OCTAGAM® 10% (TEN PERCENT) Normal immunoglobulin (human) 1g/10ml for intravenous use injection vial

OCTAGAM® 10% is a human intravenous immunoglobulin (IVIg) solution for infusion. It is available in Australia as 5g /50ml, 10g/100ml, 20g /200ml vial sizes.

Always read product information in the box carefully before commencing.

**CAUTION! DO NOT administer OCTAGAM® 10% using infusion protocols for OCTAGAM 5% or ANY other brands of IVIg (including KIOVIG 10% and INTRAGAM P 6%).**

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**Storage**

- OCTAGAM® 10% must be stored below 25°C or refrigerated (do not freeze).
- When refrigerated, OCTAGAM® 10% should be stored in a monitored blood fridge (in Transfusion Service where available). It must not be stored in a domestic/ward refrigerator.
- Do not use after the expiry date.
- Protect from light.
- OCTAGAM 10% contains no antimicrobial preservative. Use in one patient, on one occasion only.
- Contact Transfusion Service Provider for advice re handling/return of any unused bottles (not opened).

**Visual appearance**

- OCTAGAM® 10% should be a clear or slightly opalescent, colourless to pale yellow liquid.
- Do not use solutions that are cloudy or have deposits (any sediment or particles) - contact the Transfusion Service Provider.

**Contraindications & Precautions**

- Always refer to the full PI.
- Patients with rare total IgA deficiency should have the IVIg product with the lowest IgA content - INTRAGAM® P is the preferred product.

Blood Glucose Testing- some types of blood glucose testing systems may falsely interpret the maltose contained in OCTAGAM® 10% as glucose. This may result in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin. If measurement of blood glucose is required, test prior to the infusion or measure with a glucose-specific method (see PI).

**Documentation of Batch Number**

- All product batch numbers must be documented in the patient’s medical record – the vials have a peel off label with the batch number.
- The Transfusion Service Provider may also attach peel off label(s).

**Prior to administration**

- Correct reversible risk factor for adverse reactions (such as dehydration) before the infusion is given.
- **CAUTION!** Check resuscitation equipment, including oxygen and adrenaline are available and in working order.
- Check prescription is complete (including that OCTAGAM® 10% is the brand and strength of IVIg prescribed) and informed consent is documented.
- Explain procedure to patient, including possible reactions.
- Ensure intravenous (IV) access patent.
- Take baseline TPR and BP.
- Read the PI contained in the box.
- Allow the product to reach room temperature.

**Right patient / right product**

- Verify patient identification.
- Check OCTAGAM® 10% as per IV medication/hospital policy.

**IV line**

- The use of a pump is recommended to ensure constant delivery of accurate rates.
- A new standard IV line or filtered blood ‘giving set’ (170-200 micron) may be used.
- Administration from a glass bottle requires a vented system.

**Medication / other IV fluids**

- **CAUTION! Do not mix or piggy back this product with other medications or IV fluids.**
- Administered via a separate IV line.
- Flush with Normal Saline (0.9% Sodium Chloride solution).
- Premedication may be prescribed (e.g. for a history of reaction as per treating doctor).

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OCTAGAM® 10% Normal immunoglobulin (human)
1g/10ml for intravenous use

OCTAGAM® 10% infusion rates

- Start slowly, increase rate gradually only if tolerated.

**NOTE:** INFUSION RATES below are in mL/kg/hr:

- 0.5 mL/kg/hr for 30 minutes
- 1.0 mL/kg/hr for 30 minutes
- 2.0 mL/kg/hr for 30 minutes
- 3.0 mL/kg/hr with a maximum rate of 300mLs/hr (the routine use of higher rates is not recommended).

*In high risk patients e.g. > 65 years, diabetics, obese, those with pre-existing or risk factors for cardiac disease, renal failure or arterial or venous thromboembolic events, hyperviscosity, paraprotein or dehydration a maximum rate of less than 2mL/kg/hr (maximum 200mLs/hr) is recommended (see PI).*

- Infusion rates should be calculated and prescribed by the treating doctor. Use ideal body weight to calculate infusion rates in obese patients.
- In septic patients or those with multiple risk factors discuss timing of IVIg administration with an expert.
- During an infusion, subsequent vials may commence at same rate that the preceding vial finished.
- Each bottle should be completed within 4 hours.
- It is recommended that subsequent infusions are given according to the same protocol (consult treating doctor if there has been a change in health status or reaction to a previous infusion).

**Reactions**

- Tend to be related to the rate of the infusion and are more common in certain patient groups - refer to PI.
- Symptoms/signs may include: dyspnoea; wheezing; chest tightness; coughing; changes in blood pressure; tachycardia; flushing; fever; rigors; skin rash/urticaria; headache; vomiting; nausea and abdominal and back pain.

**Reactions (continued)**

- If a reaction does occur - stop administration immediately, assess vital signs, notify the medical officer, and provide emergency care as required.
- For minor reactions (headache is most common) the infusion can often be restarted cautiously at a slower rate after the patient has improved clinically.
- Follow your institutional procedure for reporting adverse events to IVIg. Inform your Transfusion Service/product provider.

**Observations**

Refer to hospital policies/procedures for IVIg infusions, product information for any specific recommendations as well as considering individual patient factors and consulting with the treating doctor. General recommendations:

- Close observation is required and the patient’s general status should be monitored regularly throughout the infusion.

A common approach is:

- Take a baseline TPR and BP prior to commencing.
- TPR and BP with each rate increase,
  - hourly once maximum rate is achieved
  - on completion
  - if the patient experiences new or increased symptoms.

**Observation post infusion**

The following patients should be monitored for 1 hour after completion of the infusion:

- those who have not had IVIg before
- those who switched from another product
- where there has been a long interval since the last infusion
- where there has been a significant deterioration in health
- those who have had a reaction to the current or previous infusion.

Other patients should be observed for at least 20 minutes. See PI & consult treating doctor.

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BloodSafe Guide to Administration