



TRANSFUSION MEDICINE PROTOCOLS

Intragam[®] 10 Intravenous Immunoglobulin

This document should be read in conjunction with the [Disclaimer](#)

AIM	To describe the indication, ordering, administration and documentation of Intragam [®] 10
DESCRIPTION	Intragam [®] 10 is a 10% concentration preparation of human immunoglobulin for intravenous use (IVIg). It is prepared from blood obtained from Australian voluntary, non-remunerated donors.
SPECIFICATIONS	<p>Intragam[®] 10 is a sterile, preservative free solution containing 10g/100mL of human plasma protein with a purity of at least 98% immunoglobulin G (IgG). It has a nominal osmolality of 350 mOsmol/kg and is approximately isotonic.</p> <p>Refer to Intragam[®] 10 Product Information</p>
VIAL SIZE	Intragam [®] 10 is available in 25mL, 50mL, 100mL and 200mL vials.
INDICATIONS	<p>Intragam 10 is supplied in accordance with The Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia which was developed to assist clinicians and transfusion medicine professionals to identify the conditions and circumstances for which the use of intravenous immunoglobulin (IVIg) is appropriate and funded under the National Blood Agreement.</p> <p>Intragam[®] 10 is indicated for replacement IgG therapy in:</p> <ul style="list-style-type: none">• Primary Immunodeficiency Diseases (PID)• Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. <p>Intragam[®] 10 is indicated for immunomodulatory therapy in:</p> <ul style="list-style-type: none">• Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count• Kawasaki disease

	<ul style="list-style-type: none"> • Guillain-Barré Syndrome (GBS) • Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) • Multifocal Motor Neuropathy (MMN) • Myasthenia Gravis (MG) • Short-term therapy for severely affected nonparaneoplastic Lambert-Eaton Myasthenic Syndrome (LEMS) patients • Treatment of significant functional impairment in patients who have a verified diagnosis of stiff person syndrome <p>In the Neonate Clinical Indications may include neonatal alloimmune thrombocytopenia (NAIT), thrombocytopenia associated with maternal autoimmune thrombocytopenia, some cases of Isoimmune Haemolytic jaundice and Sepsis (unproven).</p>
CONTRAINDICATIONS AND PRECAUTIONS	<p>⚠ CAUTION Intragam® 10 is contraindicated in patients who have had a true anaphylactic reaction to human immunoglobulins (especially in patients with antibodies against IgA) or to the excipient glycine.</p>
CONSUMER INFORMATION	<p>Intragam® 10 Consumer Medicine Information</p>
CONSENT	<p>Written consent is required as Intragam® 10 is manufactured from pooled human plasma. Refer to Transfusion Medicine Protocol Blood Product Prescription, Informed Consent. And Refusal</p>
DOSE	<p>Dose is dependent on patient's body weight and clinical indication. Refer to Consult Haematologist for advice.</p>
ORDERING	<p>Intragam® 10 must be ordered on a named patient basis from the Transfusion Medicine Unit. Haematologist and ARCBS approval is required. The product will be ordered from ARCBS and is issued with a peel off product label which can be affixed to the transfusion medicine record form (MR735).</p>
ADMINISTRATION	<ul style="list-style-type: none"> • Two staff to perform checks as per the Clinical Practice Manual, WNHS Pharmacy Medication Checking and Administration processes. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact TMU and prescribing doctor. • Trough immunoglobulin levels, if ordered, should be taken

prior to the commencement of the IVIg infusion.

- Patients should be optimally hydrated prior to commencing IVIg infusion.
- **WARNING** Ensure prescription is complete, including the **BRAND and CONCENTRATION** of IVIg.
- The product must be used immediately after opening. Any unused solution must be discarded.
- Do not use the product if it appears turbid or cloudy.
- Allow product to reach room temperature before administration.
- Intragam® 10 should be administered through a standard intravenous infusion giving set.
- Intragam® 10 should be administered separately from intravenous fluids (other than normal saline) or medications the patient might be receiving.
- Intragam® 10 may be infused undiluted or diluted with up to 2 parts of 0.9% saline.
- The infusion should be commenced at the rate of 1 mL per minute.
- After 15 minutes the rate may be gradually increased to a maximum of 3 to 4 mL per minute over a further 15 minutes.
- Infusion rates higher than recommended may increase the incidence of headache. Consideration should be given to reducing the rate of infusion in patients naive to Intragam® 10, patients switching from an alternative IVIg, patients who have not received IVIg for a long time, elderly patients and in patients with pre-existing renal disease.

Neonates

Dosage depends on clinical indication. Refer to Neonatologist /Consultant Haematologist for advice. Administer as an IV infusion. In some circumstances a second dose may be required on subsequent days.

See [Neonatology Clinical Care Guidelines](#) Section Metabolic Management for Further Information on Immunoglobulin Administration in Isoimmune Haemolytic Jaundice

<p>OBSERVATIONS</p>	<p>Undertake observations as for all blood products. Vital signs (temperature, pulse, respiration, blood pressure) must be recorded on the observation chart in the medical record.</p> <ul style="list-style-type: none"> • Before the start of each infusion. • At 15 minutes from start of infusion. • Thereafter, hourly throughout the infusion. • On the completion of infusion. <p>Observe for signs of adverse reactions – Refer to Intragam® 10 Product Information for the full list of adverse reactions.</p>
<p>ADVERSE REACTIONS</p>	<p>Adverse reactions are usually rate related & are most likely to occur within the first hour.</p> <p><i>Mild reactions</i></p> <p>Flushing, headache, mild changes in heart rate or blood pressure. These types of reactions may be rate dependent and may respond to a reduction in the rate of infusion. Reduce the rate by half and contact the Medical Officer for further orders.</p> <p><i>Moderate to severe reactions</i></p> <p>Anaphylaxis, haemolytic anaemia, thromboembolism, renal impairment and aseptic meningitis have been reported to have occurred after IVIg treatment. Refer to Intragam® 10 Product Information for the full list of adverse reactions.</p> <p>If you suspect an adverse reaction:</p> <ul style="list-style-type: none"> • STOP transfusion • Provide emergency patient care • Arrange immediate medical review. • Keep IV line open with normal saline (do not flush existing line – use a new IV line if required) • Monitor vital signs at least every 15 minutes until stable (document in medical record) • All suspected reactions should be reported to the Clinical Haematologist and TMU <p>Refer to Transfusion Reaction and Adverse Event Management and Reporting, as a guide to further treatment</p>

	and management of the patient.
DOCUMENTATION	<p>A record should be kept in the patient's history of the following:</p> <p>Diagnosis and indication for treatment</p> <p>Discussion of treatment, benefits, risks and consent</p> <p>Prescription/medical order including doctors signature, date, time and product of ordered</p> <p>The batch number and expiry date of each bottle used (place a sticker with the batch number on the Transfusion Medicine Record sheet MR735). This information is important should the patient have a reaction to the infusion or if there is a need to trace recipients of certain batch numbers at a later date</p> <p>Total dose of IVIg (in grams) administered to patient</p> <p>Patient observation and general condition during the infusion.</p>
<p>For further information, refer to product insert</p> <p>Return product to TMU immediately if no longer required.</p> <p>Product should be used for intended patient (issue label) only.</p>	

References

- Australian Red Cross Blood Service – Blood products and transfusion practice for health professionals. [Australian Red Cross](#) website
- Australian Red Cross Blood Service – Blood products and transfusion practice for health professionals.
http://www.transfusion.com.au/blood_products/fractionated_plasma/immunoglobulins
- The Australian Blood Service (ARCBS) Blood Component Information
<http://www.transfusion.com.au/sites/default/files/BCI%202009.pdf>
- Flippin' Blood BloodSafe SA / ARCBS Second Edition June 2012
<http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/20>
- [CSL Global Intragam 10](#)

Related policies

- National Safety and Quality Health Service Standards, October 2012. [Standard 7: Blood and Blood Products](#)

Related WNHS policies, procedures and guidelines

- [Blood Product Prescription Consent and Refusal](#)
- [WNHS Pharmacy Medication Checking and Administration](#)
- [Neonatology Clinical Care Guidelines](#)
- [Obstetrics and Gynaecology Clinical Guidelines](#)

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