

12 PLASMA DERIVED BLOOD COMPONENTS

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12.17 Octagam
Section 12
Transfusion Medicine Protocols
Women's & Newborn Health Services
Perth Western Australia

12.17 OCTAGAM (2.5G 5G AND 10 G)

DESCRIPTION

Octagam contains human normal Immunoglobulin (IgG) in a 5% solution (50mg/mL) with a broad spectrum of antibodies against infectious agents. It is supplied as a ready to use liquid and requires no filtration prior to intravenous infusion. It is available in 2.5g (50 mL), 5g (100mL) and 10g (200mL) vials.

Octagam is issued on a named patient basis only and is ordered 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

The *Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia* has been 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 (NBA). As such **Intragam P** and **Octagam** are available through the Blood Bank and funded through the cost shared arrangements of the National Blood Agreement for approved indications.

Full criteria available at <http://www.nba.gov.au/ivig/index.html>

PRECAUTIONS

Caution must be used if administering the product for the first time or if the patient has had a reaction previously.

Side effects include headache, nausea, vomiting, chest tightness, flushing, coughing and chills. If side effects occur – reduce the rate by half and contact the 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 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) method will report falsely elevated glucose readings in the presence of maltose.

As Octagam contains maltose, only systems which utilise the glucose oxidase, hexokinase or glucose dehydrogenase– NAD (GDH-NAD) method of glucose determination should be used after Octagam 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 when receiving Intragam/Octagam. This type of meter could suffer from maltose interference.

Further information is available on the Octapharma website

http://www.octapharma.com/Australia/au_octagam.php

Maltose Warning Information

<http://www.octapharma.com/Australia/docs/FINAL%20Maltose%20WARNING%20Letter%202019-10-5%20Australia.pdf>

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

http://www.octapharma.com/Australia/docs/Octagam_CMI_feb06.pdf

ADMINISTRATION

- Allow the preparation to reach room temperature before use.
- Administer through a standard IV infusion set via an infusion device. An in-line filter is not necessary when administering Octagam; however, if there is a filter already in an infusion line it will not pose any problems.
- Normal saline, water for injections or glucose 5% may be used to prime and flush the IV line. Compatibility of Octagam with other IV fluids has not been evaluated therefore Octagam should not be mixed with other fluids.
- Octagam should be used immediately after opening the bottle and any unused portion should be discarded. Do not use after expiry date.
- If the Product appears turbid or contains sediment it must not be used. Return to the Blood Bank.
- Dosage varies and depends on the clinical indication and the age of the patient. If advice required refer to Clinical Immunologist or Haematologist.
- **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 kept on the ward for allocated patients OR reallocated to other patients.**

Octagam should be infused intravenously at an initial rate of 1mL/Kg/Hr for 30 minutes and if well tolerated, the rate of administration may be gradually increased to a maximum of 5mL/Kg/Hr for the remainder of the infusion.

Administration is started slowly and increased steadily if no adverse events are noted.

FIRST INFUSION OF OCTAGAM OR IF >8 WEEKS SINCE LAST INFUSION

Rate	Comments
1 mL/kg/hour	After 30 minutes if tolerated increase rate
2 mL/kg/hour	After 30 minutes if tolerated increase rate
3 mL/kg/hour	After 30 minutes if tolerated increase rate
4 mL/kg/hour	After 30 minutes if tolerated increase rate
5 mL/kg/hour	

- ✓ **A maximum of 5 mL/kg/hour should not be exceeded for any patient.** A recommended maximum of 480 mL/hour regardless of patient weight should be considered.
- ✓ Consideration should be given to a **lower rate** of infusion in those patients with pre-existing, or risk factors for renal disease and a maximum rate of 4 mL/kg/hour.
- ✓ If headaches occur, reduce the current rate by half.
- ✓ If trough immunoglobulin levels are ordered these are taken at time of IV insertion (before administration of Octagam).

SUBSEQUENT INFUSIONS

Octagam should be infused intravenously at an initial rate of 1 mL/kg/hour for 30 minutes. If well tolerated, the rate of administration may gradually be increased (over 30 minutes) to a maximum of 5 mL/kg/hour for the remainder of the infusion if no adverse events are noted. However consideration should be given to a **lower rate** of infusion in those patients with pre-existing, or risk factors for renal disease and a maximum rate of 4 mL/kg/hour.

Further information may be obtained on the Octapharma website
http://www.octapharma.com/Australia/au_octagam.php

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.

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

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.