

GAMUNEX[®] 10% Intravenous Immunoglobulin

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

It is available in Australia in bottles containing 5g (50 mL), 10g (100 mL) and 20g (200 mL) of IVIg.

Follow Health Service protocols where available & refer to the product information (PI).

⚠ DO NOT administer GAMUNEX[®] 10% using protocols for ANY other concentrations or brands of IVIg.

STORAGE

- GAMUNEX[®] 10% should 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 and use within 6 months.
- 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.
- GAMUNEX[®] 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

- GAMUNEX[®] 10% should be clear or slightly opalescent, colourless to pale yellow liquid.
- Do not use solutions that are cloudy, discoloured or have deposits (any sediment or particles) - contact the transfusion service provider. Do not shake.

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.
- 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 Australian PI.
- 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 bottles 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!** Gamunex[®] 10% is incompatible with Heparin - for more information see PI.
- **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.
- 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% Dextrose in water on completion of infusion.

Disclaimer: This is a guide only and the information contained herein is general in nature and does not correspond to or reflect any particular patient's circumstances or condition(s). It is not a substitute for expert opinion and/or clinical advice. Each of the parties involved in developing this document expressly disclaims and accepts no responsibility for any undesirable consequences arising from relying on the information, products, procedures or services referred to herein.

Produced by SA BloodSafe Program, in conjunction with the SA Immunoglobulin Therapy Advisory Group, based on Australian Product Information & with infusion rates adapted from the ASCIA IVIg Infusion Guidelines. For updates see IVIg infusion guides at www.sahealth.sa.gov.au/bloodsafe

GAMUNEX[®] 10% Intravenous Immunoglobulin

GAMUNEX[®] 10% INFUSION RATES

- Follow health service protocols where available.
- Use neonatal specific protocols in 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.

GAMUNEX[®] 10% INFUSION RATES

Start slowly, increase rate incrementally, only if tolerated.

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 final rate until complete (max. 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 insufficiency or arterial or venous thromboembolism;
- those with hyperviscosity; paraprotein or dehydration (for more information see PI & consult treating doctor).
- those with first exposure to IVIg.
- In septic patients or those with multiple risk factors, discuss timing of IVIg administration with an expert.
- During an infusion, subsequent bottles may commence at same rate that preceding bottle finished.
- Each bottle should be completed within 4 hours from puncturing the bottle's seal.
- 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.

REACTIONS (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 health service procedure for reporting & recording 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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