| TRANSFUSION MEDICINE PROTOCOL | |
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| **Immunoglobulin Products** | |
| **Scope (Staff):** | All staff |
| **Scope (Area):** | All areas |

There are a large range of immunoglobulin products available for the prevention and treatment of vaccine-preventable disease and in the management of various immune-mediated diseases. Note that Rh(D) Immunoglobulin is also an immunoglobulin product but is **NOT** discussed in this document. Refer to the Rh(D) Immunoglobulin Products & Applications Protocol.

- Limited stock is kept on site. If demand for a particular product is anticipated, advance notification (and Haematology referral) is required.
- Immunoglobulin products are not interchangeable. Check the Product Information prior to use.
- Batch numbers must be documented in the medical notes for traceability.

## Immunoglobulin Product and Indication

| Product | Indication |
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| CMV Immunoglobulin-VF | Prophylaxis of CMV infection or treatment of established CMV infection. |
| Hepatitis B Immunoglobulin VF | Prophylaxis of Hepatitis B infection following exposure. |
| Intragam 10 | Complex. See below and Criteria for the Clinical Use of Immunoglobulin in Australia. |
| Privigen 10 | Prevention of exchange transfusion in haemolytic disease of the newborn (see below). |
| Tetanus Immunoglobulin VF – **Intramuscular** | Prophylaxis of tetanus following wound/injury. |
| Tetanus Immunoglobulin VF – **Intravenous** | Treatment of clinical tetanus. |
| Zoster Immunoglobulin VF | Prophylaxis of varicella (chickenpox). |

## Consent

Immunoglobulins are blood products. Treatment consent, documented on the Generic Consent Form (MR295), is required prior to administration. Refer also to WA Health Consent to Treatment Policy.

## Ordering

Immunoglobulin products must be ordered on a named patient basis from the Transfusion Medicine Unit (TMU). If use is anticipated, Haematologist consultation and communication with the TMU to ensure stock availability is required. If collected and not required, the product should be returned to TMU immediately.

## Administration

Refer to individual Product Information for administration of each immunoglobulin product. However, general points include:

- Verify that the prescription is complete and clearly states the product name. Immunoglobulin products are **NOT** interchangeable. If not clear, contact prescribing doctor and TMU.
- Follow the 6 Rights of Medication Administration (Right Patient, Product, Dose, Route, Time/Date, Documentation)
- Two staff to perform double independent checks as per the Blood Product Administration guidelines. Double independent checking helps minimise the risk of error at the final checks before administering the product. If discrepancies are identified, contact prescribing doctor and TMU. **DO NOT PROCEED** with administration.
- Inspect product and allow to reach room temperature before administration. **DO NOT** administer if turbid/cloudy. Use immediately after opening; discard unused solution.
- Undertake observations as for all blood products (see Blood Product Administration). Vital signs must be recorded on the Observation Response Chart. If required, escalate as per the WNHS Recognising and Responding to Acute Physiological (Clinical) Deterioration.

## Adverse Reactions

All adverse reactions should be reported to the Haematologist and TMU. Refer to WNHS Management of Transfusion Reactions and Adverse Events. Complete MR735.2.

| CMV Immunoglobulin-VF | | |
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| | **CMV Immunoglobulin-VF** | |
| | **INDICATIONS** | Prevention of CMV infection in bone marrow, renal, cardiac and liver transplant recipients who are CMV antibody negative where the donor is CMV antibody positive. Therapy in patients with established CMV infection (e.g. CMV pneumonitis). |
| | **DOSE**<br><br>**PRESCRIPTION** | Dose is dependent on patient weight and clinical indication. Refer to Consultant Immunologist or Microbiologist for advice. |
| | **CONSUMER INFORMATION** | CMV Immunoglobulin-VF Consumer Medicine Information |
| | **CONTRAINDICATIONS**<br><br>**PRECAUTIONS** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies<br><br>Maltose may interfere with blood glucose testing. |
| | **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Manufactured from pooled human plasma. Contains 55-65mg/mL plasma proteins (at least 98% IgG) and 292mmol/L maltose.<br><br>50mL/vial corresponding to CMV Ig activity 1.5 million units/vial.<br><br>CMV Immunoglobulin-VF Product Information |
| | **ADMINISTRATION DOCUMENTATION** | Administer intravenously only using infusion pump and appropriate giving device. Should not be co-administered or piggybacked with other IV fluids.<br><br>Commence the infusion at a rate of 1mL/minute. After 15 minutes the rate may gradually be increased to a maximum of 3-4mL/minute over a further 15 minutes. Refer to Product Information. |
| | **ADVERSE REACTIONS** | Adverse reactions are usually rate related & are most likely to occur within the first hour. Refer to the Product Information. |

| Hepatitis B Immunoglobulin-VF | | |
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| | **Hepatitis B Immunoglobulin-VF** | |
| | **INDICATIONS** | Post-exposure prophylaxis if unvaccinated, prior vaccination program is incomplete or if hepatitis B antibody level is inadequate (HBsAb <10 IU/L). Further information is available in the Australian Immunisation Handbook – Hepatitis B. |
| | **DOSE**<br><br>**PRESCRIPTION** | Seek advice from the requesting Microbiologist or Haematologist regarding dose. |
| | **CONSUMER INFORMATION** | Hepatitis B Immunglobulin-VF Consumer Medicine Information |
| | **CONTRAINDICATIONS**<br><br>**PRECAUTIONS**<br><br>**WARNING** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies<br>• Severe thrombocytopenia or other coagulation disorder posing a contraindication to intramuscular injection<br>• Patients who are Hepatitis B surface antigen (HBsAg) positive<br><br>Hepatitis B Immunoglobulin-VF is unnecessary in patients with adequate circulating hepatitis B surface antibody (HBsAb >10 IU/L). |
| | **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Manufactured from pooled human plasma. Contains 160mg/mL plasma proteins (98% immunoglobulins, mainly IgG) yielding a Hepatitis B antibody titre of not less than 100 units/mL. Also contains glycine 22.5mg/mL.<br><br>Available in two vial sizes:<br>• 100 unit<br>• 400 units<br><br>Hepatitis B Immunoglobulin-VF Product Information |
| | **ADMINISTRATION**<br><br>**DOCUMENTATION** | Give slowly by deep intramuscular injection using appropriately sized needle. If a large dose is required this may be administered in divided doses at different sites. Suitable local anaesthetic may be added to the injection if desired. Refer to Product Information. |
| | **ADVERSE REACTIONS** | Adverse reactions include:<br>• Local tenderness, erythema and stiffness at the injection site<br>• Mild pyrexia, malaise and drowsiness (uncommon)<br>• Generalised hypersensitivity (rare) |

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| Intragam | **Intragam** | |
| | **INDICATIONS** | Intragam is supplied in accordance with the Criteria for the Clinical Use of Immunoglobulin in Australia. These criteria set out the conditions and circumstances under which the use of IVIg is appropriate and funded under the National Blood Agreement.<br><br>Common indications in adults at KEMH include:<br>• Immune thrombocytopenic purpura (ITP) in those at high risk of bleeding (e.g. prior to surgery or during pregnancy)<br>• Prophylaxis of neonatal alloimmune thrombocytopenia (NAIT)<br>• Primary immunodeficiency (e.g. common variable immunodeficiency) or secondary hypogammaglobulinaemia<br><br>Common indications in neonates at KEMH include:<br>• Treatment of established NAIT<br><br>Refer to the full eligibility Criteria. |
| | **DOSE**<br><br>**PRESCRIPTION** | Dose is dependent on patient body weight and clinical indication. Discuss dose with Haematologist. |
| | **CONSUMER INFORMATION** | Intragam Consumer Medicine Information |
| | **CONTRAINDICATIONS**<br><br>**PRECAUTIONS** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies |
| | **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Intragam contains 10g/100mL of human plasma protein with a purity of at least 98% IgG. It has a nominal osmolality of 350mOsmol/kg and is approximately isotonic.<br><br>Refer to Intragam Product Information.<br><br>Intragam is available in the following vial sizes:<br>• 2.5g/25mL<br>• 5g/50mL<br>• 10g/100mL<br>• 20g/200mL |

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| | **ADMINISTRATION**<br><br>**DOCUMENTATION** | Trough immunoglobulin levels, if ordered, should be taken prior to commencement of IVIg infusion.<br><br>Ensure adequate hydration prior to commencing infusion.<br><br>Administer intravenously only using infusion pump and appropriate giving device. Should not be co-administered or piggybacked with IV fluids other than 0.9% saline.<br><br>Intragam may be infused undiluted or diluted with up to 2 parts 0.9% saline. The infusion should commence at the rate of 1mL/minute. After 15 minutes the rate may gradually be increased to a maximum of 3-4mL/minute over a further 15 minutes. |
| | **ADVERSE REACTIONS** | Adverse reactions are usually rate related & are most likely to occur within the first hour. These may include:<br>• Flushing, headache and mild changes in heart rate or blood pressure. These may respond to reduction in infusion rate – reduce by half and contact the Medical Officer<br>• Anaphylaxis, haemolytic anaemia, venous thromboembolism, renal failure and aseptic meningitis have been reported rarely after IVIg treatment.<br><br>Refer to the Product Information. |

| Privigen | | |
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| | **Privigen** | |
| | **INDICATIONS** | Privigen is available under Jurisdictional Direct Order (JDO) from the Chief Medical Officer, Department of Health, WA, for KEMH neonatal patients in exceptional circumstances.<br><br>It is indicated to prevent the need for first or repeat exchange transfusion in select cases of severe haemolytic disease of the newborn (HDN) undergoing intensive phototherapy. Specifically, it may be used when:<br>• the total serum bilirubin (TSB) continues to rise at 8-17mmol/L/hour despite intensive phototherapy<br>• the TSB is within 35-50mmol/L of the threshold for exchange transfusion.<br><br>If necessary Privigen may be re-dosed 12 hours after first administration. |
| | **DOSE**<br><br>**PRESCRIPTION** | 1g/kg body weight. Refer to Neonatologist and Haematologist. |
| | **CONSUMER INFORMATION** | Privigen Consumer Product Information |
| | **CONTRAINDICATIONS**<br><br>**PRECAUTIONS** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies<br><br>Caution should be used in patients with hyperprolinaemia type I/II as the product contains the stabiliser L-proline. The risks and benefits should be considered on an individual patient basis. |
| | **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Privigen contains 5g/50mL of human plasma protein with a purity of at least 98% IgG. It has a nominal osmolality of 320mOsmol/kg and is approximately isotonic. It has a pH of 4.8 (range 4.6 – 5). It has low sodium content (≤1mmol/L) but contains 250mmol/L (range 210 – 290) L-proline stabiliser.<br><br>Refer to Privigen Product Information.<br><br>Privigen is available as a 5g/50mL vial. |
| | **ADMINISTRATION**<br><br>**DOCUMENTATION** | Ensure adequate hydration prior to Privigen administration.<br><br>Administer intravenously only using infusion pump and appropriate giving device. Should not be co-administered or piggybacked with other IV fluids. |

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| | | Infuse the prescribed dose over 4 hours. Refer to Neonatologist/Haematologist, or Product Information, for advice. |
| **Privigen** | **ADVERSE REACTIONS** | Adverse reactions are usually rate related & are most likely to occur within the first hour. These may include:<br>• Flushing, headache and mild changes in heart rate or blood pressure. These may respond to reduction in infusion rate – reduce by half and contact the Medical Officer<br>• Anaphylaxis, haemolytic anaemia, venous thromboembolism, renal failure and aseptic meningitis have been reported rarely after IVIg treatment.<br><br>Refer to the Product Information. |

| Tetanus Immunoglobulin-VF – Intramuscular | | |
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| | **Tetanus Immunoglobulin-VF – Intramuscular** | |
| | **INDICATIONS** | Passive protection of individuals who have sustained a tetanus-prone wound and who have either not been actively immunised against tetanus or whose immunisation history is doubtful. Refer to the Australian Immunisation Handbook – Tetanus for more information. |
| | **DOSE**<br><br>**PRESCRIPTION** | The minimum prophylactic dose is 250 IU in adults and children if ≤24 hours since injury. 500 IU should be administered if >24 hours since injury.<br><br>Refer to the Australian Immunisation Handbook – Tetanus or seek advice from Consultant Microbiologist. |
| | **CONSUMER INFORMATION** | Tetanus Immunoglobulin-VF Intravenous Consumer Medicine Information |
| | **CONTRAINDICATIONS**<br><br>**PRECAUTIONS** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies<br>• Severe thrombocytopenia or other coagulation disorder posing a contraindication to intramuscular injection |
| | **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Manufactured from pooled human plasma. Contains 160mg/mL plasma proteins (98% immunoglobulins, mainly IgG) yielding a tetanus antitoxin activity of at least 100 units/mL. Also contains glycine 22.5mg/mL.<br><br>Available in a 250 IU vial.<br><br>Tetanus Immunoglobulin-VF Intramuscular Product Information |
| | **ADMINISTRATION**<br><br>**DOCUMENTATION**<br><br>**WARNING** | Give slowly by deep intramuscular injection. As this product is viscous an appropriately sized needle (e.g. 21 gauge in adults, 23 gauge in children) should be used. If a large dose is required this may be administered in divided doses at different sites. Suitable local anaesthetic may be added to the injection if desired. Refer to Product Information.<br><br>**Tetanus Immunoglobulin-VF for Intramuscular Use MUST NOT be administered intravenously.** |
| | **ADVERSE REACTIONS** | Adverse reactions include:<br>• Local tenderness, erythema and stiffness at the injection site<br>• Mild pyrexia, malaise and drowsiness (uncommon)<br>• Generalised hypersensitivity (rare) |

**Tetanus Immunoglobulin-VF - Intravenous**

| Tetanus Immunoglobulin-VF – Intravenous | |
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| **INDICATIONS** | Treatment of clinical tetanus. |
| **DOSE**<br><br>**PRESCRIPTION** | Seek advice from the Clinical Microbiologist regarding dose. The recommended dose is 4000 IU. Administration of this dose has been shown to maintain circulating antibody levels above the minimum protective titre for at least 6 weeks. |
| **CONSUMER INFORMATION** | Tetanus Immunoglobulin-VF – Intravenous Consumed Medicine Information |
| **CONTRAINDICATIONS**<br><br>**PRECAUTIONS** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies<br><br>Maltose may interfere with blood glucose testing. |
| **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Manufactured from pooled human plasma. Contains 50-70mg/mL plasma proteins (at least 98% immunoglobulins, mainly IgG) yielding a tetanus antitoxin activity of 4000 IU per vial. Also contains 292mmol/L maltose.<br><br>Available in a 4000 IU vial.<br><br>Tetanus Immunoglobulin-VF – Intravenous Product Information. |
| **ADMINISTRATION**<br><br>**DOCUMENTATION** | Administer intravenously only using infusion pump and appropriate giving device. Should not be co-administered or piggybacked with other IV fluids.<br><br>Commence the infusion at a rate of 1mL/minute. After 15 minutes the rate may gradually be increased to a maximum of 3-4mL/minute over a further 15 minutes. Refer to Product Information.<br><br>**Tetanus Immunoglobulin-VF for Intravenous Use MUST NOT be administered intramuscularly.** |
| **ADVERSE REACTIONS** | Reactions tend to be related to the infusion rate and are most likely to occur during the first hour of the infusion. For more information see Tetanus Immunoglobulin-VF Intravenous Product Information |

| Zoster Immunoglobulin-VF | | |
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| Zoster Immunoglobulin-VF | **INDICATIONS** | Prophylaxis of varicella in patients who meet the criteria detailed in the Australian Immunisation Handbook – Varicella. |
| | **DOSE**<br><br>**PRESCRIPTION** | The dose is generally based on body weight. Seek advice from the Clinical Microbiologist regarding dose. |
| | **CONSUMER INFORMATION** | Zoster Immunoglobulin-VF Consumer Medical Information |
| | **CONTRAINDICATIONS**<br><br>**PRECAUTIONS** | Contraindicated in:<br>• Previous true anaphylactic reaction to the active substance or any of its constituents<br>• Isolated IgA deficiency, unless patient is shown **not** to have circulating anti-IgA antibodies |
| | **SPECIFICATIONS**<br><br>**PRODUCT INFORMATION** | Manufactured from pooled human plasma. Contains 160mg/mL plasma proteins (98% immunoglobulins, mainly IgG) yielding not less than 200 IU/vial varicella zoster antibody. Also contains glycine 22.5mg/mL.<br><br>Available in a 200 IU vial.<br><br>Refer to Zoster Immunoglobulin-VF Product Information. |
| | **ADMINISTRATION**<br><br>**DOCUMENTATION** | Give slowly by deep intramuscular injection. If a large dose is required this may be administered in divided doses at different sites. Suitable local anaesthetic may be added to the injection if desired. Refer to Product Information.<br><br>**DO NOT** administer intravenously. |
| | **ADVERSE REACTIONS** | Adverse reactions include:<br>• Local tenderness, erythema and stiffness at the injection site<br>• Mild pyrexia, malaise and drowsiness (uncommon)<br>• Generalised hypersensitivity and angioedema (rare) |

## References


- Australian Red Cross Blood Service. Blood products and transfusion practice for health professionals – Australian Red Cross Lifeblood Website.
- Australian Red Cross Blood Service – Immunoglobulins Website
- CSL Behring: Biotherapies for Life Product List Website


## Related WNHS policies, procedures and guidelines

- WA Health Consent To Treatment Policy
- Transfusion Medicine: Management of Transfusion Reactions and Adverse Events Protocol
- Medication Administration Guideline
- Obstetrics and Gynaecology Clinical Guidelines

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