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 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.

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 pyrroloquinonequinone (GDH-PQQ) will report *falsely elevated glucose readings* in the presence of maltose. As Intragram contains maltose, only systems which utilise the glucose oxidase, hexokinase or glucose dehydrogenase– NAD (GDH-NAD) method of glucose determination should be used after Intragram 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. **Patients SHOULD NOT utilise personal meters with GDH-PQQ methodology if receiving Intragram/Octagam administration. This type of meter could suffer from maltose interference.**


**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 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://kemh.health.wa.gov.au/services/nccu/guidelines/index.htm](http://kemh.health.wa.gov.au/services/nccu/guidelines/index.htm)
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.