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Non-Fresh Blood Products Intravenous Administration Procedure

1. Purpose

This procedure outlines the use and administration of plasma-derived and recombinant products by WA Country Health Service (WACHS) staff. Plasma can be fractionated to create other types of treatment products, including:

- clotting factors to treat people with haemophilia and other bleeding disorders
 - Fiona Stanley Hospital (FSH) is the State Haemophilia and Haemostasis Centre, contact the centre on 08 6152 4137, or the Clinical Nurse Consultant (CNC) on 08 6152 6527 for referrals and specialist advice
- immunoglobulin (Ig) to help patients with immune system disorders and immunemediated conditions
- hyperimmune Ig products to treat exposures to specific diseases
- albumin for burns, surgery, and kidney disease treatment.

Recombinant products are synthetic alternatives to some plasma-derived products and are not made from human blood. Recombinant products are used in the treatment of haemophilia and other bleeding disorders to control bleeds when they occur and prevent future bleeds.

This procedure is to be read in conjunction with the WACHS <u>Patient Blood Management</u> Policy.

2. Procedure

Prescribing and ordering of non-fresh blood products and obtaining and documenting informed patient consent is in accordance with:

- the WACHS Consent to Treatment Policy
 - informed consent must be documented on the <u>MR30G WACHS Consent to Blood</u> <u>Products</u> and filed in the patient's medical record
 - see also: WACHS <u>Patient Blood Management Policy</u> for information about emergency treatment, advance health directives and refusal of blood products
- National Safety and Quality Health Service (NSQHS) Standard 7: <u>Blood Management</u>
- the <u>Australian and New Zealand Society of Blood Transfusion (ANZSBT) guidelines</u> for the Administration of Blood Products
- the National Blood Authority (NBA) Patient Blood Management guidelines
- MP 0077/18 Statewide Medicines Formulary Policy
- Product Information/TGA/ARTG Listing

Accurate, legible, and complete documentation of patients' blood and blood product transfusion history and indications for the use of blood and blood products is a mandatory requirement under the WACHS <u>Patient Blood Management Policy</u>.

Appendices:

Appendix A lists the Non-Fresh Blood Products details profiles for each product.

- Appendix B provides "Initial" and "Subsequent" infusion rates for specified immunoglobulin products.
- Appendix C provides an example of a stepped rate infusion calculation.

2.1. Patient demographics

This guideline procedure is applicable to adult, non-pregnant patients. For other demographics see below:

- for pregnant patients, see <u>Women's and Newborn Health Service (WNHS) Transfusion</u>
 <u>Medicine Policies</u> (HealthPoint)
- for paediatric patients, see <u>Child and Adolescent Health Service (CAHS) Transfusion</u> Medicine Protocols (HealthPoint)
- for neonatal patients, see <u>CAHS Blood Components and Blood Products</u> <u>Administration (Neonatology)</u> (HealthPoint)

2.2. Intramuscular and subcutaneous immunoglobulins

This procedure is not applicable to intramuscular and subcutaneous immunoglobulin products. For information on the administration and management of these products, refer to:

- the product information available from AusDI or TGA eBusiness Services websites
- the policy, guideline, procedure, or resource from the patient's tertiary referral centre:
 - Fiona Stanley Hospital
 - Royal Perth Hospital
 - Sir Charles Gairdner Hospital
 - Perth Children's Hospital
 - King Edward Memorial Hospital

A non-exhaustive list of available intramuscular and subcutaneous immunoglobulin products is in the table below:

| Intramuscular | Subcutaneous |
|---------------------------------|------------------|
| Hepatitis B Immunoglobulin-VF | Cuvitru® 20% |
| Normal Immunoglobulin-VF (NHIg) | Hizentra® AU 20% |
| Rh (D) Immunoglobulin-VF | Hizentra® 20% |
| Rhophylac® ** | Xembify® 20% |
| Tetanus Immunoglobulin-VF ** | |
| Zoster Immunoglobulin-VF | |

^{** =} May also be administered intravenously, see IVIg: Rhophylac@ and IVIg: Tetanus Immunoglobulin-VF.

3. Roles and Responsibilities

Staff who prescribe, order, process, store, handle, or administer non-fresh blood products are to work within their scope of practice, level of training, education and experience, and job role.

All staff are required to comply with the directions in WACHS policies and procedures as per their roles and responsibilities. Guidelines are the recommended course of action for

WACHS and staff are expected to use this information to guide practice. If staff are unsure which policies procedures and guidelines apply to their role or scope of practice, and/or are unsure of the application of directions they should consult their manager in the first instance.

4. Monitoring and Evaluation

Adverse events and clinical incidents relating to blood products are to be reported via the approved clinical incident management system (CIMS) e.g. DATIX and managed as per the WACHS <u>Patient Blood Management Policy</u> and MP 0122/19 <u>Clinical Incident Management Policy</u>.

This procedure will be reviewed as required to determine effectiveness, relevance, and currency. At a minimum it will be reviewed every five years by the WACHS Blood Management CNC.

5. References

We acknowledge the following previous site endorsed work and/or contributors used to compile this document:

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Jie Zhou, Transfusion Nurse RPBG

Pauline Coutts, Blood Management and Transfusion Nurse RPBG

RPBG Blood Products Administration Guideline

6. Definitions

Nil.

7. Document Summary

| Coverage | WACHS-wide |
|---|---|
| Audience | All WACHS Staff involved in prescribing, ordering, processing, storing, handling, or administering non-fresh blood products. |
| Records Management | Clinical: <u>Health Record Management Policy</u> |
| Related Legislation | Health Services Act 2016 (WA) |
| Related Mandatory Policies / Frameworks | MP 0175/22 Consent to Treatment Policy MP 017/22 Recognising and Responding to Acute Deterioration Policy Clinical Governance, Safety and Quality Framework |
| Related WACHS Policy Documents | Consent to Treatment Policy Blood Management Policy Patient Identification Policy Primary Postpartum Haemorrhage Guideline Specialised Medication – Adult Intravenous Iron Therapy Guideline |
| Other Related Documents | ACSQHC Blood Management ANZSBT Australian and New Zealand Society of Blood Transfusion Guidelines CAHS Blood Components and Blood Products Administration (Neonatology) CAHS Transfusion Medicine Protocols (HealthPoint) NBA Patient Blood Management guidelines WACHS Major Haemorrhage Protocol for sites WITH Blood Products WACHS Major Haemorrhage Protocol for sites WITH ONLY EMERGENCY Blood Products WACHS Major Haemorrhage Protocol for Sites WITHOUT Blood Products WHNS Transfusion Medicine Policies |
| Related Forms | MR30G WACHS Consent to Blood Products MR30H WACHS Release of Liability - Refusal of Blood Products MR70B WACHS Rh D Immunoglobulin (Anti D) Record MR173C WACHS Intravenous Iron Consent and Prescription MR175A WACHS Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Related Training | Optional Training Available from MyLearning: BloodSafe: Clinical Transfusion Practice (BLDCT EL2) BloodSafe: Clinical Transfusion Practice Refresher (BLDTF EL2) BloodSafe: Immunoglobulin Essentials (BLDI1 E2) |

| | BloodSafe: Immunoglobulin Governance and Access (BLDI2 EL2) BloodSafe: Immunoglobulin Prescribing (BLDI3 EL2) BloodSafe: Immunoglobulin Administration (BLDI4 EL2) BloodSafe: Immunoglobulin Adverse Events (BLDI5 EL2) BloodSafe: RhD Immunoglobulin (BLDRI EL2) |
|--|---|
| Aboriginal Health Impact Statement Declaration (ISD) | ISD Record ID: 4082 |
| National Safety and Quality Health Service (NSQHS) Standards | 1.27, 2.07, 3.05, 4.03, 4.07, 6.06, 7.03, 7.05, 7.06, 7.07, 7.09, 8.04, 8.10 |
| Aged Care Quality Standards | Nil |
| Chief Psychiatrist's Standards for Clinical Care | Nil |
| Other Standards | Nil |

8. Document Control

| Version | Published date | Current from | Summary of changes |
|---------|------------------|------------------|---|
| 3.00` | 21 March 2025 | 21 March 2025 | change of title and policy type intramuscular and subcutaneous product information removed references to Transfusion Medicines Unit (TMU) removed and replaced with standard statement referring users to local Pathology and/or Pharmacy Services administration rate tables for IVIg products amalgamated to appendices A and B. |

9. Approval

| Policy Owner | Executive Director Medical Services |
|----------------------|--|
| Co-approver | Executive Director Clinical Excellence |
| Contact | Blood Management Clinical Nurse Consultant |
| Business Unit | Patient Safety & Quality |
| EDRMS# | ED-CO-19-97014 |

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This document can be made available in alternative formats on request.

Appendix A: Non-Fresh Blood Products List

| Albumin: Alburex® 5 AU | 8 |
|--------------------------------------|----|
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| Factors: Beriplex® P/N | 13 |
| Factors: Biostate® | 14 |
| Factors: ELOCATE® | 15 |
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| Factors: FEIBA® NF | 17 |
| Factors: MonoFIX®-VF | 18 |
| Factors: NovoSeven® RT | 19 |
| Factors: Prothrombinex®-VF | 20 |
| Factors: RiaSTAP® | 21 |
| Factors: Xyntha® | 22 |
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| IVIg: Privigen® 10% | 31 |
| IVIg: Rhophylac® | 32 |
| IVIg: Tetanus Immunoglobulin-VF (IV) | 33 |

Albumin: Alburex® 5 AU

| Product | Alburex® 5 AU (human albumin 50 g/L) |
|---|--|
| Specifications | One litre of Alburex® 5 AU contains 4 mmol of sodium acetyltryptophanate and 4 mmol of sodium octanoate. Sodium chloride is added to give a sodium content of 140 mmol/L. Half-life: 19 days Fractionated from pooled human plasma collected in Australia. Caution: sodium level of this product should be noted when used for patients requiring sodium restriction |
| Vial sizes / Volume | 12.5 g in 250 mL 25 g in 500 mL |
| Use | Used when albumin in blood is low, resuscitation in shock, extensive burns, respiratory distress. (CSL product information) |
| Dose | Varies depending on clinical indication - Refer to Product Information |
| Contra- indications and Precautions | A known allergy to this product or any of the excipients Used with CAUTION in hypervolaemia or haemodilution conditions: Cardiac failure Hypertension Oesophageal varices Pulmonary oedema Haemorrhagic diathesis Severe anaemia Renal and post-renal anuria |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 30°C (Do not freeze). Protect from light. Do not use if product appears turbid. Standard IV infusion giving set. Contains no antimicrobial preservative, to be used immediately after opening. NOT compatible with any IV medications, other blood products, other albumins, or water for injections Rate as per medical officer instructions. Infusion time should not exceed 4 hours/bottle. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations For further information | Baseline TPR, BP & 0₂ sats At 30 mins post commencement TPR, BP & 0₂ sats Hourly monitoring of vital signs as clinically indicated. Monitor urine output and electrolytes. Observe for signs of adverse reaction particularly monitor patient for circulatory overload. At the first signs of circulatory overload or increased blood pressure associated with pulmonary oedema the infusion should be stopped. Respond and report accordingly. on, refer to Product Information or CSL Behring. |

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Albumin: Alburex® 20 AU

| Product | Alburex® 20 AU (human albumin 200 g/L) |
|---|---|
| Specifications | One litre of Alburex® 20 AU contains 16 mmol of sodium acetyltryptophanate and 16 mmol of sodium octanoate. Sodium chloride is added to give a sodium content of 140 mmol/L. Half-life: 19 days Fractionated from pooled human plasma collected in Australia. Caution: sodium level of this product should be noted when used for patients requiring sodium restriction |
| Vial sizes / Volume | 10 g in 50 mL 20 g in 100 mL |
| Use | Used when albumin in blood is low, resuscitation in shock, extensive burns, respiratory distress. (CSL product information) |
| Dose | Varies depending on clinical indication - Refer to Product Information |
| Contra- indications and Precautions | A known allergy to this product or any of the excipients Used with CAUTION in hypervolaemia or haemodilution conditions: Cardiac failure Hypertension Oesophageal varices Pulmonary oedema Haemorrhagic diathesis Severe anaemia Renal and post-renal anuria |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 30°C (Do not freeze). Protect from light. Do not use if product appears turbid. Standard IV infusion giving set. Contains no antimicrobial preservative, to be used immediately after opening. NOT compatible with any IV medications, other blood products, other albumins or water for injections Rate as per medical officer instructions Infusion time should not exceed 4 hours/bottle Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations For further informati | Baseline TPR, BP & O₂ sats At 30 mins post commencement TPR, BP & O₂ sats Hourly monitoring of vital signs as clinically indicated. Monitor urine output and electrolytes. Observe for signs of adverse reaction particularly monitor patient for circulatory overload. At the first signs of circulatory overload or increased blood pressure associated with pulmonary oedema the infusion should be stopped. Respond and report accordingly. Ion, refer to Product Information or CSL Behring. |

For further information, refer to <u>Product Information</u> or <u>CSL Behring</u>.

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: ADVATE®

| Product | ADVATE® (recombinant factor VIII (eight)) |
|----------------|---|
| Specifications | After reconstitution with diluent, contains approximately 40 to 960 units per mL recombinant coagulation factor VIII (antihemophilic factor). Contains 0.45 mmol (10 mg) sodium per vial. |
| Vial sizes | 250, 500, 1000, 1500 units (including 2 mL water for injection (WFI) diluent) 2000, 3000, 4000 units (including 5 mL water for injection (WFI) diluent) |
| Use | Prophylaxis or treatment of patients with Factor VIII deficiency |
| Dose | Refer to Haematology Specialist |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au |
| | Out of hours, contact on-call Haematologist. Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right |
| Administration | dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow product and diluent to reach room temperature. Reconstitution of the lyophilised product – refer to instructions supplied with the product. Swirl vial, do not shake. Advate® is a white to slightly yellow powder before reconstitution and a clear liquid after reconstitution. Do not use if a clot or gel forms or if appears turbid. If using multiple vials, pool into 20 mL syringe Rate: 2 mL/minute or as tolerated by patient via intravenous route During administration monitor for increased pulse rate, if this occurs slow infusion rate or pause until symptoms subside. Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. |

For further information, refer to <u>Product Information</u> and TGA: <u>Product Information FVIII ADVATE</u> and <u>http://www.advate.com/</u>

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services). Product should be used for intended patient (issue label) only.

Factors: ALPROLIX®

| Product | ALPROLIX® (recombinant factor IX) |
|----------------|--|
| Specifications | Recombinant factor IX, polysorbate 20, sodium chloride, sucrose, histidine, mannitol |
| Vial sizes | 250, 500, 1000, 2000, 3000, 4000 units (including 5 mL diluent in a pre-filled syringe) |
| Use | Prophylaxis or treatment of patients with Factor IX deficiency |
| Dose | Refer to Haematology Specialist |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow to reach room temperature prior to reconstitution. Contains no preservatives, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Reconstitution of the lyophilised product – refer to instructions supplied with the product. Swirl, do not shake. Infusion set provided with the kit. If using multiple vials, pool into 20 mL syringe Rate:3 mL/minute or as tolerated by patient via intravenous route Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. |

For further information, refer to product insert or Product Information FIX ALPROLIX (tga.gov.au) Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services). Product should be used for intended patient (issue label) only.

Factors: BeneFix®

| Product | FIX BeneFix® (recombinant factor IX) |
|----------------|---|
| Specifications | Coagulation factor IX, recombinant |
| Vial sizes | 250, 500, 1000, 2000, 3000 IU (including a pre-filled diluent syringe containing 0.234% sodium chloride) |
| Use | Prophylaxis or treatment of patients with Factor IX deficiency |
| Dose | Refer to Haematology Specialist. |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze) Allow to reach room temperature prior to reconstitution. Contains no antimicrobial preservative and should be used immediately. Reconstitution of the lyophilised product – refer to instructions supplied with the product. Swirl, do not shake. Infusion set provided in the kit. If using multiple vials, pool into 20 mL syringe Rate: A maximum rate of 3 mL/minute via intravenous route Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. |

For further information, refer to product insert or from TGA: <u>Product Information FIX BeneFix (tga.gov.au)</u> and: <u>http://www.medicines.org.au//files/pfpbenev.pdf</u>

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: Beriplex® P/N

| Fractionated from pooled human plasma. Content per 500 unit vial: Coagulation factors II (400-960 IU), VII (200-500 IU), IX (400-620 IU), X (404-1200 IU), Protein C (300-900 IU) & Protein S (240 -760IU), Note: contains up to 343 mg sodium (approximately 15 mmol) and up to 200 units heparin per 100 mL reconstituted solution Vial sizes 500 units (including 20 mL water for injections (WFI) diluent) Prevention and treatment of bleeding in patients with acquired or congenital factor deficiency. i.e., reversal of warfarin therapy. For congenital deficiencies: Consult with Haematologist. For warfarin reversal: dose dependent on patient INR level. 25-50 units per kg. Refer to Product Information for dose calculation. Dose is based on body weight up to but not exceeding 100 kg. If weight > 100 kg, refer to Product Information Correction of INR is commonly reached approx. 30 mins after administration. Repeated dosing is NOT recommended. For details refer to Product Information. Contraindications The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. Two staff to perform checks as per Patient Blood Management Policy. Check issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g., pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not wis if a clot or gel forms or it appears turbid. Administration Administration is a contain any antimicrobial preservative, so it must be used immediately in to room temperature prior to reconstitution. Do not use if a clot or gel forms or it ap | Product | Beriplex® P/N (human prothrombin complex) |
|--|----------------|--|
| Prevention and treatment of bleeding in patients with acquired or congenital factor deficiency. i.e., reversal of warfarin therapy. For congenital deficiencies: Consult with Haematologist. For warfarin reversal: dose dependent on patient INR level. 25-50 units per kg. Refer to Product Information for dose calculation. Dose is based on body weight up to but not exceeding 100 kg. If weight > 100 kg, refer to Product Information for dose calculation. Correction of INR is commonly reached approx. 30 mins after administration. Repeated dosing is NOT recommended. For details refer to Product Information. Contraindications Nepeated dosing is NOT recommended. For details refer to Product Information. The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. Two staff to perform checks as per Patient Blood Management Policy. Check issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution. Place vial on flat surface to add WFI. Gently swirl vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administer via also IV infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/hour), via either: Syringe pump; pool vial contents into s | Specifications | Content per 500 unit vial: Coagulation factors II (400-960 IU), VII (200-500 IU), IX (400-620 IU), X (440-1200 IU), Protein C (300-900 IU) & Protein S (240 -760IU). Note: contains up to 343 mg sodium (approximately 15 mmol) and up to 200 units |
| deficiency, i.e., reversal of warfarin therapy. For congenital deficiencies: Consult with Haematologist. For warfarin reversal: dose dependent on patient INR level. 25-50 units per kg. Refer to Product Information for dose calculation. Dose is based on body weight up to but not exceeding 100 kg. If weight > 100 kg, refer to Product Information Correction of INR is commonly reached approx. 30 mins after administration. Repeated dosing is NOT recommended. For details refer to Product Information. Contraindications **Nown history of heparin induced thrombocytopenia (contains heparin) Hypersensitivity to the active substances or to any of the excipients The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. Two staff to perform checks as per Patient Blood Management Policy. Check issue label and patient ID. Check right patient, right product, right dose prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution. Beriplex® P/N should be reconstituted aseptically and according to the Mix2vial® reconstitution instructions on the Product Information. Place vial on flat surface to add WFI. Gently swirt vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administer via slow IV, infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/mour), via either: Syringe pump: pool vial contents into 50 mL syringe/s and prime line. Volumetric pump: pool vial co | Vial sizes | 500 units (including 20 mL water for injections (WFI) diluent) |
| Por warfarin reversal: dose dependent on patient INR level. 25-50 units per kg. Refer to Product Information for dose calculation. Dose is based on body weight up to but not exceeding 100 kg. If weight > 100 kg, refer to Product Information Correction of INR is commonly reached approx. 30 mins after administration. Repeated dosing is NOT recommended. For details refer to Product Information. Repeated dosing is NOT recommended. For details refer to Product Information. Repeated dosing is NOT recommended. For details refer to Product Information. Repeated dosing is NOT recommended. For details refer to Product Information. Repeated dosing is NOT recommended. For details refer to Product Information. The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. Two staff to perform checks as per Patient Blood Management Policy. Check issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution. Beriplex® P/N should be reconstituted aseptically and according to the Mix2vial® reconstitution instructions on the Product Information. Place vial on flat surface to add WFI. Gently swiri vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administration Administer via slow IV infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/hour), via either: Syringe pump: pool via | Use | |
| Ordering The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. Two staff to perform checks as per Patient Blood Management Policy. Check issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution Beriplex® P/N should be reconstituted aseptically and according to the Mix2vial® reconstitution instructions on the Product Information. Place vial on flat surface to add WFI. Gently swirl vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administer via slow IV infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/hour), via either: Syringe pump: pool vial contents into 50 mL syringe/s and prime line. Volumetric pump: pool vial contents into sterile empty IV bag NEAT - do not dillute. In the event appropriate equipment is unavailable, slow IV push of 1-2 vials (max) is safe to give at a maximum rate (8 mL/min). On completion of infusion, flush line with 50 mL sodium chloride 0.9% at same infusion rate. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart Vital signs pre and post administration. Observe for signs of an adverse reaction, respond and report accordingly. Due to risk of thromboembolic complications, closely monitor patients with history | Dose | For warfarin reversal: dose dependent on patient INR level. 25-50 units per kg. Refer to Product Information for dose calculation. Dose is based on body weight up to but not exceeding 100 kg. If weight > 100 kg, refer to Product Information Correction of INR is commonly reached approx. 30 mins after administration. |
| procedures and/or contact local Pathology or Pharmacy Services for advice. Two staff to perform checks as per Patient Blood Management Policy. Check issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution Beriplex® P/N should be reconstituted aseptically and according to the Mix2vial® reconstitution instructions on the Product Information. Place vial on flat surface to add WFI. Gently swirl vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administration Administer via slow IV infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/hour), via either: Syringe pump: pool vial contents into 50 mL syringe/s and prime line. Volumetric pump: pool vial contents into 50 mL syringe/s and prime line. In the event appropriate equipment is unavailable, slow IV push of 1-2 vials (max) is safe to give at a maximum rate (8 mL/min). On completion of infusion, flush line with 50 mL sodium chloride 0.9% at same infusion rate. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart Vital signs pre and post administration. Observe for signs of an adverse reaction, respond and report accordingly. Due to risk of thromboembolic complications, closely monitor patients with history | | |
| issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution Beriplex® P/N should be reconstituted aseptically and according to the Mix2vial® reconstitution instructions on the Product Information. Place vial on flat surface to add WFI. Gently swirl vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administer via slow IV infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/hour), via either: Syringe pump: pool vial contents into 50 mL syringe/s and prime line. Volumetric pump: pool vial contents into 50 mL syringe/s and prime line. Volumetric pump: pool vial contents into sterile empty IV bag NEAT - do not dilute. In the event appropriate equipment is unavailable, slow IV push of 1-2 vials (max) is safe to give at a maximum rate (8 mL/min). On completion of infusion, flush line with 50 mL sodium chloride 0.9% at same infusion rate. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart Vital signs pre and post administration. Observe for signs of an adverse reaction, respond and report accordingly. Due to risk of thromboembolic complications, closely monitor patients with history | Ordering | |
| Observations respond and report accordingly. Due to risk of thromboembolic complications, closely monitor patients with history | Administration | issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, so it must be used immediately following re-constitution. Do not mix with other medicinal products; administer though a separate line. Bring diluent to room temperature prior to reconstitution Beriplex® P/N should be reconstituted aseptically and according to the Mix2vial® reconstitution instructions on the Product Information. Place vial on flat surface to add WFI. Gently swirl vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or it appears turbid. Administer via slow IV infusion at a rate of no more than 3 units/kg body weight/minute, with a maximum rate of 210 units/minute, approximately 8 mL/minute (480 mL/hour), via either: Syringe pump: pool vial contents into 50 mL syringe/s and prime line. Volumetric pump: pool vial contents into sterile empty IV bag NEAT - do not dilute. In the event appropriate equipment is unavailable, slow IV push of 1-2 vials (max) is safe to give at a maximum rate (8 mL/min). On completion of infusion, flush line with 50 mL sodium chloride 0.9% at same infusion rate. |
| | Observations | Vital signs pre and post administration. Observe for signs of an adverse reaction, respond and report accordingly. Due to risk of thromboembolic complications, closely monitor patients with history |

For further information, refer to <u>Product Information</u> or <u>CSL Behring</u>.

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Do not store in ward. Product should be used for intended patient (issue label) only.

Factors: Biostate®

| Product | FVIII and VWF: Biostate® (human coagulation factor VIII and human von Willebrand factor) |
|------------------------|--|
| Specifications | Human coagulation factor VIII (FVIII) (100 units/mL activity) and von Willebrand (VWF) factor (240 units/mL activity) Half- life: 12-14 hours Fractionated from pooled human plasma. |
| Vial sizes / Volume | NOTE vials state FVIII and VWF activity: 500 units FVIII / 1200 units VWF (including 5 mL water for injections (WFI) for reconstitution) 1000 units FVIII / 2400 units VWF (including 10 mL water for injections (WFI) for reconstitution) |
| Use | Von Willebrand disease, Factor VIII deficiency |
| Dose | Refer to Haematology Specialist-prescribe dose to FVIII IU |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow the vial and WFI to reach room temperature (between 20°C and 30°C) prior to reconstitution. Each vial contains no antimicrobial preservative and should be used immediately. Not to be added or mixed with any other fluids. Refer to Mix2vial® instructions for reconstitution - note place vial on flat surface to add water for injections. Swirl vial, do not shake. If using multiple vials, pool into 20 mL syringe Rate: slow intravenous injection over 5 to 6 minutes or as tolerated by patient Intravenous infusion rate should not exceed 6 mL per minute via an infusion pump. Any reaction maybe rate related, decrease rate of infusion or stop. Flush with sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. |

For further information, refer to Product Information or CSL Behring

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: ELOCATE®

| Product | FVIII ELOCTATE® (recombinant factor VIII) |
|----------------|---|
| Specifications | Recombinant factor VIII, polysorbate 20, sodium chloride, sucrose, calcium chloride dihydrate, histidine. |
| Vial sizes | 250, 500, 750, 1000, 1500, 2000, 3000 units (including 3 mL diluent in a pre-filled syringe) |
| Use | Prophylaxis or treatment of patients with factor VIII deficiency |
| Dose | Refer to Haematology Specialist |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow to reach room temperature prior to reconstitution. Does not contain an antimicrobial agent, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Reconstitution of the lyophilised product – refer to instructions supplied with the product. Swirl, do not shake. Infusion set provided with the kit. If using multiple vials, pool into 20 mL syringe Rate: 3 mL/minute or as tolerated by patient via intravenous route Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. |

For further information, refer to product insert or Product Information: <u>Product Information FVIII</u> <u>ELOCTATE (tga.gov.au)</u> or <u>Product information (guildlink.com.au)</u>

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: Factor XI (BPL®)

| Factors: Factor XI Concentrate (BPL®) |
|---|
| Human coagulation factor XI Half- life: 48 hours Fractionated from pooled human plasma. |
| 1000 units nominal vial size, variable – 10 mL water for injection for reconstitution Not held as stock but emergency dose may be available at FSH |
| Treatment and prophylaxis in patients with Factor XI deficiency |
| Refer to Haematology Specialist – Initial aim to 70% factor level: Weight (Kg) x required rise (%) / 2.4 = dose IU Post op dosing: 10-15 units/kg second daily Dose not to exceed 30 units/kg |
| The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Allow to reach room temperature prior to reconstitution. Reconstitute with 10 mL water for injections – note swirl vial, do not shake. Do not use if a clot or gel forms or if appears turbid. If using multiple vials, pool into 20 mL syringes Rate: do not exceed 3 mL per minute via intravenous route Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observe for signs of adverse reaction, respond and report accordingly. |
| |

For further information, refer to product insert or

 $\underline{FSH. Haemophilia and Haemostas is Centre@health.wa.gov.au}$

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: FEIBA® NF

| Product | FEIBA-NF® (factor VIII inhibitor bypassing fraction) |
|-------------------------------|---|
| Specifications | 500 units pack contains 200-600 mg human plasma protein, 1000 units pack contains: 400-1200 mg human plasma protein. Factor II, IX, X (mainly non activated) and Factor VII (mainly activated) Fractionated from pooled human plasma. |
| Vial sizes / Volume | 500 IU, 1000 IU. (including 10 mL or 20 mL water for injections (WFI) for reconstitution) |
| Use | Patients with Factor VIII or IX deficiency with inhibitors for whom recombinant factor VIIa treatment is not suitable. |
| Dose | Haemophilia or other indications: discuss with Haematology Specialist. Dose must not exceed 200 units/kg per day |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 25°C (do not freeze). Protect from light. Allow to reach room temperature before reconstitution. Contains no antimicrobial preservative, , therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Refer to package insert for reconstitution (Baxject®) – note swirl vial, do not shake. Do not use if product appears turbid. Administer at a maximum rate of 2 units FEIBA / kg of body weight per minute, via intravenous route via either: Syringe pump: pool vials into 50 mL syringe/s and prime line with FEIBANF® Volumetric pump: use burette attached to IV pump giving set, prime line with sodium chloride 0.9%, then pool vials into 50 mL syringe and then load into burette. Flush with sodium chloride 0.9% on completion. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations / Precautions | Observe for signs of adverse reaction, respond and report accordingly. High doses have been associated with disseminated intravascular coagulopathy. |

For further information, refer to product insert or TGA <u>Product information FVIII FEIBA-NF (tga.gov.au)</u>
Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Product should be used for intended patient (issue label) only.

Factors: MonoFIX®-VF

| Product | MonoFIX® - VF (human coagulation factor IX) |
|----------------------------|---|
| Specifications | Human coagulation factor IX, 100 units/mL Note: MonoFIX®-VF contains 50–140 units heparin sodium in each 500 units vial and 100–280 units in each 1000 units vial Fractionated from pooled human plasma. |
| Vial sizes | 500 units Factor IX activity (including 5 mL water for injections (WFI) for reconstitution) 1000 units Factor IX activity (including 10 mL water for injections (WFI) for reconstitution) |
| Use | Treatment and prophylaxis in patients with haemophilia B Note: First ^t choice product is usually recombinant FIX (MonoFIX®-VF). |
| Dose | Refer to Haematology Specialist. |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow the vial and WFI to reach room temperature (between 20°C and 30°C) prior to reconstitution. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Must not be added or mixed with any other fluids. Refer to instructions for reconstitution using Mix2Vial® - note place vial on flat surface to add water for injections. Swirl vial, do not shake. Do not use if clots or gel forms. If using multiple vials, pool into 20 mL syringe Rate: 3mL per minute or as tolerated by patient via intravenous route Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations / Precautions | Observe for signs of adverse reaction, respond and report accordingly. High doses have been associated with disseminated intravascular coagulopathy. |

For further information, refer to Product Information or CSL Behring

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services). Product should be used for intended patient (issue label) only.

Factors: NovoSeven® RT

| Product | FVIIa NOVOSEVEN®RT (recombinant activated factor VII) |
|-----------------|---|
| Specifications | After reconstitution with solvent, each vial contains recombinant Factor VII 1 mg/mL, sodium chloride 2.3 mg/mL, calcium chloride dihydrate 1.5 mg/mL, glycylglycine 1.3 mg/mL, polysorbate 80 0.1 mg/mL, mannitol 25 mg/mL, sucrose 10 mg/mL, methionine 0.5 mg/mL, histidine 1.6 mg/mL. |
| Vial sizes | 1 mg, 2 mg, use 3 mL syringe solvent for reconstitution. 5 mg, 8 mg, use 10 mL syringe solvent for reconstitution. Available for treatment of bleeding disorders in adults via FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au |
| Use | Bleeding disorders : control of bleeding in congenital FVII deficiency, patients with inhibitors to coagulation Factors VII or IX, Glanzmann's Thrombasthenia, rare bleeding disorders. |
| Dose | Guided by Haematology Specialist. |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Administrations | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Refer to product information for reconstitution directions. Store below 25°C (Do not freeze). Protect from light. Each vial contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Not to be mixed with infusion solutions or be given as intravenous infusion Swirl vial, do not shake. Do not use NovoSeven® RT exhibiting particulates or discolouration. If using multiple vials, pool into 10 mL syringe Rate: intravenous bolus injection over a period of 2 to 5 minutes Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse effects, respond and report accordingly. |
| | |

For further information, refer to Product Information & www.novonordisk.com.au

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Product should be used for intended patient (issue label) only.

Factors: Prothrombinex®-VF

| Product | Prothrombinex® -VF (human prothrombin complex) |
|-------------------------|--|
| Specifications | Coagulation factors II, IX, X (approx. 500 units of each) Fractionated from pooled human plasma. Note: contains heparin sodium |
| Vial sizes | 500 units (including 20 mL water for injections (WFI) diluent) |
| Use | Prevention and treatment of bleeding in patients with acquired or congenital factor deficiency. i.e. reversal of warfarin therapy. |
| Dose / Efficacy | Refer to Anticoagulation chart MR170C 25 units per kg. Maximum limit 2500 units (5 vials). Further use requires discussion with Haematology Specialist. Efficacy: decrease INR within 15 mins post infusion Effect lasts 6-12 hours and up to 48 hours if concurrent with Vit K FFP is not required unless patient actively bleeding or at high risk. |
| Contra- indications | Hypersensitivity to the active substances or to any of the excipients History of heparin-induced thrombocytopenia (HIT) Active thrombosis Disseminated intravascular coagulation (DIC) |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose — prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. This product does not contain any antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Must not be added to or mixed with any other fluids. Before reconstitution, allow the vials and WFI to reach a temperature between 20°C and 30°C. Refer to Mix2vial® reconstitution instructions – place vial on flat surface to add WFI. Swirl vial, do not shake. Remove reconstituted fluid from vial, do not spike vials to infuse. Do not use if a clot or gel forms or if appears turbid. Administer at a maximum rate of 3 mL/minute via either: Syringe pump: pool vials into 50 mL syringe/s and prime line with Prothrombinex®-VF. Volumetric pump: use burette set, prime line with sodium chloride 0.9%, pool vials into 50 mL syringe and then load into burette NEAT do not dilute with sodium chloride 0.9%, In the event, appropriate equipment is unavailable, slow IV push of 1-2 vials (max) is safe to give at a maximum rate (3 mL/min) Flush line with sodium chloride 0.9% on completion. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Vital signs pre and post administration. Observe for signs of an adverse reaction and report, respond and report accordingly. Thrombosis has been associated with product |
| For further information | ion, refer to Product Information or CSL Behring |

Any unused (unopened) product, or products that are no longer required should be immediately returned

to the issuing department (e.g. pathology or pharmacy services). Product should be used for intended patient (issue label) only.

Factors: RiaSTAP®

| Specifications | Coagulation factors, I albumin, arginine hydrochloride, sodium hydroxide, sodium chloride, sodium citrate. Contains up to 164 mg (7.1 mmol) sodium per vial. Fractionated, treated, lyophilised from pooled human cryoprecipitate. |
|----------------|---|
| Vial sizes | 1 g vial size (fibrinogen potency varies with batch – see side of box) (including 50 mL water for injections (WFI) diluent for reconstitution) |
| Storage | RiaSTAP and all contents are to be refrigerated at 2°C to 8°C. |
| Use | NBA Approved Use: treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenaemia. Off label use in trauma or obstetric haemorrhage: for treatment of severe acquired hypofibrinogenaemia in patients suffering critical bleeding, coagulopathy, or low fibrinogen where cryoprecipitate is not immediately available. |
| Dose | For trauma or obstetric haemorrhage: 4 g as a single dose For afibrinogenaemia: refer to Haematology Specialist and PI for dosage. For haemorrhage that is non-trauma / obstetric, the treating Consultant to discuss with on-call Haematology Consultant. |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | IV use only: Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Do not mix with other medicinal products or intravenous solutions. Allow to reach room temperature prior to reconstitution, WFI included can be warmed with a fluid warmer. Use aseptic technique, remove caps, clean rubber stopper with antiseptic wipe. Remove the cover from one end of the provided transfer set. Pierce the stopper of the RiaSTAP® vial with the uncovered spike of the Provided transfer set. Remove the cover from the other end of the Provided transfer set. Invert the WFI vial down onto the spike and allow the WFI to drain completely into the RiaSTAP® vial. [WFI – Water for Injections.] Gently swirl the RiaSTAP® vial to ensure the product is fully dissolved. Avoid shaking which causes formation of foam. The powder should be completely reconstituted within 15 minutes (generally 5 to 10 minutes). Do not use if a clot or gel forms (a small amount of froth is OK). Draw up each 1 g vial aseptically into a 50 mL syringe, ready for administration. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Infusion rate | If life threatening haemorrhage: administer each 1 g/50 mL via a syringe driver over 2 to 4 minutes. Non-life-threatening haemorrhage: administer each 1 g/50 mL via a syringe driver over 10 minutes. |
| Observations | Observe for signs of an adverse reaction, respond and report accordingly. |

For further information, refer to Product Information RiaSTAP (cslbehring.com), or section of Major Haemorrhage Protocol for sites WITH Blood Products. Product should be used for intended patient only. Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: Xyntha®

| Product | FVIII Xyntha® (recombinant factor VIII) |
|----------------|---|
| Specifications | Recombinant factor VIII, Contains 1.23 mmol (29 mg) of sodium per vial/syringe. |
| Vial sizes | 250, 500, 1000, 2000, 3000 units Diluent syringe contains sodium chloride 0.9% |
| Use | Prophylaxis or treatment of patients with Factor VIII deficiency |
| Dose | Refer to Haematology Specialist |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. In some cases, this product may be managed by Fiona Stanley Hospital: In hours, contact FSH.HaemophiliaandHaemostasisCentre@health.wa.gov.au Out of hours, contact on-call Haematologist. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Each vial contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Not to be mixed with infusion solutions Reconstitution of the lyophilised product – refer to instructions supplied with the product. Swirl, do not shake. Infusion set provided in the kit. If using multiple vials, pool into 20 mL syringe Rate: 2 mL/minute or as tolerated by patient via intravenous route Flush with 10 mL sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. |

For further information, refer to Product Information from TGA: XYNTHA (tga.gov.au) And: http://labeling.pfizer.com/showlabeling.aspx?id=504

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Factors: Thrombotrol®-VF

| Product | Thrombotrol®-VF (antithrombin III concentrate) |
|----------------|--|
| Specifications | Purified human antithrombin III (ATIII) 1000 units per vial. Fractionated from pooled human plasma. |
| Vial sizes | 1000 units of ATIII (including 20 mL water for injection (WFI) for reconstitution) |
| Use | Indicated in patients with hereditary deficiency of ATIII under following circumstances (requires Haematology consult): • Prophylaxis for prevention of thrombosis or PE in surgery, pregnancy, or childbirth – see PI for Precautions: Use in Pregnancy. • Therapeutic administration in thrombosis or PE |
| Dose | Dose units = (desired – pre-treatment ATIII%) x weight (kg) 2.2 |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow vials and WFI to reach a temperature between 20°C and 30°C prior to reconstitution. Must not be added to or mixed with any other fluids. This product does not contain any antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Refer to Mix2vial® instructions for reconstitution - place vial on flat surface to add water for injection. Swirl vial, do not shake. If using multiple vials, pool into large syringe Must be administered using a syringe pump, standard IV line. Rate: 3 mL per minute via intravenous route Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Observations | Observe for signs of an adverse reaction, respond and report accordingly. |

For further information, refer to <u>Product Information</u> or <u>CSL Behring</u>
Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: CMV Immunoglobulin-VF

| Product | CMV Immunoglobulin – VF (human cytomegalovirus immunoglobulin) |
|---------------------------------------|--|
| Specifications | Contains 50-70 mg/mL human plasma protein (at least 98% lgG). Isotonicity achieved by addition of 292 mmol/L of maltose. Fractionated from pooled human plasma |
| Vial sizes | CMV immunoglobulin activity of 1.5 million units per vial |
| Use | Prevention of CMV infection in at risk CMV seronegative patient i.e. lung transplant CMV neg recipient, CMV positive donor graft Caution: maltose may interfere in blood glucose testing—see Product Information |
| Dose | Dose is dependent on patient's body weight and clinical indication – refer to PI or Lung Transplant protocol |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Allow product to reach room temperature. Do not use if product turbid or contains any sediment. Must be administered using an infusion control device via standard IV giving set for designated device, diluted or undiluted. May be diluted with up to four times its volume with sodium chloride 0.9% or glucose 5%. Administer separately from other intravenous fluids or medications. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart |
| Infusion rate | Rate per hour VTBI |
| Observations For further information | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. Observe for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. refer to Product Information or CSL Behring |

For further information, refer to Product Information or CSL Behring

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: Flebogamma® 5%

| Product | Flebogamma® 5% Intravenous Immunoglobulin (human normal |
|------------------|--|
| | immunoglobulin) |
| Specifications | 5 g of human normal immunoglobulin /100 mL (≥ 97% lgG). lgA content < 0.05 |
| | mg/mL. Stabiliser: sorbitol 5 g/100 mL |
| | Fractionated from pooled human plasma. |
| | 0.5 g in 10 mL, 2.5 g in 50 mL, 5 g in 100 mL, 10 g in 200 mL, 20 g in 400 mL |
| Vial sizes | Caution: Flebogamma® IVIg is also available in a 10% solution. |
| | Replacement of immunoglobulins and treatment of selected autoimmune diseases |
| Use | according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) |
| 030 | http://www.blood.gov.au/ivig-criteria |
| | Caution: sorbitol is contraindicated in patients with fructose intolerance. |
| Dose | Dose is dependent on patient's body weight and clinical indication as in the criteria |
| D 030 | above |
| Ordering | The ordering process for blood products differs between sites, refer to local |
| Ordering | procedures and/or contact local Pathology or Pharmacy Services for advice. |
| | Two staff to perform checks as per Patient Blood Management Policy. Check |
| | Issue label and patient ID. Check right patient, right product, and right dose – |
| | prescription matches product supplied. If not identical, contact issuing department |
| | (e.g. pathology or pharmacy services) and prescribing doctor. |
| | Store below 30°C. Do not freeze. Protect from light. |
| | Contains no antimicrobial preservative, therefore, must be used immediately after |
| | opening and any unused product or waste material must be disposed of |
| | appropriately. |
| | It is recommended to read Product Information before infusing this product, click |
| | |
| A durinistration | on link below or see product insert provided with product. |
| Administration | Allow product to reach room temperature (approx. 30 mins). Paratural if any dust approximately the sale and a said. |
| | Do not use if product appears cloudy or has deposits. |
| | Ensure patient has had adequate hydration prior to the infusion of IVIg. |
| | Must be administered using an infusion control device via standard IV giving set |
| | for designated device. |
| | Administer smallest vial first (e.g. 50 mL before 100 mL when administering |
| | 7.5 g). |
| | Sodium chloride 0.9% solution can be used to flush the line. |
| | Should be administered separately from other intravenous fluids or medications. |
| | Document and place Issue label on MR175A Intravenous Blood Transfusion |
| | and Blood Product Treatment Order Chart |
| Infusion rate | • For the first 3 infusions (new patient or change of product) see Appendix B Initial |
| | For subsequent infusions, see <u>Appendix B Subsequent</u> |
| | Vital signs: |
| | Record baseline patient vital signs (temperature, blood pressure, pulse |
| | rate, respiratory rate, and oxygen saturations) before starting infusion. |
| | Recheck and record vital signs every 15 minutes AND at each rate |
| | change. |
| | Once maximum infusion rate is reached, recheck and record vital signs |
| Observations | every 60 minutes until the infusion is complete. |
| | All patients should be observed during and for 20 minutes after |
| | administration for signs of adverse reactions, respond and report accordingly. |
| | They are usually rate related & are most likely to occur within the first hour. |
| | <u>Caution:</u> Patient who receive IVIg for the first time <u>or</u> when products are |
| | changed or there has been a long interval since the previous infusion should be |
| | monitored for 1 hour after the <u>first infusion</u> |
| | - |

For further information, refer to refer to Flebogamma 5% DIF PI or Grifols Australia Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services). Product should be used for intended patient (issue label) only.

IVIg: Flebogamma® 10%

| Specifications | | | |
|----------------|---|--|--|
| | mg/mL Stabiliser: sorbitol 5 g/100mL Fractionated from pooled human plasma. | | |
| I VISI 61706 | 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL Caution: Flebogamma IVIg is also available in a 5% solution. | | |
| Use | Replacement of immunoglobulins and treatment of selected autoimmune diseases according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) http://www.blood.gov.au/ivig-criteria Caution: sorbitol is contraindicated in patients with fructose intolerance. | | |
| LINSE | Dose is dependent on patient's body weight and clinical indication as in the Criteria above | | |
| ()rdoring | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | | |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, and right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store below 30°C. Do not freeze. Protect from light. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. It is recommended to read Product Information before infusing this product, click on link below or see product insert provided with product. Allow product to reach room temperature (approx.30 mins). Do not use if product appears cloudy or has deposits. Ensure patient has had adequate hydration prior to the infusion of IVIg. Must be administered using a pump device via standard IV giving set for designated pump. Administer smallest vial first (e.g. 50 mL before 100 mL when administering 15 g) Sodium chloride 0.9% I solution can be used to flush the line. Should be administered separately from other intravenous fluids or medications. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | | |
| Infusion rate | For the first 3 infusions (new patient or change of product) see <u>Appendix B Initial</u> For subsequent infusions, see <u>Appendix B Subsequent</u> | | |
| Observations | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. All patients should be <u>observed during and for 20 minutes after administration</u> for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. <u>Caution:</u> Patient who receive IVIg for the first time <u>or</u> when products are changed <u>or</u> there has been a long interval since the previous infusion should be monitored for 1 hour after the <u>first infusion</u> refer to Product Information or Grifols Australia | | |

For further information, refer to Product Information or Grifols Australia

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: Gamunex® 10%

| Product | Gamunex® 10% Intravenous Immunoglobulin (human normal immunoglobulin) | | |
|----------------|---|--|--|
| Specifications | 10 g of human normal immunoglobulin /100 mL (≥ 98% IgG). IgA content ≤ 0.084mg/mL Stabiliser: glycine Fractionated from pooled human plasma. | | |
| Vial sizes | 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL | | |
| Use | Replacement of immunoglobulins and treatment of selected autoimmune diseases according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) http://www.blood.gov.au/ivig-criteria | | |
| Dose | Dose is dependent on patient's body weight and clinical indication as in the Criteria above | | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | | |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, and right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. See Product Information for storage conditions and prior to infusing this product, click on link below or see product insert provided with product. Allow product to reach room temperature (approx.30 mins). Do not use if product appears cloudy or has deposits. Ensure patient has had adequate hydration prior to the infusion of IVIg. Must be administered using an infusion control device via standard IV giving set for designated device. Administer smallest vial first (e.g. 50 mL before 100 mL when administering 15 g) Compatible fluid for priming and flush: glucose 5% or sodium chloride 0.9% If dilution is required, Gamunex® maybe diluted with glucose 5% only. Should be administered separately from other intravenous fluids or medications. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | | |
| Infusion rate | For the first 3 infusions (new patient or change of product) see <u>Appendix B Initial</u> For subsequent infusions, see <u>Appendix B Subsequent</u> | | |
| Observations | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. All patients should be <u>observed during and for 20 minutes after administration</u> for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. <u>Caution:</u> Patient who receive IVIg for the first time <u>or</u> when products are changed <u>or</u> there has been a long interval since the previous infusion should be monitored for 1 hour after the <u>first infusion</u> | | |

For further information, refer to Product Information or Grifols Australia

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: Kiovig® 10%

| Product | Kiovig® 10% Intravenous Immunoglobulin (human normal immunoglobulin) | |
|---------------------|--|--|
| Specifications | 10 g of human normal immunoglobulin / 100 mL; Excipient: glycine Fractionated from pooled human plasma. | |
| Vial sizes | 1 g in 10 mL, 2.5 g in 25 mL, 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL, 30 g in 300 mL | |
| Use | Replacement of immunoglobulins and treatment of selected autoimmune diseases according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) | |
| Dose | Dose is dependent on patient's body weight and clinical indication – http://www.blood.gov.au/ivig-criteria | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | |
| Administration | Two staff to perform checks independently as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. It is recommended to read Product Information before infusing this product, click on link at bottom of page, or see product insert provided with product. Allow product to reach room temperature (approx. 30 mins) Do not use if product appears turbid or contains sediment. Ensure patient has adequate hydration prior to the infusion of IVIg Must be administered using a pump device via standard IV giving set for designated pump. Should be administered separately from other intravenous fluids or medications. Compatible fluid for priming and flush: glucose 5% or sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | |
| Adult infusion rate | For the first 3 infusions (new patient or change of product) see <u>Appendix B Initial</u> For subsequent infusions, see <u>Appendix B Subsequent</u> | |
| Observations | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. All patients should be observed during and for 20 minutes after administration for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. Caution: Patient who receive IVIg for the first time or when products are changed or there has been a long interval since the previous infusion should be monitored for 1 hour after the first infusion | |

For further information, refer to product insert or <u>Product Information</u>. Product should be used for intended patient (issue label) only.

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: Octagam® 10%

| Product | Octagam® 10% Intravenous Immunoglobulin (human normal immunoglobulin) | |
|---------------------|--|--|
| Specifications | 10 g of human normal immunoglobulin (minimum 95% IgG) / 100 mL. Excipients: maltose Fractionated from pooled human plasma. | |
| Vial sizes | 2 g in 20 mL, 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL | |
| Use | Replacement of immunoglobulins and treatment of selected autoimmune diseases according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) Caution: maltose may interfere in blood glucose testing–see PI | |
| Dose | Dose is dependent on patient's body weight and clinical indication – http://www.blood.gov.au/ivig-criteria | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | |
| Administration | Two staff to perform checks independently as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow product to reach room temperature (approx. 30 mins) It is recommended to read Product Information before infusing this product, click on link at bottom of page, or see product insert provided with product. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Do not use if product appears turbid or contains sediment. Ensure patient has adequate hydration prior to the infusion of IVIg. Must be administered using a pump device via standard IV giving set for designated pump. Administer smallest vial first (e.g. 50 mL before 100 mL when administering 15 g) Should be administered separately from other intravenous fluids or medications. Compatible fluid for priming and flush: glucose 5% or sodium chloride 0.9% Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | |
| Adult infusion rate | For the first 3 infusions (new patient or change of product) see <u>Appendix B Initial</u> For subsequent infusions, see <u>Appendix B Subsequent</u> | |
| Observations | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. All patients should be <u>observed during and for 20 minutes after administration</u> for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. Caution: Patient who receive IVIg for the first time <u>or</u> when products are changed <u>or</u> there has been a long interval since the previous infusion should be monitored for 1 hour after the <u>first infusion</u> | |

For further information, refer to product insert or Octagam PI.

Product should be used for the intended patient (issue label) only.

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: Privigen® AU 10%

| Product | Privigen® AU 10% Intravenous Immunoglobulin (human normal immunoglobulin) | | |
|----------------|--|--|--|
| Specifications | 10 g of human plasma protein /100 mL (≥ 98% IgG). Maximum IgA content is 0.025 mg/mL. Stabiliser: L-proline 250 mmol/L (non-essential amino acid) Fractionated from pooled human plasma collected in Australia. | | |
| Vial sizes | 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL and 40 g in 400 mL | | |
| Use | Replacement of immunoglobulins and treatment of selected autoimmune diseases according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) http://www.blood.gov.au/ivig-criteria | | |
| Dose | Dose is dependent on patient's body weight and clinical indication as per Criteria above | | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | | |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, and right dose – prescription matches product supplied. If not identical, contact prescribing doctor. Store below 25°C (Do not freeze). Protect from light. Allow product to reach room temperature (approx. 30 mins). Do not shake. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. It is recommended to read Product Information before infusing this product, click on link below or see product insert provided with product. Do not use if product appears turbid or contains sediment. Ensure patient has had adequate hydration prior to the infusion of IVIg. Must be administered using a pump device via standard IV giving set for designated pump. Administer smallest vial first (e.g. 50 mL before 100 mL when administering 15 g) Should be administered separately from other intravenous fluids or medications. Compatible fluid for priming or flushing: sodium chloride 0.9%. Compatible diluent: 5% glucose ONLY. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | | |
| Infusion rate | For the first 3 infusions (new patient or change of product) see <u>Appendix B Initial</u> For subsequent infusions, see <u>Appendix B Subsequent</u> | | |
| Observations | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. All patients should be <u>observed during and for 20 minutes after administration</u> for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. <u>Caution:</u> Patient who receive IVIg for the first time <u>or</u> when products are changed <u>or</u> there has been a long interval since the previous infusion should be monitored for 1 hour after the <u>first infusion</u> n, refer to <u>Product Information</u> or <u>CSL Behring</u> | | |

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

IVIg: Privigen® 10%

| Product | Privigen® 10% Intravenous Immunoglobulin (human normal immunoglobulin) | | |
|----------------|---|--|--|
| Specifications | 10 g of human plasma protein /100 mL (≥ 98% IgG). Maximum IgA content is 0.025 mg/mL. Stabiliser: L-proline 250 mmol/L (non-essential amino acid) Fractionated from pooled human plasma. | | |
| Vial sizes | 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL and 40 g in 400 mL | | |
| Use | Replacement of immunoglobulins and treatment of selected autoimmune diseases according to NBA Criteria for Clinical Use of Intravenous Immunoglobulin (Criteria) http://www.blood.gov.au/ivig-criteria | | |
| Dose | Dose is dependent on patient's body weight and clinical indication as per Criteria above | | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | | |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, and right dose – prescription matches product supplied. If not identical, contact prescribing doctor. Store below 25°C (Do not freeze). Protect from light. Allow product to reach room temperature (approx. 30 mins). Do not shake. It is recommended to read Product Information before infusing this product, click on link below or see product insert provided with product. Contains no antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Do not use if product appears turbid or contains sediment. Ensure patient has had adequate hydration prior to the infusion of IVIg. Must be administered using a pump device via standard IV giving set for designated pump. Administer smallest vial first (e.g. 50 mL before 100 mL when administering 15 g) Should be administered separately from other intravenous fluids or medications. Compatible fluid for priming or flushing: sodium chloride 0.9%. Compatible diluent: 5% glucose ONLY. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | | |
| Infusion rate | For the first 3 infusions (new patient or change of product) see <u>Appendix B Initial</u> For subsequent infusions, see <u>Appendix B Subsequent</u> | | |
| Observations | Vital signs: Record baseline patient vital signs (temperature, blood pressure, pulse rate, respiratory rate, and oxygen saturations) before starting infusion. Recheck and record vital signs every 15 minutes AND at each rate change. Once maximum infusion rate is reached, recheck and record vital signs every 60 minutes until the infusion is complete. All patients should be <u>observed during and for 20 minutes after administration</u> for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. <u>Caution:</u> Patient who receive IVIg for the first time <u>or</u> when products are changed <u>or</u> there has been a long interval since the previous infusion should be monitored for 1 hour after the <u>first infusion</u> | | |
| | on, refer to Product Information or CSL Behring led) product, or products that are no longer required should be immediately returned to | | |

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the issuing department (e.g. pathology or pharmacy services). Product should be used for intended patient (issue label) only.

IVIg: Rhophylac®

| Product | Rhophylac® (human anti-D (Rh₀) immunoglobulin) – see general notes on Rh(D) and FMH Testing in links below from KEMH | |
|----------------|---|--|
| Specifications | Contains 750 units/mL Human anti-D immunoglobulin. Fractionated from pooled human plasma. | |
| Vial sizes | 1500 units in 2 mL pre-filled syringe | |
| Use | Used in large foetomaternal haemorrhage or in event of transfusion of Rh(D) positive red cells to a Rh(D) negative female of childbearing potential (requires Haematologist consult) – includes Rh(D) solid organ transplant i.e. lungs (CSL product information) | |
| Dose | 100 units per 2 mL Rh(D) positive (foetal) red blood cells determined by Kleihauer or Flow Cytometry estimation. 1500 units IV. Dose should be administered within 72 hours of event. In event of transfusion of large volume Rh(D) positive cells, a maximum dose of 15,000 units is sufficient. | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow to reach room temperature before use. Does not contain an antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Do not use if product turbid or contains any sediment. Administration via intravenous IV commence at 1 mL/minute Administration-Guide.pdf (cslbehring.com) In case of haemorrhagic disorders Rhophylac® should be given intravenously Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | |
| Observations | All patients should be <u>observed during and for 20 minutes after</u> <u>administration</u> for signs of adverse reactions, respond and report accordingly. They are usually rate related & are most likely to occur within the first hour. | |

For further information, refer to <u>Product Information</u> or <u>CSL Behring</u> or http://www.cslbiotherapies.com.au

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Product should be used for intended patient (issue label) only.

KEMH links - RhD Negative Women and Kleihauer Test for Foetomaternal Haemorrhage

IVIg: Tetanus Immunoglobulin-VF (IV)

| Product | Tetanus Immunoglobulin-VF (For Intravenous Use) (human tetanus immunoglobulin) | | |
|----------------|--|--|--|
| Specifications | Contains 50-70 mg/mL plasma proteins (at least 98% immunoglobulins mainly IgG). Fractionated from pooled human plasma | | |
| Vial sizes | 4000 units tetanus antitoxin activity. | | |
| Use | Used to treat tetanus infection (CSL product information) Note: For prevention of tetanus in a person "at risk" who has not been recently immunised – use intramuscular product Tetanus Immunoglobulin-VF IM 250 units Caution: maltose may interfere in blood glucose testing—see Product Information | | |
| Dose | 4000 units | | |
| Ordering | The ordering process for blood products differs between sites, refer to local procedures and/or contact local Pathology or Pharmacy Services for advice. | | |
| Administration | Two staff to perform checks as per Patient Blood Management Policy. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact issuing department (e.g. pathology or pharmacy services) and prescribing doctor. Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Allow product to reach room temperature before use. Do not use if product turbid or contains any sediment. Does not contain an antimicrobial preservative, therefore, must be used immediately after opening and any unused product or waste material must be disposed of appropriately. Administered using a pump device via standard IV giving set for designated pump. May be infused undiluted or diluted with up to 4 times its volume of sodium chloride 0.9% or glucose 5%. Should be administered separately via a dedicated IV line – do not mix with other fluids or medicines. Commence infusion rate at 1 mL/minute. After 15 minutes the rate may be gradually increased to 3 to 4 mL/minute over a further 15 minutes. Document and place Issue label on MR175A Intravenous Blood Transfusion and Blood Product Treatment Order Chart | | |
| Observations | Observe for signs of adverse reaction, respond and report accordingly. Refer to Product Information for specific adverse reactions | | |

For further information, refer to <u>Product Information</u> or <u>CSL Behring</u> or http://www.cslbiotherapies.com.au

Any unused (unopened) product, or products that are no longer required should be immediately returned to the issuing department (e.g. pathology or pharmacy services).

Appendix B: Infusion rates for specified immunoglobulin products

"Initial" infusion rates

Applicable to the following products for the first 3 infusions of:

- Flebogamma® 5% and 10%
- Gamunex® 10%
- Kiovig® 10%
- Octagam® 10%
- Privigen® 10% and Privigen® AU 10%

| Infusion Rate | Step Time | Volume to be Infused (VTBI) mL | |
|-------------------|----------------------------|--------------------------------|--|
| 1 ml /kg/bour | 30 minutes | 0.5 x patient weight | |
| 1 mL/kg/hour | | infused over 30 minutes | |
| 2 ml /kg/bour | 4.5 minutes | 0.5 x patient weight | |
| 2 mL/kg/hour | 15 minutes | infused over 15 minutes | |
| 4 ml /kg/bour *** | Until infusion complete (3 | 12 x patient weight | |
| 4 mL/kg/hour *** | hours) | infused over 3 hours | |

The initial infusion rates should be used for the first 3 infusions of each product. That is, a patient previously stable on Gamunex® 10% will must revert to the "initial" rate for 3 infusions if they are changed to Flebogamma®.

Consideration should be given to reducing the rate of infusion (refer to Product Information) in patients with pre-existing risk factors:

- Previous thrombotic events,
- Pre-existing renal impairment,
- Diabetes Mellitus,
- Overweight (threshold not defined in product information)
- Over 65 years of age.

The prescriber may indicate a different infusion rate slower than this guideline on a patient-specific basis (e.g. previous adverse reaction, or pre-existing condition). Where a decision has been made to use slower infusion rates, this must be clearly and accurately documented on the administration chart and in the patient's medical record.

Prescribers **may not** indicate rates greater than detailed in this guideline.

Patients with Immune Thrombocytopaenia Purpura (ITP) should have all infusions administered using the "initial" infusion rates. That is, ITP patients should not advance to the "subsequent" infusion rates.

*** When using B. Braun SafeSet® lines (green band on drip chamber), and Program Mode on the B. Braun DERS-enabled Infusomat® devices, the pump will alarm when the drip chamber is empty. Overestimating the VTBI for the final step ensures all the product is infused without needing to return and reprogram the pump.

"Subsequent" infusion rates

Applicable to the following products:

- Flebogamma® 5% and 10%
- Gamunex® 10%
- Kiovig® 10%
- Octagam® 10%
- Privigen® 10% and Privigen® AU 10%

| Infusion Rate | Step Time | Volume to be Infused (VTBI) mL |
|-----------------|-----------------------------------|--|
| 1 mL/kg/hour | 30 minutes | 0.5 x patient weight infused over 30 minutes |
| 2 mL/kg/hour | 15 minutes | 0.5 x patient weight infused over 15 minutes |
| 4 mL/kg/hour | 15 minutes | 1 x patient weight infused over 15 minutes |
| 6 mL/kg/hour | 30 minutes | 3 x patient weight infused over 30 minutes |
| 7 mL/kg/hour*** | Until infusion complete (3 hours) | 21 x patient weight infused over 3 hours |

Consideration should be given to reducing the rate of infusion (refer to Product Information) in patients with pre-existing risk factors:

- Previous thrombotic events,
- Pre-existing renal impairment,
- Diabetes Mellitus,
- Overweight (threshold not defined in product information)
- Over 65 years of age.

The prescriber may indicate a different infusion rate slower than this guideline on a patient-specific basis (e.g. previous adverse reaction, or pre-existing condition). Where a decision has been made to use slower infusion rates, this must be clearly and accurately documented on the administration chart and in the patient's medical record.

Prescribers **may not** indicate rates greater than detailed in this guideline.

"Subsequent" infusion rates are **not** suitable for patients with Immune Thrombocytopaenia Purpura (ITP).

*** When using B. Braun SafeSet® lines (green band on drip chamber), and Program Mode on the B. Braun DERS-enabled Infusomat® devices, the pump will alarm when the drip chamber is empty. Overestimating the VTBI for the final step ensures all the product is infused without needing to return and reprogram the pump.

Appendix C: Example stepped rate infusion calculations

See IVIg Rate Calculator Record

Patient Addressograph

IVIg Rate Record

Use 'Initial Infusion Rates' for the first 3 infusions of prescribed IVIg product, then move to 'Subsequent Infusion Rates' for the fourth and subsequent infusions.

Initial Infusion Rates

Product Name: Flebogamma 10% Total Dose in grams: 879 = 870 mL

| Infusion Time | Rate of Infusion | Patient Weigh | t: <u>87k9</u> |
|---------------|------------------|---------------|----------------|
| | | mL/hr | VTBI |
| 30 minutes | 1 mL/kg/hr | 87 mL/hr | 43.5 mL |
| 15 minutes | 2 mL/kg/hr | 174 mL/hr | 43.5 mL |
| Completion | 4 mL/kg/hr | 348 mL/hr | (870-87=783) |
| | | | 783 mL |

Checked against pump, final calculated step volume 1044mL, green band on drip chamber, pump will alarm when drip chamber empty.

Subsequent Infusion Rates

| Product Name: | Total dose in grams: |
|---------------|----------------------|
|---------------|----------------------|

| Infusion Time | Rate of Infusion | Patient Weight: | |
|---------------|------------------|-----------------|------|
| | | mL/hr | VTBI |
| 30 minutes | 1 mL/kg/hr | | |
| 15 minutes | 2 mL/kg/hr | | |
| 15 minutes | 4 mL/kg/hr | | |
| 30 minutes | 6 mL/kg/hr | | |
| Completion | 7 mL/kg/hr | | |

^{*}Due to calculation rounding, values displayed on pump may vary slightly to calculated figures