TRANSFUSION MEDICINE PROTOCOLS

Intragam® P Intravenous Immunoglobulin

This document should be read in conjunction with the Disclaimer

AIM	To describe the indication, ordering, administration and documentation of Intragam® P
DESCRIPTION	Intragam® P is a preparation of human immunoglobulin for intravenous use (IVIg). It is prepared from blood obtained from Australian voluntary, non-remunerated donors and is used to treat patients who need replacement of antibodies which form part of our immune system and can provide protection against some infections. Intragam® P is also used in the treatment of autoimmune disorders. Intragam® P is intended for intravenous administration.
SPECIFICATIONS	Intragam® P is a sterile, preservative free solution containing 6 g of human protein and 10 g of maltose in each 100 mL. The solution has a pH of 4.25. Isotonicity is achieved by the addition of maltose. At least 98% of the protein has the electrophoretic mobility of immunoglobulin G (IgG). Refer to Intragam® P Product Information
VIAL SIZE	Intragam® P is available in 3g (50mL) and 12g (200mL) vials.
INDICATIONS	Intragam P 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. Intragam® P is indicated for replacement IgG therapy in: • Primary Immunodeficiency Diseases (PID) • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. Intragam® P is indicated for immunomodulatory therapy in: • Idiopathic Thrombocytopenic Purpura (ITP), in adults or

	children at high risk of bleeding or prior to surgery to correct the platelet count These include primary immunodeficiencies and other named immunological disorders such as Kawasaki disease, neurological disorders and haematological disorders such as idiopathic thrombocytopenic purpura (ITP) and neonatal alloimmune thrombocytopenia (NAIT). 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)
CONTRAINDICATIONS AND PRECAUTIONS	⚠CAUTION Intragam® P is contraindicated in patients who have had a true anaphylactic reaction to a human immunoglobulin preparation. The maltose present in Intragam® P may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. Only certain glucose tests have been implicated, so when monitoring glucose levels to ensure that maltose does not interfere with the blood glucose reading of the test being used. The *Abbott Medisense Sensor System* of Meters and test strips use the glucose dehydrogenase method for measurement of glucose and do not suffer from significant maltose interference. The current *Radiometer POCT* blood gas analysers uses glucose oxidase methodology to measure blood glucose and does not suffer from significant maltose interference. **Patients SHOULD NOT utilise personal meters with GDH-PQQ methodology if receiving Intragam/Octagam administration. This type of meter could suffer from maltose interference.** Live vaccine should not normally be given until three months after a dose of gammaglobulin injection. If a live virus vaccine has been given, gammaglobulin should not be given for at least two weeks except in exceptional circumstances. Contact the Consultant Haematologist/Clinical Immunologist for advice. Patients receiving regular gammaglobulins should have six monthly monitoring of liver function.
CONSUMER INFORMATION	Intragam® P Consumer Medicine Information

CONSENT	Written consent is required as Intragam® P is manufactured from pooled human plasma. Refer to Transfusion Medicine Protocol Blood Product Prescription, Informed Consent. And Refusal
DOSE	Dose is dependent on patient's body weight and clinical indication. Refer to Consult Haematologist for advice.
ORDERING	Intragam® P is ordered on a named patient basis only, through the Blood Bank. It is supplied by the Australian Red Cross Blood Service (ARCBS) after ARCBS Haematologist Approval. **For new patients, one off approvals OR where each dose requires ARCBS Haematologist approval**, an '*ARCBS IVIG Patient Information Form*' will be supplied by the Blood Bank for completion by the requesting Clinician. The IVIg indication categories are *a) Haematological b) Neurological or c) Immunological/General***.** The relevant form (a, b or c) must be completed by the Clinician for each treatment plan or one-off order. A new form is required if the dose or frequency of infusion changes. *The completed form **must** be returned to the Blood Bank **before** the product can be ordered* **For regular patients** a *"Weekly Infusion Schedule for Regular Intravenous Immunoglobulin Patients" form* may be used. The TM Scientist will fax this form to ARCBS to order approved doses for multiple patients for infusion the following week. The product will be ordered from ARCBS and is issued with a peel off product label which can be stuck on the transfusion medicine record form (MR735).
ADMINISTRATION	• 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. • **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. Notify

Blood bank.

- Allow product to reach room temperature before administration.
- Administer through a standard IV infusion set via an infusion device.
- Administration **usually** requires 2-6 hours but may be administered more slowly where there is a reaction or where clinical indications dictate e.g. in Kawasaki disease, toxic shock syndrome, the recommended dose is usually 2 grams/Kg over 10 hours though variations to this should be discussed with the treating medical team. Consideration must be given to the possibility of cardiac overload especially in the presence of pancarditis and poor LV function and IVIg should be administered at a slower rate.
- The product should only be used for the patient for whom it was issued. Any unwanted vials MUST be returned to the Blood Bank as soon as possible. Unused vials must not be returned to the ward fridge or allocated to other patients.

Neonates

Dosage depends on clinical indication. Refer to Neonatologist /Consultant Haematologist for advice. Indications include Isoimmune haemolytic Jaundice, Thrombocytopenia, NAIT (Neonatal Alloimmune Thrombocytopenia) and Sepsis,

Administer as an IV infusion over 4 hours. In some circumstances a second dose may be required on subsequent days.

See Neonatology CCU Guidelines Section Metabolic Management for Further Information on Immunoglobulin Administration in Isoimmune Haemolytic Jaundice

Adults

- 1mL/min for 15 minutes
- 2mL/min for 15 minutes
- 3-4mL/min until infusion complete

Consideration should be given to reducing the infusion rate in elderly patients or patients with pre-existing renal disease.

OBSERVATIONS	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. Observe for signs of adverse reactions –Refer to Intragam® P Product Information • Before the start of each infusion. • At 15 minutes from start of infusion. • Thereafter, hourly throughout the infusion. • On the completion of infusion.
ADVERSE REACTIONS	Adverse reactions are usually rate related & are most likely to occur within the first hour. ***Mild reactions*** 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. ***Moderate to severe reactions*** Anaphylaxis, haemolytic anaemia, thromboembolism, renal impairment and aseptic meningitis have been reported to have occurred after IVIg treatment. Refer to Intragam® P Product Information for the full list of adverse reactions. If you suspect an adverse reaction: • **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 Refer to Transfusion Reaction and Adverse Event Management and Reporting, as a guide to further treatment

	and management of the patient.
DOCUMENTATION	A record should be kept in the patient's history of the following: Diagnosis and indication for treatment Discussion of treatment, benefits, risks and consent Prescription/medical order including doctors signature, date, time and product of ordered The batch umber 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 Total dose of IVIg (in grams) administered to patient Patient observation and general condition during the infusion.
For further information, refer to product insert Return product to TMU immediately if no longer required. Product should be used for intended patient (issue label) only.	

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 P

Related policies

- National Safety and Quality Health Service Standards, October 2012. Standard 7: Blood and Blood Products

Related WNHS policies, procedures and guidelines

- Neonatology Clinical Care Guidelines
- Obstetrics and Gynaecology Clinical Guidelines
- Blood Product Prescription Consent and Refusal
- WNHS Pharmacy Medication Checking and Administration

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Standards Applicable:	NSQHS Standards: 1 Governance, 5 Patient ID/Procedure Matching, 7 Blood Products		
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