PRIVIGEN® 10% Intravenous Immunoglobulin

PRIVIGEN® 10% is a human intravenous (IV) immunoglobulin (IVIg) solution for IV infusion. It is available in Australia as 5 g (50 mL), 10 g (100 mL), 20 g (200 mL) and 40 g (400 mL) vials. Always read the Product Information (PI) in the box carefully before commencing.

**WARNING!** DO NOT administer PRIVIGEN® 10% using infusion protocols for FLEBOGAMMA® 10% DIF or ANY other brands of IVIg (including FLEBOGAMMA® 5% & INTRAGAM® P 6%).

### STORAGE
- PRIVIGEN® 10% must be stored below 25°C or refrigerated in a monitored blood fridge (in transfusion service where available).
- It must not be stored in a domestic/ward refrigerator.
- 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.
- PRIVIGEN® 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
- PRIVIGEN® 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 6% is the preferred product.
- Contraindicated in those with known hypersensitivity to this product.
- Contraindicated in those with hyperprolinaemia (contains proline).

### 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 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
- **WARNING!** Verify correct patient, product (including brand & concentration) & prescription.
- The patient’s identity MUST always be confirmed prior to administration.
- 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.
- 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 mix or piggy back this product with other medications or IV fluids.
- Administered via a separate IV line.
- 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) or 5% Glucose on completion of infusion.

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Produced by SA BloodSafe Program, in conjunction with the SA Immunoglobulin Therapy Advisory Group, based on Australian Product information.
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PRIVIGEN® 10% INFUSION RATES
- Infusion rates should be calculated & prescribed by the treating doctor. Use ideal body weight to calculate infusion rates in obese patients.
- Start slowly, increase rate gradually only if tolerated.
- If the line is not primed with IVIg, consider this volume in the timing of rate increases.

PRIVIGEN® 10% INFUSION RATES
NOTE: 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 for 30 mins with max. rate of 400 mL/hr
   Routine use of higher rates is not recommended.
   "Lower max. rate of up to 2 mL/kg/hr (max. 200 mL/hr) is 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 thromboembolism;
   those with hyperviscosity; paraprotein or dehydration
   (for more info see PI & consult treating doctor).
- 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).

RECEPTIONS (continued)
- 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 institutional 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
  - 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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