

12 PLASMA DERIVED BLOOD COMPONENTS

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12.9 Intragam P
Section 12
Transfusion Medicine Protocols
Women's & Newborn Health Services
Perth Western Australia

12.9 INTRAGAM P (3G AND 12 G)

DESCRIPTION

Intragam-P is a sterile, preservative free solution administered to supply IgG antibodies. It is made by fractionation of pooled human plasma obtained from voluntary blood donors. It is an Immunoglobulin solution containing 6g of mainly IgG Immunoglobulin per 100mL. It is available in 3g (50mL) and 12g (200mL) vials.

Intragam 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 to the requesting Clinician. The Transfusion Medicine Scientist will ask the requestor to specifically class the IVIg indication category as either *a) Haematological b) Neurological or c) Immunological/General*. The relevant form (a, b or c) will then be supplied for completion by the Clinician. Clinicians must complete one form per 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 Transfusion Medicine Unit 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.

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. The criteria may be viewed at www.nba.gov.au

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)

PRECAUTIONS

Caution must be used if administering product for the first time or if the patient has previously reacted. Side effects include headache, nausea, vomiting, chest tightness, flushing, coughing and chills. Observe the IV site for signs of swelling or pain.

If side effects occur – reduce the rate by half and contact MO. Refer severe reactions to the Consultant Haematologist.

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.

Diabetic Patients - Precaution regarding Blood glucose determination:

Glucose monitoring systems (test strips) utilising the glucose dehydrogenase pyrroloquinone (GDH-PQQ) will report *falsely elevated glucose readings* in the presence of maltose.

As Intragam contains maltose, only systems which utilise the glucose oxidase, hexokinase or glucose dehydrogenase– NAD (GDH-NAD) method of glucose determination should be used after Intragam administration.

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.

However, patients SHOULD NOT utilise personal meters with GDH-PQQ methodology if receiving Intragam/Octagam administration. This type of meter could suffer from maltose interference.

Further information is available on the CSL website at

http://www.csl.com.au/s1/cs/auhq/1196562765747/Web_Product_C/1196562710265/ProductDetail.htm

To reduce the risk of inappropriate administration of insulin due to falsely elevated glucose readings after Intragam the **CSL Intragam Consumer Medicine Leaflet** may be given on discharge.

<http://www.csl.com.au/docs/507/943/CT374001001.pdf>

DOSE AND ADMINISTRATION

Dosage and administration varies and depends on the clinical indication and the age of the patient. Refer to the Consultant Haematologist.

Administration **usually** requires 2-6 hours but it 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. Please refer to the *children's procedure chart* on page 3

- Administer through a standard IV infusion set via an infusion device.
- Allow the preparation to reach room temperature before use.
- If the Product appears turbid or contains sediment it must not be used. Return to the Blood Bank.
- The product should be used immediately after opening the bottle and any unused portion should be discarded. Do not use after expiry date.
- 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 Clinical Immunologist/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

<http://intranet.pmhkcmh.health.wa.gov.au/clinical.html>

CHILDREN

PROCEDURE	ADDITIONAL INFORMATION
Assemble a giving set with a 3-way tap, extension tubing.	Administer via an infusion device.
Prime with Intragam®.	
Take baseline TPR and BP.	
If bloods for trough immunoglobulin levels are ordered these are taken at the time of IV insertion (before commencement of Intragam infusion).	2mL of blood required. Use a white topped tube.
Commence infusion: 15mL/hr for the first 15 mins then increase the rate to 35 mL/hr for the next 15 mins.	Children over 5 years old with a diagnosis of primary immunodeficiency will follow this protocol for the first three infusions. Subsequently, if no adverse events are noted, infusions may commence directly at the Kg weight rate indications listed below. Any queries should be referred to the Clinical Immunology team. If headaches occur, reduce the current rate by half.
After 30 mins increase the rate to a maximum based on the child's weight 5-10kg 35 – max 50mL/hr 11-20kg 50 – max 75mL/hr 21-40kg 75 – max 100mL/hr 41-60kg 100 – max 140mL/hr > 61kg 140 – max 180mL/hr	Caution must be used: <ul style="list-style-type: none"> if administering this product for the first time If the child has had a reaction previously N.B. For certain indications e.g. Kawasaki Disease, consider the possibility of cardiac overload. Children in lower end of weight range do not normally receive the maximum rate.
Measure T&P at 15 minutes then throughout the infusion monitor TPR & BP hourly.	Observe the IV site for signs of swelling or pain.
At any sign of side effects, decrease the rate of infusion by half and contact the Medical Officer. Refer severe reactions to the Consultant Haematologist unless the patient is under the care of the PMH Department of Immunology in which case contact the immunology ROM, registrar or fellow (if unavailable contact the on call immunologist).	Side effects include headache, nausea, vomiting, chest tightness, flushing, coughing, and chills.
After the infusion is complete, flush the line with 30mL sodium chloride 0.9%.	
Continue to observe the patient for adverse reactions for 2 hours before discharging them.	Children on regular gammaglobulin infusions may be discharged on the completion of the infusion if their observations are stable.

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.

PATIENT MONITORING

Take observations as for all blood products

- Baseline TPR and BP
- TP at 15 minutes then hourly until completion.
- TPR and BP on completion.

After the infusion is complete flush the line with sodium chloride 0.9%

Continue to observe the patient for adverse reactions for 2 hours before discharging them.

However, patients on regular gammaglobulin infusions may be discharged on completion if their observations are stable.

DOCUMENTATION

A record should be kept in the patient's history of the following

- The date of infusion
- Patients observations and general condition during the infusion
- Amount given
- The batch number and expiry date of each bottle used (place a sticker with the batch number on the Transfusion Medicine Record sheet KEMH 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.