken product as a start-up pack. Resources include: Administration Diary, links to the mobile application (Hizentra), product consumer information and cold Bag.

Consumer support

Patients will be educated to initially administer SCIg within office hours to ensure support is available from the treating clinical area. For out of hours emergency care, patients must present to the emergency department. Ongoing education and support will be provided by the treating clinical area on a regular basis on pickup of product and consumables. CSL (Evogam® and Hizentra®) are available for additional patient support, resources are supplied in the patient start up pack and in the administration diaries supplied.

Equipment

The following items are the minimum required prior to each standard infusion:

Supplied on commencing SCIg:

- Administration device (e.g., Springfusor)
- Cooler bag with cold pack
- Infusion Diary or App
- Sharps container

Required each collection:

- SCIg product for administration
- Neria dual administration/ giving set (additional set required if using more than 2 administration sites)
- SCIg product
- Drawing up needles (only for Hizentra)
- Alcohol swabs
- Luer Lock Syringe/s (size and flow tubing as required)
- Gauze
- Band-Aids

Note: SCIg has multiple infusion methods. SCUH opt to use the Springfusor which is a spring-loaded mechanical pump, however patient preference is paramount. If patients are unable or unwilling to use the Springfusor, other methods of administration are available. These options include the manual/push method battery powered mechanical infusion pump or spring-loaded mechanical infusion pump.

If used correctly, a single Springfusor device should last for 2 – 4 years. Patients may continue to use their Springfusor past this time frame, provided it is functioning well. If at any time patients report that their device is broken, or is not infusing properly, a new Springfusor will be provided at no cost to the patient.

Intragam® 10 (10%) Normal Human Intravenous Immunoglobulin (IVIg) (to be discontinued 2023 and replaced with Privigen AU)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	Replacement IgG therapy Immunomodulatory therapy
Contraindications	Intragam 10 is contraindicated in patients who have had a true anaphylactic reaction to a human immunoglobulin especially those with antibodies against IgA or to the excipient glycine
Presentation	Available in 25, 100 and 200mL vials containing 2.5, 10 and 20 g of IgG with glycine
Storage Conditions	• Store at 2°C to 8°C (Refrigerate. Do not freeze) • If refrigerated, should be stored in a designated and monitored blood refrigerator. • Once removed from refrigeration, store below 25°C and use within 3 months. • Do not use after the expiry date • Protect from light • Any unused bottles must be returned to the Blood Bank / Transfusion Department
Incompatibilities	Intragam 10 should be administered separately from other intravenous fluids or medications the patient might be receiving
Inspection	• Do not use if particulate matter and/or discolouration is observed • Only clear or slightly opalescent fluids are to be administered
Infusion Equipment	• Use of an infusion pump is recommended to ensure accurate delivery of infusion rates • Standard IV giving set or an IV blood line. An inline filter is not necessary but will not pose any problems if used • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required • Attachment to extension tubing on an IV cannula is acceptable and may be of use in the event of a transfusion reaction if patient does not have alternative IV access
Priming and Flushing	0.9% sodium chloride, water for injection or 5% glucose may be used for flushing and priming (approx. 30-80mLs -this may vary depending on the clinical context). Other fluids have not been evaluated so therefore must not be used
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient. Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent • No blood product is to be stored on wards/units, if not being transfused return to the laboratory
Administration	• Administration from glass bottles requires a vented system (Vented giving set or air vent) • Burette should be used for paediatric patients • May be infused undiluted. If dilution is required dilute with up to 2 parts of 0.9% sodium chloride or 5% glucose

	• Record Batch Numbers (or stickers if available) on the IV & SC Fluid order form against the prescription • Intragam 10 should be commenced slowly, and the rate increased by increments providing there are no indications of possible reaction. **Adult Infusion Rate (First Dose or > 8 weeks since last infusion):** • 0.5ml/kg/hr for 30 minutes • 1ml/kg/hr for 30 minutes • 2ml/kg/hr for 30 minutes • 3ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Adult Infusion Rate (Subsequent doses if no adverse reaction):** • 0.5ml/kg/hr for 15 minutes • 1ml/kg/hr for 15 minutes • 2ml/kg/hr for 15 minutes • 3ml/kg//hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed. **Paediatric Infusion rate:** Calculated and ordered by Medical Officer. Ideal body weight to be used in overweight patients. • 1mL/kg/hr for 15 minutes if well tolerated increase rate to • 2mL/kg/hr for 15 minutes if well tolerated increase rate to • 3mL/kg/hr for 15 minutes if well tolerated increase rate to • 4mL/kg/hr until transfusion is complete Record Batch Numbers (or stickers if available) against the prescription. **Paediatric** administration should align with the Childrens Health Queensland Blood and Blood Products: Intravenous Immunoglobulin procedures
Observations	T, P, R & BP, and oxygen saturation**:** • Baseline and every 15 minutes prior to increase in infusion rates then • Hourly once maximum rate is achieved • First infusion and when transitioning patient to a different product, observe for 30 mins to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	• Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically **Delayed reaction** may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and Reactions • Report all adverse events in Clinical Incident Reporting System and record in the Patient health record • Report all adverse events to Blood Bank / Transfusion and CSL and no later than 24 hours from the event via: CSL Suspected Adverse Reaction Report form or phoning 1800 642 865
Reference	CSL. Intragam 10 Product Information, 2021 Australasian Society of Clinical Immunology and Allergy Guidelines of Standardised Infusion Rates for IVIg 2023

Privigen® 10% – Normal Human Intravenous Immunoglobulin (IVIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	Replacement Therapy Immunomodulatory Therapy
Contraindications	• Hypersensitivity to the active substance or to the excipient • Hypersensitivity to homologous immunoglobulins, especially in the very rare cases of IgA deficiency when the patient has antibodies against IgA. • Patients with hyperprolinaemia.
Presentation	10% solution (100g/L) • 5 g: 50 mL solution • 10 g: 100 mL solution • 20 g: 200 mL solution • 40 g: 400 mL solution
Storage Conditions	• Privigen® can be stored at room temperature (below 25°C) for its entire 36-month shelf life • Do not freeze • Keep the bottle in the outer carton to protect from the light while in storage • Do not use after the expiry date
Incompatibilities	• Privigen® should be administered separately from other intravenous fluids or medications the patient might be receiving • The interaction of Privigen® with other medicines has not been established
Inspection	• Do not use if particulate matter and/or discolouration is observed, or the vial is missing the protective aluminium cap • Only clear or slightly opalescent fluids are to be administered • Slight yellow colouration is of no concern and the product can still be used
Infusion Equipment	• Use of an IV pump is recommended to ensure accurate delivery of infusion rates • Standard IV giving set **or** an IV blood line and inline filter is not necessary but will not pose any problems if used. • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required • Attachment to extension tubing on an IV cannula is acceptable and may be of use in the event of a transfusion reaction if patient does not have alternative IV access
Priming and Flushing	• 0.9% sodium chloride, water for injection or 5% glucose may be used for flushing and priming (approx. 30-80 mLs – this may vary depending on the clinical context) • Other fluids have not been evaluated so therefore must not be used
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent • No blood product is to be stored on wards/units, if not being transfused return to the laboratory

Administration	• Privigen® is infused as an **intravenous infusion** only • The product should be at room or body temperature before use. • Do not shake • Administration from glass bottles requires a vented system (Vented giving set or air vent) • May be infused undiluted. If desired, Privigen® can be diluted with glucose 5% solution, using aseptic technique. Do not mix other medicinal products in the same infusion line • Record Batch Numbers (or stickers if available) against the prescription • Privigen® should be commenced slowly and the rate increased by increments providing there are no indications of possible reaction. • A gradual increase in infusion rate is recommended each 30 minutes. • Patients must be closely monitored for any reactions during the infusion – refer to Adverse effects below
Infusion rates	**Infusion Rate (First Dose or > 8 weeks since last infusion):** • 0.5 ml/kg/hr for 30 minutes • 1 ml/kg/hr for 30 minutes • 2ml/kg/hr for 30 minutes • 3ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Infusion Rate (Subsequent doses if no adverse reaction):** • 0.5ml/kg/hr for 15 minutes • 1ml/kg/hr for 15 minutes • 2ml/kg/hr for 15 minutes • 3ml/kg//hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed.
Observations	• T, P, R & BP, and oxygen saturation: • Baseline and every 30 minutes prior to increase in infusion rates then, • hourly once maximum rate is achieved. • First infusion and when transitioning patient to a different product, observe for 30 minutes to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	• Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically **Delayed reaction** may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and reactions • Report all adverse events in Clinical Incident Reporting system and record in the Patient health record • Report all adverse events to Blood Bank / Transfusion and CSL and no later than 24 hours from the event via: CSL Suspected Adverse Reaction Report form or phoning 1800 642 865
Reference	CSL Behring Our Products - Privigen® Australasian Society of Clinical Immunology and Allergy Guidelines for Standardised Infusion Rates for IVIg 2023

Privigen AU® 10% – Normal Human Intravenous Immunoglobulin (IVIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria. **NB Privigen AU can be found in Auslab and ieMR as AU Privigen**	
Indications	Replacement Therapy Immunomodulatory Therapy
Contraindications	• Hypersensitivity to the active substance or to the excipient • Hypersensitivity to homologous immunoglobulins, especially in the very rare cases of IgA deficiency when the patient has antibodies against IgA. • Patients with hyperprolinaemia.
Presentation	10% solution (100g/L) • 5 g: 50 mL solution • 10 g: 100 mL solution • 20 g: 200 mL solution
Storage Conditions	• Privigen® can be stored at room temperature (below 25°C) for its entire 36-month shelf life • Do not freeze • Keep the bottle in the outer carton to protect from the light while in storage • Do not use after the expiry date
Incompatibilities	• Privigen® should be administered separately from other intravenous fluids or medications the patient might be receiving • The interaction of Privigen® with other medicines has not been established
Inspection	• Do not use if particulate matter and/or discolouration is observed, or the vial is missing the protective aluminium cap • Only clear or slightly opalescent fluids are to be administered • Slight yellow colouration is of no concern and the product can still be used
Infusion Equipment	• Use of an IV pump is recommended to ensure accurate delivery of infusion rates • Standard IV giving set **or** an IV blood line. An inline filter is not necessary but will not pose any problems if used. • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required • Attachment to extension tubing on an IV cannula is acceptable and may be of use in the event of a transfusion reaction if patient does not have alternative IV access
Priming and Flushing	• 0.9% sodium chloride, water for injection or 5% glucose may be used for flushing and priming (approx. 30-80 mLs – this may vary depending on the clinical context) • Other fluids have not been evaluated so therefore must not be used
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent • No blood product is to be stored on wards/units, if not being transfused return to the laboratory
Administration	• Privigen® is infused as an intravenous infusion only

	• The product should be at room or body temperature before use. • Do not shake • Administration from glass bottles requires a vented system (Vented giving set or air vent) • May be infused undiluted. If desired, Privigen® can be diluted with glucose 5% solution, using aseptic technique. Do not mix other medicinal products in the same infusion line • Record Batch Numbers (or stickers if available) against the prescription • Privigen® should be commenced slowly and the rate increased by increments providing there are no indications of possible reaction. • A gradual increase in infusion rate is recommended each 30 minutes. • Patients must be closely monitored for any reactions during the infusion – refer to Adverse effects below
Infusion rates	Infusion Rate (First Dose or > 8 weeks since last infusion): • 0.5 ml/kg/hr for 30 minutes • 1 ml/kg/hr for 30 minutes • 2ml/kg/hr for 30 minutes • 3ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed Infusion Rate (Subsequent doses if no adverse reaction): • 0.5ml/kg/hr for 15 minutes • 1ml/kg/hr for 15 minutes • 2ml/kg/hr for 15 minutes • 3ml/kg//hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed.
Observations	• T, P, R & BP, and oxygen saturation: • Baseline and every 30 minutes prior to increase in infusion rates then, • hourly once maximum rate is achieved. • First infusion and when transitioning patient to a different product, observe for 30 minutes to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	• Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically Delayed reaction may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and reactions • Report all adverse events in Clinical Incident Reporting system and record in the Patient health record • Report all adverse events to Blood Bank / Transfusion and CSL and no later than 24 hours from the event via: CSL Suspected Adverse Reaction Report form or phoning 1800 642 865
Reference	CSL Behring Our Products - Privigen® Australasian Society of Clinical Immunology and Allergy Guidelines ofr Standardised Infusion Rates for IVIg 2023

Flebogamma® 5% and 10% Normal Human Intravenous Immunoglobulin (IVIg)

Product	**Flebogamma® 5%** (50mg/mL) Product Information Consumer Information	**Flebogamma® 10% (100mg/mL)** Product Information Consumer Information
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria. Flebogamma® is available in 5% and 10% concentrations. It is clinician choice which concentration to order based on the patient's clinical picture.		
Indications	Replacement IgG therapy Immunomodulatory therapy	
Contraindications	• Hypersensitivity to any of the components. • Hypersensitivity to homologous immunoglobulins, especially in very rare cases of IgA deficiency, when the patient has antibodies against IgA. • Fructose intolerance.	
Presentation	**Flebogamma® 5%** (50mg/mL) Supplied as 0.5g/10mL, 2.5g/50mL, 5g/100mL, 10g/200mL and 20g/400mL vials.	**Flebogamma® 10% (100mg/mL)** Supplied as 5g/50mL, 10g/100mL, 20g/200mL vials.
Storage conditions	Shelf life is 2 years Store below 30^{0}C. Do not freeze. Protect from light.	
Incompatibilities	• Flebogamma® should be administered separately from other intravenous fluids or medications the patient might be receiving.	
Inspection	**Visually Inspect Product:** • Do not use if particulate matter and/or discolouration is observed. • Only clear or slightly opalescent and colourless or pale-yellow solutions are to be administered.	
Infusion Equipment	**Infusion Equipment:** • Use of an IV pump is recommended to ensure accurate delivery of infusion rates • Standard IV giving set or an IV blood line may be used. An inline filter is not necessary but will not pose any problems if used • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required • Addition of an extension set when setting up an infusion line can be of use in the event of a transfusion reaction if patient does not have alternative IV access.	
Priming and Flushing	• Flush with 0.9% sodium chloride may be used for flushing and priming (approx. 30-80mLs - this may vary depending on the clinical context). • Do not mix with any other fluids, medications, or blood products.	
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing.	
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.	

Administration	• Flebogamma® is infused as an intravenous infusion only. • The product should to be brought to room temperature prior to administration. • Do not mix with any other intravenous fluid, medication, or blood product other than 0.9% sodium chloride for prime or flush. • Commence infusion slowly and only increase rate if tolerated. • Rate of infusion is based on patient weight, round the patient's weight down to the nearest weight as indicated in the infusion rate calculator. • Consider slower infusion rates in the elderly or patients with cardiac or renal disease. • Record Batch Numbers (or stickers if available) against the prescription
Infusion rate	**Flebogamma® 5%** (50mg/mL) **Infusion Rate (First Dose or > 8 weeks since last infusion):** • 1 ml/kg/hr for 30 minutes • 2 ml/kg/hr for 30 minutes • 4 ml/kg/hr for 30 minutes • 6 ml/kg/hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Infusion Rate (Subsequent doses if no adverse reaction):** • 1 ml/kg/hr for 15 minutes • 2 ml/kg/hr for 15 minutes • 4 ml/kg/hr for 15 minutes • 6 ml/kg//hr until complete (rate not to exceed 500 ml/hr) A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed. **Flebogamma® 10% (100**mg/ml) **Infusion Rate (First Dose or > 8 weeks since last infusion):** • 0.5 ml/kg/hr for 30 minutes • 1 ml/kg/hr for 30 minutes • 2 ml/kg/hr for 30 minutes • 3 ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Infusion Rate (Subsequent doses if no adverse reaction):** • 0.5 ml/kg/hr for 15 minutes • 1 ml/kg/hr for 15 minutes • 2 ml/kg/hr for 15 minutes • 3 ml/kg//hr until complete (rate not to exceed 300 ml/hr) A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed.
Observations	• T, P, R & BP, and oxygen saturation: • Baseline and every 30 minutes prior to increase in infusion rates then, • hourly once maximum rate is achieved. • First infusion and when transitioning patient to a different product, observe for 30 minutes to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	**Reactions tend to be related to the rate of infusion** • Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically

	Delayed reaction may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and reactions • Report all adverse events in Clinical Incident Reporting System and record in the Patient health record • Report all adverse events to Blood Bank / Transfusion and CSL and no later than 24 hours 24 hours from the event via: (03) 9535 9333 or email orders@lateralgrifols.com.
Reference	Flebogamma 5% Product Information Flebogamma 10% Product Information Flebogamma 5% Consumer Product Information Flebogamma 10% Consumer Medicine Information Australasian Society of Clinical Immunology and Allergy Guidelines ofr Standardised Infusion Rates for IVIg 2023

Octagam ® 10% – Normal Human Intravenous Immunoglobulin (IVIg)

Octagam Product Information and Consumer Medicine Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	**Replacement Therapy** **Immunomodulation**
Contraindications	• Hypersensitivity to any of the components. • Hypersensitivity to homologous immunoglobulins, especially in very rare cases of IgA deficiency, when the patient has antibodies against IgA.
Precautions	• Certain adverse reactions may occur more frequently in cases of high rate of infusion • Patients with hypogammaglobulinaemia or agammaglobulinemia with or without IgA deficiency. • Patients who receive intravenous immunoglobulin (IVIg) for the first time or, in rare cases, when the human normal immunoglobulin product is switched or when there has been a long interval since the previous infusion. • Blood Glucose Testing: Some types of blood glucose testing systems falsely • Interpret the maltose contained in OCTAGAM® 10% which may result in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin (with potential for life-threatening consequences) OR masking of a true hypoglycaemic state blood glucose should be tested prior to the infusion and/or measure with a glucose-specific method.
Presentation	Supplied as 5.0 g(50ml); 10.0g (100ml); 20.0g (200ml) vials.
Storage conditions	Shelf life is 2 years Store below 30^{0}C. Do not freeze. Protect from light.
Incompatibilities	Octagam ® should be administered separately from other intravenous fluids or medications the patient might be receiving.
Inspection	**Visually Inspect Product:** Do not use if particulate matter and/or discolouration is observed. Only clear or slightly opalescent and colourless or pale-yellow solutions are to be administered.
Infusion Equipment	**Infusion Equipment:** • Use of an IV pump is recommended to ensure accurate delivery of infusion rates. • Standard IV giving set or an IV blood line may be used. An inline filter is not necessary but will not pose any problems if used. • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required. • Addition of an extension set when setting up an infusion line can be of use in the event of a transfusion reaction if patient does not have alternative IV access.
Priming and Flushing	• Flush with 0.9% sodium chloride may be used for flushing and priming (approx. 30-80mLs - this may vary depending on the clinical context). • Do not mix with any other fluids, medications, or blood products.
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.

Administration	Octagam® is infused as an **intravenous infusion** only • The product should be at room or body temperature before use. • Do not shake • Administration from glass bottles requires a vented system (Vented giving set or air vent) • Do not mix with any other intravenous fluid, medication, or blood product other than 0.9% sodium chloride for prime or flush. • Record Batch Numbers (or stickers if available) against the prescription Octagam ® should be commenced slowly and the rate increased by increments providing there are no indications of possible reaction. • A gradual increase in infusion rate is recommended each 30 minutes. **OCTAGAM® 10% INFUSION RATES for Adult Patients** **Infusion Rate (First Dose or > 8 weeks since last infusion):** • 0.5 ml/kg/hr for 30 minutes • 1 ml/kg/hr for 30 minutes • 2ml/kg/hr for 30 minutes • 3ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Infusion Rate (Subsequent doses if no adverse reaction):** • 0.5ml/kg/hr for 15 minutes • 1ml/kg/hr for 15 minutes • 2ml/kg/hr for 15 minutes • 3ml/kg//hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed.
Observations	• T, P, R & BP, and oxygen saturation: • Baseline and every 30 minutes prior to increase in infusion rates then, hourly once maximum rate is achieved. • First infusion and when patient is transitioning to a different product, observe for 30 minutes to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	**Reactions tend to be related to the rate of infusion** • Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically **Delayed reaction** may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and Reactions • Report all adverse events in Clinical Incident Reporting System and record in the Patient health record Report all adverse events to Blood Bank / Transfusion and Octapharma and no later than 24 hours 24 hours from the event via: Octapharma
Reference	Octagam® 10% Product Information Australasian Society of Clinical Immunology and Allergy Guidelines ofr Standardised Infusion Rates for IVIg 2023

Gamunex ® 10% – Normal Human Intravenous Immunoglobulin (IVIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	**Replacement Therapy** **Immunomodulatory therapy**
Contraindications	• Hypersensitivity to the active substance or to the excipient. • Hypersensitivity to homologous immunoglobulins, especially in the very rare cases of IgA deficiency when the patient has antibodies against IgA. • Patients with known hypersensitivity to the excipient glycine.
Presentation	Supplied as 5.0 g(50ml); 10.0g (100ml); 20.0g (200ml) vials.
Storage Conditions	• Should be refrigerated in a monitored blood fridge at 2°C to 8°C • Once removed from refrigeration, store below 25°C and use within 6 months. • Do not freeze • Store protected from light.
Incompatibilities	• Gamunex ® should be administered separately from other intravenous fluids or medications the patient might be receiving • The interaction of Gamunex ® with other medicines has not been established
Inspection	• Do not use if particulate matter and/or discolouration is observed, or the vial is missing the protective aluminium cap • Only clear or slightly opalescent fluids are to be administered • Slight yellow colouration is of no concern and the product can still be used
Infusion Equipment	• Use of an IV pump is recommended to ensure accurate delivery of infusion rates • Standard IV giving set **or** an IV blood line. An inline filter is not necessary but will not pose any problems if used. • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required. • Attachment to extension tubing on an IV cannula is acceptable and may be of use in the event of a transfusion reaction if patient does not have alternative IV access
Priming and Flushing	• 0.9% sodium chloride, water for injection or 5% glucose may be used for flushing and priming (approx. 30-80mLs - this may vary depending on the clinical context) • Other fluids have not been evaluated so therefore must not be used
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription Form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent • No blood product is to be stored on wards/units, if not being transfused return to the laboratory
Administration	• Gamunex ® is infused as an intravenous infusion • The product should be at room or body temperature before use. • Do not shake • Administration from glass bottles requires a vented system (Vented giving set or air vent)

	• Infuse undiluted. • Record Batch Numbers (or stickers if available) on the Blood and Blood Products Prescription form • Gamunex ® should be commenced slowly and the rate increased by increments providing there are no indications of possible reaction. • Timing of the infusion rate rise should be based on the patient tolerability and discretion of the clinical staff • A gradual increase in infusion rate is recommended each 30 minutes. **10% INFUSION RATES for Adult Patients** **Infusion Rate (First Dose or > 8 weeks since last infusion):** • 0.5 ml/kg/hr for 30 minutes • 1 ml/kg/hr for 30 minutes • 2ml/kg/hr for 30 minutes • 3ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Infusion Rate (Subsequent doses if no adverse reaction):** • 0.5ml/kg/hr for 15 minutes • 1ml/kg/hr for 15 minutes • 2ml/kg/hr for 15 minutes • 3ml/kg//hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed.
Observations	• T, P, R & BP, and oxygen saturation: • every 30 minutes prior to increase in infusion rates then, • hourly once maximum rate is achieved. • First infusion and when patient is transitioning to a different product, observe for 30 minutes to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	**Reactions tend to be related to the rate of infusion** • Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically **Delayed reaction** may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and Reactions • Report all adverse events in Clinical Incident Reporting System and record in the Patient health record • Report all adverse events to Blood Bank / Transfusion and CSL and no later than 24 hours 24 hours from the event via: (03) 9535 9333 or email orders@lateralgrifols.com.
References	Gamunex® 10% Product Information Australasian Society of Clinical Immunology and Allergy Guidelines ofr Standardised Infusion Rates for IVIg 2023

Kiovig ® 10% – Normal Human Intravenous Immunoglobulin (IVIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	**Replacement Therapy** **Immunomodulatory therapy**
Contraindications	• Hypersensitivity to the active substance or to the excipient. • Hypersensitivity to homologous immunoglobulins, especially in the very rare cases of IgA deficiency when the patient has antibodies against IgA. • Patients with known hypersensitivity to the excipient glycine.
Presentation	Supplied as 1.0 g(10ml); 2.5g (25 mL), 5.0g (50mL) 10.0g (100ml); 20.0g (200ml), 30g (300mL) vials.
Storage Conditions	• Should be refrigerated in a monitored blood fridge at 2°C to 8°C and used within 36 months of date of manufacture • Do not freeze • Store protected from light.
Incompatibilities	• Kiovig ® should be administered separately from other intravenous fluids or medications the patient might be receiving • The interaction of Kiovig ® with other medicines has not been established
Inspection	• Do not use if particulate matter and/or discolouration is observed, or the vial is missing the protective aluminium cap • Only clear or slightly opalescent fluids are to be administered • Slight yellow colouration is of no concern and the product can still be used
Infusion Equipment	• Use of an IV pump is recommended to ensure accurate delivery of infusion rates • Standard IV giving set **or** an IV blood line. An inline filter is not necessary but will not pose any problems if used. • Administration from glass bottles requires a vented system. Open air vent on IV line, if line is not vented, an air inlet needle maybe required. • Attachment to extension tubing on an IV cannula is acceptable and may be of use in the event of a transfusion reaction if patient does not have alternative IV access
Priming and Flushing	• 0.9% sodium chloride, water for injection or 5% glucose may be used for flushing and priming (approx. 30-80mLs - this may vary depending on the clinical context) • Other fluids have not been evaluated so therefore must not be used
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on the SCHHS Blood and Blood Products Prescription Form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation. • Venous access obtained and patent. • Allow the product to reach room temperature before infusing
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent • No blood product is to be stored on wards/units, if not being transfused return to the laboratory
Administration	• Kiovig ® is infused as an intravenous infusion • The product should be at room or body temperature before use. • Do not shake

	• Administration from glass bottles requires a vented system (Vented giving set or air vent) • Infuse undiluted. • Record Batch Numbers (or stickers if available) on the Blood and Blood Products Prescription form or in ieMR • Gamunex ® should be commenced slowly and the rate increased by increments providing there are no indications of possible reaction. • Timing of the infusion rate rise should be based on the patient tolerability and discretion of the clinical staff • A gradual increase in infusion rate is recommended each 30 minutes. **10% INFUSION RATES for Adult Patients** **Infusion Rate (First Dose or > 8 weeks since last infusion):** • 0.5 ml/kg/hr for 30 minutes • 1 ml/kg/hr for 30 minutes • 2ml/kg/hr for 30 minutes • 3ml/kg/hr until complete (rate not to exceed 150 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed **Infusion Rate (Subsequent doses if no adverse reaction):** • 0.5ml/kg/hr for 15 minutes • 1ml/kg/hr for 15 minutes • 2ml/kg/hr for 15 minutes • 3ml/kg//hr until complete (rate not to exceed 300 ml/hr) • A change of bottle where the batch number differs does not require a reduction in rate when the bottle is changed.
Observations	• T, P, R & BP, and oxygen saturation: • every 30 minutes prior to increase in infusion rates then, • hourly once maximum rate is achieved. • First infusion and when patient is transitioning to a different product, observe for 30 minutes to 1 hour post infusion. Observe the patient for 30 minutes after subsequent infusions.
Adverse Effects	Reactions tend to be related to the rate of infusion • Tend to be related to the rate of the infusion • Headache is the most common symptom. This is usually rate-related, and the infusion can often continue at a slower rate • For minor reactions the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically Delayed reaction may develop within 24hours such as: nausea, vomiting, chest pain, rigors, dizziness, aching legs, or arthralgia In the case of serious adverse events Refer to: • Transfusion Adverse Events and Reactions • Report all adverse events in Clinical Incident Reporting System and record in the Patient health record • Report all adverse events to Blood Bank / Transfusion and CSL and no later than 24 hours 24 hours from the event via: (03) 9535 9333 or email orders@lateralgrifols.com.
References	Kiovig® 10% Product Information Australasian Society of Clinical Immunology and Allergy Guidelines of Standardised Infusion Rates for IVIg 2023

Subcutaneous Immunoglobulins (SCIg)

Evogam® 16% – Normal Human Subcutaneous Immunoglobulin (SCIg) (To be replaced by Hizentra AU in 2023)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	Evogam is indicated in adults and children for replacement therapy in: • Primary Immunodeficiency Diseases (PID) and • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment
Precautions	• Evogam® must not be administered intravenously or intramuscularly. If Evogam® is inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be observed • Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when there has been a long interval since previous infusion • Evogam® should be used with caution in patients with a known allergy to constituents of the preparation. Evogam® contains traces of IgA which may provoke anaphylaxis in IgA deficient patients with anti-IgA antibodies. • Caution should be exercised in prescribing and administering Evogam® in obese patients and in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolaemic patients and patients with diseases which increase blood viscosity). • Aseptic Meningitis Syndrome (AMS) has been reported to occur infrequently in association with human immunoglobulin administration • For further information on precautions refer to: Product Information
Contraindications	Evogam® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to the excipient glycine
Incompatibilities	Must not be mixed with any other product
Presentation	Evogam® contains human normal immunoglobulin G (IgG): • 5mL vial contains 0.8 grams of IgG • 20mL vial contains 3.2 grams of IgG
Storage Conditions	• Shelf life is 2 years • Store at 2°C to 8°C (Refrigerate. Do not freeze). • Protect from light • Do not use after expiry date • Once removed from refrigeration the product may be stored below 25°C and used within two weeks. The date of removal from refrigeration and the new expiry date must be noted on the outer carton
Inspection	• Do not use if particulate matter and/or discolouration is observed • Only clear or slightly opalescent fluids are to be administered
Infusion Equipment	• Alcohol cleansing wipe, subcutaneous needle/s, luer lock syringes and if required an extension set • Subcutaneous Infusion Pump if required (these pumps must be used in compliance with manufacturer's instruction). • Sterile dressing (if required)
Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient.

	• Medical order / prescription is documented on the Medical order documented on the Subcutaneous Immunoglobulin (SCIg) Home therapy Prescription/Order form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation (inpatient). • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.
Home Treatment	Home treatment should be initiated by a clinician experienced in the guidance of patients for home treatment in accordance with the Administration and Management of Immunoglobulin Procedure
Rate and Dose	The dosage may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. • Initial infusion rate: 10mL/hour/site. The infusion rate may be gradually increased up to 20mL/hour/site as comfort and tolerability allows. • When large doses are given (>20mL), it is advisable to administer them in divided doses at different sites. (The maximum dose administered must not exceed 40mL/hour per site). • Trough IgG levels should be measured to adjust the dose and dosage interval.
Administration	• **Evogam® is to be administered via the subcutaneous route only**, preferentially into the upper/outer arms, thighs, abdomen and/or lateral hip. • Administration methods for Evogam® include use of an infusion pump or push techniques. The choice of administration technique and equipment is at the discretion of the treating healthcare professional in collaboration with the patient.
Instruction for use	• Remove the peel-off batch number from the Evogam® vial and insert into the patient diary. • Remove the protective cap from the vial and wipe the rubber stopper with alcohol. • For withdrawing Evogam®, use a sterile syringe and the supplied transfer device. • Inject air into the vial that is equivalent to the amount of Evogam® to be withdrawn. Then withdraw Evogam® from the vial. If multiple vials are required to achieve the desired amount of Evogam®, repeat this step. • Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with Evogam®. • Subcutaneous infusion pump only - Follow the manufacturer's instructions for preparing the pump. • Clean the injection site(s) with antiseptic solution. • Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart. • Grasp the skin between two fingers and insert the needle into the subcutaneous tissue. • Evogam® must not be injected into a blood vessel. To test that no blood vessel has been accidentally hit undertake a double-checking process: • Gently pull back on the syringe plunger and look to see if any blood is flowing back into the tubing. • Disconnect the syringe from the tubing and hang tubing lower than the injection site for 3-5 seconds. • If blood return is noticed, remove, and discard the needle and tubing. Repeat priming and needle insertion steps using a new needle, tubing, and a new infusion site. • Secure the needle in place by applying a transparent dressing. • Infuse Evogam® slowly • follow the manufacturer's instructions for the pump • The infusion site may be changed if patient comfort becomes an issue.
Observations (in hospital use only)	Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 30 minutes after the infusion. • Baseline observations immediately prior to the commencement 1st infusion / 1st dose • As deemed necessary through-out the infusion or in response to clinical symptoms

Adverse Effects	• Patient's naïve to immunoglobulin may experience a higher frequency of adverse effects including those of a minor nature. • In case of severe reactions, the infusion must be stopped, and an appropriate treatment initiated. Type of reactions may include: **Very Common** – infusion site reaction, fever, nausea, vomiting, diarrhoea **Common** – chills, back pain, arthralgia, hypotension **Rare** – allergic reactions, anaphylactic shock, thrombotic reactions. • Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the Medical Officer, and provide emergency care as required. • Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved. • In the case of serious adverse events stop the infusion and Refer to: Transfusion Adverse Events and Reactions. • Report all adverse events to Blood bank/Transfusion and CSL Medical Enquiries no later than 24 hours from the event via: CSL Suspected Adverse Reaction Report form or phoning 1800 642 865. • Report all adverse events in Clinical Incident Reporting System and record in the Patient health record.
Reference	CSL Product Information, Evogam.

Hizentra® 20% – Normal Human Subcutaneous Immunoglobulin (SCIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria. **NB Privigen AU can be found in Auslab and ieMR as AU Privigen.**	
Indications	Hizentra® is indicated in adults and children for replacement therapy in: • Primary Immunodeficiency Diseases (PID) and • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment • Immunomodulatory therapy in CIDP
Precautions	• **Hizentra® must not be administered intravenously or intramuscularly**. If Hizentra® is inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be observed • Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when there has been a long interval since previous infusion • Known allergies: use with caution in patients with a known allergy to anti-IgA as it may cause severe hypersensitivity or anaphylaxis • Thrombotic Events: caution should be exercised in prescribing and administering Hizentra® in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolaemic patients and patients with diseases which increase blood viscosity) • An aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with human immunoglobulin administration • Transmissible infective agents may be a possibility. For further information on precautions refer to: Product Information.
Contraindications	Hizentra® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to any of its excipients. Must not be used in hyperprolinaemia type I or II.
Incompatibilities	Must not be mixed with any other product.
Presentation	Hizentra® contains human normal immunoglobulin G (IgG): • 1 g in a 5 mL solution • 2 g in a 10 mL solution • 4 g in a 20 mL solution • 10 g in a 50 mL solution
Storage Conditions	• Shelf life is 2 years • Store below 25°C (Do not freeze) • Keep the vial in the outer carton in order to protect from light • Do not use after expiry date
Inspection	This product is normally clear and pale-yellow or light brown • Do not use if particulate matter and/or discolouration is observed • Only clear or slightly opalescent fluids are to be administered
Infusion Equipment	• Alcohol cleansing wipe, subcutaneous needle/s, luer lock syringe/s and subcutaneous extension set (if required). • Sterile dressing (if required) • Subcutaneous Infusion Pump if required (these pumps must be used in compliance with manufacturer's instruction) i.e. Niki T34 or Springfuser.

Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on Medical order documented on the Subcutaneous Immunoglobulin (SCIg) Home Therapy Prescription/Order form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation (inpatient). • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.
Home Treatment	Home treatment should be initiated by a clinician experienced in the guidance of patients for home treatment in accordance with the Administration and Management of Immunoglobulin Procedure
Rate and Dose	• The dosage may need to be individualised for each patient dependent on the pharmacokinetic and clinical response • A loading dose may be required • Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order • Injection sites should be at least 5 cm apart • The recommended initial infusion rate depends on individual needs of the patient and should not exceed 20 mL/hour/site. If well-tolerated, the infusion rate can then gradually be increased to 35 mL/hour/site • If larger doses are given (>25 mL each site), it is advisable to administer them at multiple sites • Trough levels should be measured to adjust the dose and dosage interval
Administration	**Hizentra® is to be administered via the subcutaneous route only**, • Preferentially into the upper/outer arms, thighs, abdomen and/or lateral hip. • Administration methods for Hizentra® include use of an infusion pump or push techniques. The choice of administration technique and equipment is at the discretion of the treating healthcare professional. **Instruction for use** • Remove the protective cap from the vial and wipe the rubber stopper with alcohol • For withdrawing Hizentra®, use a sterile syringe and the supplied transfer device • Inject air into the vial that is equivalent to the amount of Hizentra® to be withdrawn. Then withdraw Hizentra® from the vial. If multiple vials are required to achieve the desired amount of Hizentra®, repeat this step • Follow the manufacturer's instructions for preparing the pump • If required Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with Hizentra® • Clean the injection site(s) with antiseptic solution • Grasp the skin between two fingers and insert the needle into the subcutaneous tissue. **Hizentra® must not be injected into a blood vessel**. To test that no blood vessel has been accidentally hit, 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 needle, tubing, and a new infusion site. • Secure the needle in place by applying sterile gauze or transparent dressing. • Infuse Hizentra® slowly

	• Follow the manufacturer's instructions for the pump if required. • The infusion site may be changed if patient comfort becomes an issue. • Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart. • Remove the peel-off label from the Hizentra® vial and insert into the patient diary
Observations (in hospital use only)	Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 30 minutes after the infusion: • Baseline observations immediately prior to the commencement • Closely monitor the patient for the first 15 minutes • Document observations at 15 minutes; then • Hourly until completion; and • At the completion of the infusion
Adverse Effects	• Patient's naïve to immunoglobulin may experience a higher frequency of adverse effects including those of a minor nature. • In case of severe reactions, the infusion must be stopped, and an appropriate treatment initiated • Type of reactions may include: • **Very Common** – injection/infusion site reaction • **Common** – headache • **Rare** – allergic reactions, anaphylactic shock, thrombotic reactions, chills, back pain, neck pain, arthralgia, hypotension, muscle weakness. For further rare reactions refer to Product Information • Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the Medical Officer, and provide emergency care as required • Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved • In the case of serious adverse events stop the infusion and follow the SCHHS Blood Product Administration Procedure: Transfusion Adverse Events and Reactions • Report all adverse events to blood bank / transfusion and CSL Medical Enquiries ASAP and no later than 24 hours from the event via: CSL Suspected adverse reaction report form or phoning 1800 642 865 • Report all adverse events in to the Clinical Incident Reporting System database
Reference	CSL Product Information, Hizentra.

Hizentra® AU 20% – Normal Human Subcutaneous Immunoglobulin (SCIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria. **NB Hizentra AU can be found in Auslab and ieMR as AU Hizentra**	
Indications	Hizentra® is indicated in adults and children for replacement therapy in: • Primary Immunodeficiency Diseases (PID) and • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment • Immunomodulatory therapy in CIDP
Precautions	• **Hizentra® AU must not be administered intravenously or intramuscularly**. If Hizentra® is inadvertently administered into a blood vessel, patients could develop shock. In the case of shock, current medical standards for shock treatment should be observed • Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when there has been a long interval since previous infusion • Known allergies: use with caution in patients with a known allergy to anti-IgA as it may cause severe hypersensitivity or anaphylaxis • Thrombotic Events: caution should be exercised in prescribing and administering Hizentra® in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolaemic patients and patients with diseases which increase blood viscosity) • An aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with human immunoglobulin administration • Transmissible infective agents may be a possibility. For further information on precautions refer to: Product Information.
Contraindications	Hizentra® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to any of its excipients. Must not be used in hyperprolinaemia type I or II.
Incompatibilities	Must not be mixed with any other product.
Presentation	Hizentra® contains human normal immunoglobulin G (IgG): • 1 g in a 5 mL solution • 4 g in a 20 mL solution
Storage Conditions	• Shelf life is 30 months • Store below 25°C (Do not freeze) • Keep the vial in the outer carton in order to protect from light • Do not use after expiry date
Inspection	This product is normally clear and pale-yellow or light brown • Do not use if particulate matter and/or discolouration is observed • Only clear or slightly opalescent fluids are to be administered
Infusion Equipment	• Alcohol cleansing wipe, subcutaneous needle/s, luer lock syringe/s and subcutaneous extension set (if required). • Sterile dressing (if required) • Subcutaneous Infusion Pump if required (these pumps must be used in compliance with manufacturer's instruction) i.e. Niki T34 or Springfuser.

Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products. • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient. • Medical order / prescription is documented on Medical order documented on the Subcutaneous Immunoglobulin (SCIg) Home Therapy Prescription/Order form at non-ieMR sites and electronically at ieMR sites. • Baseline observations taken – T, PR, RR & BP, and oxygen saturation (inpatient). • Allow the product to reach room temperature before infusing.
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent. • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.
Home Treatment	Home treatment should be initiated by a clinician experienced in the guidance of patients for home treatment in accordance with the Administration and Management of Immunoglobulin Procedure
Rate and Dose	• The dosage may need to be individualised for each patient dependent on the pharmacokinetic and clinical response • A loading dose may be required • Maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order • Injection sites should be at least 5 cm apart • The recommended initial infusion rate depends on individual needs of the patient and should not exceed 20 mL/hour/site. If well-tolerated, the infusion rate can then gradually be increased to 35 mL/hour/site • If larger doses are given (>25 mL each site), it is advisable to administer them at multiple sites • Trough levels should be measured to adjust the dose and dosage interval
Administration	**Hizentra® is to be administered via the subcutaneous route only**, • Preferentially into the upper/outer arms, thighs, abdomen and/or lateral hip. • Administration methods for Hizentra® include use of an infusion pump or push techniques. The choice of administration technique and equipment is at the discretion of the treating healthcare professional. **Instruction for use** • Remove the protective cap from the vial and wipe the rubber stopper with alcohol • For withdrawing Hizentra®, use a sterile syringe and the supplied transfer device • Inject air into the vial that is equivalent to the amount of Hizentra® to be withdrawn. Then withdraw Hizentra® from the vial. If multiple vials are required to achieve the desired amount of Hizentra®, repeat this step • Follow the manufacturer's instructions for preparing the pump • If required Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with Hizentra® • Clean the injection site(s) with antiseptic solution • Grasp the skin between two fingers and insert the needle into the subcutaneous tissue. **Hizentra® must not be injected into a blood vessel**. To test that no blood vessel has been accidentally hit, 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 needle, tubing, and a new infusion site. • Secure the needle in place by applying sterile gauze or transparent dressing. • Infuse Hizentra® slowly

	• Follow the manufacturer's instructions for the pump if required. • The infusion site may be changed if patient comfort becomes an issue. • Multiple injection sites can be used simultaneously. Injection sites should be at least 5 cm apart. • Remove the peel-off label from the Hizentra® vial and insert into the patient diary
Observations (in hospital use only)	Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 30 minutes after the infusion: • Baseline observations immediately prior to the commencement • Closely monitor the patient for the first 15 minutes • Document observations at 15 minutes; then • Hourly until completion; and • At the completion of the infusion
Adverse Effects	• Patient's naïve to immunoglobulin may experience a higher frequency of adverse effects including those of a minor nature. • In case of severe reactions, the infusion must be stopped, and an appropriate treatment initiated • Type of reactions may include: • **Very Common** – injection/infusion site reaction • **Common** – headache • **Rare** – allergic reactions, anaphylactic shock, thrombotic reactions, chills, back pain, neck pain, arthralgia, hypotension, muscle weakness. For further rare reactions refer to Product Information • Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the Medical Officer, and provide emergency care as required • Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved • In the case of serious adverse events stop the infusion and follow the SCHHS Blood Product Administration Procedure: Transfusion Adverse Events and Reactions • Report all adverse events to blood bank / transfusion and CSL Medical Enquiries ASAP and no later than 24 hours from the event via: CSL Suspected adverse reaction report form or phoning 1800 642 865 • Report all adverse events in to the Clinical Incident Reporting System database
Reference	CSL Product Information, Hizentra®.

Cuvitru 20% – Normal Human Subcutaneous Immunoglobulin (SCIg)

Product Information and Consumer Information	
Immunoglobulins are ordered on BloodSTAR, the National Blood Authority web-based system that facilitates authorisation for access and management of these products for the treatment of medical condition identified in the criteria.	
Indications	Cuvitru ® is indicated in adults and children for replacement therapy in: • Primary Immunodeficiency Diseases (PID) • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment
Precautions	Cuvitru ® is for **Subcutaneous administration only** • Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when there has been a long interval since previous infusion • Known allergies: use with caution in patients with a known allergy to anti-IgA as it may cause severe hypersensitivity or anaphylaxis • Thrombotic Events: caution should be exercised in prescribing and administering Cuvitru® in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolaemic patients and patients with diseases which increase blood viscosity) • Acute renal dysfunction/failure may occur. In patients who are at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure (monitor renal function and consider lower, more frequent dosing • Aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with human immunoglobulin administration • Transmissible infective agents may be a possibility. For further information on precautions refer to: Product Information.
Contraindications	• Cuvitru ® is contraindicated in patients who have had a true anaphylactic reaction to the active substance or to any of its excipients. • Contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity immunoglobulin
Incompatibilities	Must not be mixed with any other product.
Presentation	Cuvitru ® contains human normal immunoglobulin G (IgG): • 1 g in a 5 mL solution • 2 g in a 10 mL solution • 4 g in a 20 mL solution • 8 g in a 40 mL solution
Storage Conditions	• Stored at 2-8°C for up to 36 months (Do not freeze) • o not shake • Keep the vial in the outer carton to protect from light • Do not use after expiry date • Product issued for home use and returned will be discarded.
Inspection	This product is normally clear and pale-yellow or light brown • Do not use if particulate matter and/or discolouration is observed • Only clear or slightly opalescent fluids are to be administered
Infusion Equipment	• Alcohol cleansing wipe, subcutaneous needle/s, luer lock syringe/s and subcutaneous extension set (if required). • Sterile dressing (if required) • Subcutaneous Infusion Pump if required (these pumps must be used in compliance with manufacturer's instruction) i.e., Niki T34 or Springfuser.

Prior to commencement of infusion	**RIGHT PATIENT / RIGHT PRODUCT** • Verbal Consent is required for fractionated blood products • Clinical staff explain the administration procedure to patient Consumer Information should be given to the patient • Medical order / prescription is documented on Medical order documented on the Subcutaneous Immunoglobulin (SCIg) Home Therapy Prescription/Order form at non-ieMR sites and electronically at ieMR sites • Baseline observations taken – T, PR, RR & BP, and oxygen saturation (inpatient) • Allow the product to reach room temperature before infusing
4 Hour Rule	• Complete each bottle within 4 hours of opening/piercing as contains no antimicrobial agent • No blood product is to be stored on wards/units, if not being transfused return to the laboratory.
Home Treatment	Home treatment should be initiated by a clinician experienced in the guidance of patients for home treatment in accordance with the Administration and Management of Immunoglobulin Procedure
Rate and Dose	• The dosage may need to be individualised for each patient dependent on the pharmacokinetic and clinical response • For the first two infusions of Cuvitru ® 20%, the recommended infusion rate is 10-20 mL/hr/site. • For subsequent infusions, the infusion rate may be increased to 60 mL/hr/site as tolerated (e.g., 60 mL/hr/site x 2 sites = 120 mL/hr). For patients utilizing 4 infusion sites, the maximum infusion rate for all sites combined is 240 mL/hr • Trough levels should be measured to adjust the dose and dosage interval
Administration	• Cuvitru ® 20% is to be administered via the subcutaneous route only, preferentially into the upper/outer arms, thighs, abdomen and/or lateral hip. • Administration methods for Cuvitru ® 20% include use of an infusion pump or push techniques. The choice of administration technique and equipment is at the discretion of the treating healthcare professional. **Subcutaneous Injection via infusion pump** Cuvitru ® 20% subcutaneous infusion using a subcutaneous infusion device such as but not limited to NIKI T34 or Springfuser **Instruction for use** • Remove the protective cap from the vial and wipe the rubber stopper with alcohol • For withdrawing Cuvitru ® 20%, use a sterile syringe and the supplied transfer device • Inject air into the vial that is equivalent to the amount of Cuvitru ® 20%to be withdrawn. Then withdraw Cuvitru ® 20%from the vial. If multiple vials are required to achieve the desired amount of Cuvitru ® 20% repeat this step • Subcutaneous infusion pump only - Follow the manufacturer's instructions for preparing the pump • Prime the administration tubing to ensure that no air is left in the tubing by filling the tubing/needle with Cuvitru ® 20% • Clean the injection site(s) with antiseptic solution • Grasp the skin between two fingers and insert the needle into the subcutaneous tissue. • Cuvitru ® 20% **must not be injected into a blood vessel**. To test that no blood vessel has been accidentally hit, 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 needle, tubing, and a new infusion site. • Secure the needle in place by applying sterile gauze or transparent dressing. • Infuse Cuvitru ® 20%slowly (if using a subcutaneous infusion follow the manufacturer's instructions for the pump). • The infusion site may be changed if patient comfort becomes an issue.

	• Multiple injection sites can be used simultaneously. Injection sites should be at least 10 cm apart. • Remove the peel-off label from the Cuvitru ® 20% vial and insert into the patient diary
Observations (in hospital use only)	Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 30 minutes after the infusion: • Baseline observations immediately prior to the commencement • Closely monitor the patient for the first 15 minutes • Document observations at 15 minutes; then • Hourly until completion; and • At the completion of the infusion
Adverse Effects	• Patient's naïve to immunoglobulin may experience a higher frequency of adverse effects including those of a minor nature. • In case of severe reactions, the infusion must be stopped, and an appropriate treatment initiated • Type of reactions may include: • **Very Common** – injection/infusion site reaction • **Common** – headache • **Rare** – allergic reactions, anaphylactic shock, thrombotic reactions, chills, back pain, neck pain, arthralgia, hypotension, muscle weakness. For further rare reactions refer to Product Information • Slowing or stopping the infusion usually allows the symptoms to subside. Assess vital signs, notify the Medical Officer, and provide emergency care as required • Minor reactions: the infusion may be resumed at a slower rate or rate that does not result in recurrence of the symptoms once the patient is stable and has clinically improved • In the case of serious adverse events stop the infusion and follow the SCHHS Blood Product Administration Procedure: Transfusion Adverse Events and Reactions • Report all adverse events to blood bank / transfusion and CSL Medical Enquiries ASAP and no later than 24 hours from the event via: CSL Suspected Adverse Reaction Report form or phoning 1800 642 865 • Report all adverse events in to the Clinical Incident Reporting System database
Reference	Takeda Product information, Cuvitru ® 20%

Other immunoglobulins (not included in this manual)

CMV Immunoglobulin-VF

Hepatitis Immunoglobulin-VF

Normal Immunoglobulin-VF

Rh (D) Immunoglobulin-VF - Refer to SCHHS procedure Anti D Administration

Rhophylac®

Tetanus Immunoglobulin-VF

Zoster Immunoglobulin-VF

Partnering with consumers

Patients and family members are to be encouraged and given the opportunity to ask questions, clarify information and identify goals of care during communication processes. Staff are responsible for providing information in a way that is understandable and that meets patient's needs and health literacy level, to ensure patient's and family's understanding of discussions.

Definition of key terms

Term	Description
Subcutaneous immunoglobulin (SCIg)	Immunoglobulin given by slowly injecting purified immunoglobulin into fatty tissue just underneath the skin.
Intravenous immunoglobulin (IVIg)	Immunoglobulin given through a vein to treat immune deficiencies, and inflammatory conditions.

References and further reading

Primary legislation, policy, standards or other authority

Medicines and Poisons (Medicines) Regulation 2021

Human Rights Act 2019 (QLD)

Information Privacy Act 2009 (QLD)

Therapeutic Goods Act 1989 (Cth)

Australian Red Cross Lifeblood

Australian Standard AS3864-1997 Medical Refrigeration Equipment – For the Storage of Blood and Blood Products

Immunoglobulin Governance National Policy: Access to Government-Funded Immunoglobulin Products in Australia

National Safety and Quality Health Service (NSQHS) Standards 2nd ed – Blood Management

Forms and other related or supporting documents

Australasian Society of Clinical Immunology and Allergy Guidelines ofr Standardised Infusion Rates for IVIg 2023

Blood Product Administration procedure

Blood product information manual: Transfusion and blood management.

National Safety and Quality Health Service (NSQHS) Standard 7 Blood Management Standard

SCHHS Blood and blood products prescription

Subcutaneous Immunoglobulin program Patient/Carer Training Competency

Subcutaneous Immunoglobulin program Patient Assessment form

Subcutaneous Immunoglobulin (SCIg) Prescription/Order

Subcutaneous Immunoglobulin (SCIg) Program Nurse Training checklist

Product information Cuvitru®.

Product information Evogam®,

Product information Flebogamma 5%®,

Product information Flebogamma 10% ®

Product information Gamunex ®

Product information Hizentra®

Product information Intragam®,

Product information Octagam®

Product information Privigen®,

Consultation

Key stakeholders who contributed to and/ or reviewed this version include:

SCHHS Blood Management Committee

Department of Neurology

Department of Haematology

Day Unit Intervention Therapy

Cancer Care Units

Compliance is addressed by

☒ Existing SCHHS Audit: Annual Review of RiskMan Clinical Incident Reports –Transfusion Committee | Biannual review of the ACHS Clinical Indicators pertaining to Blood transfusion within each hospital. Audit Dates; Annually, August

☒ Department or SCHHS Quality program: CNC Transfusion | Blood Management Committee

☐ Reporting mechanism: N/A

☒ Key indicators and/ or outcomes: 100% once only competency completion for Immunoglobulin administration BloodSafe eLearning for those regularly administering IVIg and for relevant staff competent in SCig Training

Document approval

Version	Prepared by	Endorsed by	Authorised by	Review due
2.0	CNC Transfusion	Chair, Blood Management committee	Blood Management Committee	10/04/2026
Supersedes: 001652.02				
Keywords: Immunoglobulin, intravenous immunoglobulin, subcutaneous immunoglobulin				