INTRAGAM® 10% Intravenous Immunoglobulin

INTRAGAM® 10% is a human intravenous (IV) immunoglobulin (IVIg) solution for IV infusion.

It is available in Australia in vials containing 2.5 g (25 mL), 10 g (100 mL) and 20 g (200 mL) of IVIg.

Always read the Product Information (PI) in the box carefully before commencing.

⚠ DO NOT administer INTRAGAM® 10% using infusion protocols for ANY other concentrations or brands of IVIg.

STORAGE

- INTRAGAM® 10% must be refrigerated in a monitored blood fridge at 2°C to 8°C. (In transfusion service where available)
- It must not be stored in a domestic/ward refrigerator.
- Once removed from refrigeration, store below 25°C & use within 3 months. Do not return to refrigeration.
- Do not freeze.
- Removal from storage must be documented in the register or electronic system for the purposes of tracking as per health service procedures /transfusion service provider requirements.
- Do not use after the expiry date.
- Store protected from light.
- INTRAGAM®10% contains no antimicrobial preservative. Use in 1 patient, on 1 occasion only.
- Contact transfusion service provider/product provider for advice re handling/return of any unused bottles (unopened).
- Used bottles MUST be discarded in medical waste & are not suitable for recycling.

VISUALLY INSPECT PRODUCT

- INTRAGAM® 10% should be 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.
- Contraindicated in those with known hypersensitivity to this product or to the excipient glycine.
- In patients with limited or compromised acid-base compensatory mechanisms including neonates, consideration should be given to the effect of the additional acid load that the preparation might present.
- Certain adverse reactions to IVIg occur more frequently with high rates of infusion & in patients with risk factors - see PI & infusion rates on page 2.

PRIOR TO ADMINISTRATION

- Correct reversible risk factors for adverse reactions (such as dehydration) before infusion is given.
- Ensure prescription is complete including the BRAND & CONCENTRATION of IVIg prescribed.
- Check informed consent is documented & consumer leaflet provided, as per health service policy.

PRIOR TO ADMINISTRATION (*continued*)

- Explain procedure to patient, including symptoms of possible reactions.
- Ensure IV access patent.
- Record baseline observations (TPR & BP) & general patient status including pre-existing rashes.
- Ensure circumstances/situation appropriate to proceed.
- Check resuscitation equipment, including oxygen & adrenaline are available & in working order.
- Read the PI contained in the box.
- Allow the product to reach room temperature.

ENSURE RIGHT PATIENT - RIGHT PRODUCT

- ⚠ Verify correct patient, product (including brand & concentration) & prescription.
- The patient's identity MUST always be confirmed prior to administration of each bottle.
- Check as per IV medication/health service policy.

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 to use with paper based records.
- The transfusion service provider may also attach peel off label(s).

IV LINE / PUMPS

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

MEDICATION / OTHER IV FLUIDS

- CAUTION! Do not add medications or IV fluids to this product.
- Use a separate IV line: Administer product separately from any medications or IV fluids other than 0.9% Sodium Chloride solution (Normal Saline).
- Premedication may be prescribed (e.g. for a history of reaction as per treating doctor).
- Consider clearing the line with 0.9% Sodium Chloride solution (Normal Saline) on completion of infusion.

Produced *by SA BloodSafe Program, in conjunction with the SA Immunoglobulin Therapy Advisory Group, based on Australian Product information.*
For updates see IVIg infusion guides at www.sahealth.sa.gov.au/bloodsafe

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INTRAGAM® 10% INFUSION RATES

- Follow health service protocols where available.
- Use neonatal specific protocols for neonates.
- Infusion rates should be calculated & prescribed by the treating doctor. Use ideal body weight to calculate infusion rates in obese patients.
- If the line is not primed with IVIg, consider this volume in the timing of rate increases.
- Start slowly, increase rate gradually only if tolerated.

ADULT Infusion Rates:

NOTE: RATES# for Adult infusions are in mL/hr (or mL/min) and are not weight-based.

60 mL/hr (1 mL/min) for 15 min - (15 mLs)
120 mL/hr (2 mL/min) for 15 min - (30 mLs)
180 mL/hr (3 mL/min) for 15 min - (45 mLs)
240 mL/hr (4 mL/min) final rate until complete#

PAEDIATRIC* Infusion Rates:

NOTE: RATES# for paediatric infusions are in mL/kg/hr (MO to calculate - use ideal body weight in obese pts).

0.5 mL/kg/hr for 15 - 30 minutes
1.0 mL/kg/hr for 15 - 30 minutes
2.0 mL/kg/hr final rate until complete (max 120 mL/hr)

- *Routine use of higher rates is not recommended.*
- *#Consideration should be given to reducing the rate of infusion in pts naïve to INTRAGAM® 10%, switching from an alternative IVIg, pts who have not received IVIg for a long time and other high risk patients e.g.*
  - *>65 years; diabetics; obese; those with pre-existing or risk factors for: cardiac disease, renal insufficiency or arterial or venous thromboembolism;*
  - *those with hyperviscosity; paraprotein or dehydration (for more info see PI & consult treating doctor).*
- **Paediatric infusion rates are not contained in the PI & were determined by the SA Immunoglobulin Therapy Advisory Group based on experience with INTRAGAM® P 6% (6% rates were halved given this 10% product is roughly double the concentration). Use hospital & specialty unit protocols where available.*
- 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 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 rate of the infusion & 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 & abdominal & back pain.
- **If a reaction does occur:**
  - stop administration immediately
  - assess vital signs
  - notify the medical officer
  - 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 health service procedure for reporting adverse events to IVIg. Inform your transfusion service/product provider.

OBSERVATIONS

Refer to health service policies/procedures for IVIg infusions, PI for any specific recommendations, as well as considering individual patient factors & consulting with treating doctor.

General recommendations:

- Close observation is required & patient's general status should be monitored regularly throughout the infusion.
- A common approach is to take a TPR & BP:
  - as a baseline prior to commencing
  - immediately prior to 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 have 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. Refer to PI, health service procedures & consult treating doctor.

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