

FLEBOGAMMA[®] 5% DIF Intravenous Immunoglobulin

FLEBOGAMMA[®] 5% DIF is a human intravenous (IV) immunoglobulin (IVIg) solution for IV infusion.

It is available in Australia in bottles containing 2.5 g (50 mL), 5 g (100 mL), 10 g (200 mL), 20 g (400 mL) of IVIg.

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

⚠ DO NOT administer FLEBOGAMMA[®] 5% DIF using infusion protocols for FLEBOGAMMA[®] 10% DIF or ANY other concentrations or brands of IVIg.

STORAGE

- FLEBOGAMMA[®] 5% DIF must be stored below 30°C or refrigerated in a monitored blood fridge (in transfusion service where available).
- It must not be stored in 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 the light.
- FLEBOGAMMA[®] 5% DIF 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

- FLEBOGAMMA[®] 5% DIF 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. 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.
- Product contains 50 mg/mL of sorbitol as excipient.
- **⚠ WARNING!** Contraindicated in patients with rare hereditary problems of fructose intolerance.
 - **Babies & young children should NOT receive this product** as hereditary fructose intolerance may not yet be diagnosed & may be fatal.
 - SA Immunoglobulin Therapy Advisory Group has determined that **this product must NOT be issued to children under 5 years old.**
- Interferences with determination of blood glucose levels are not expected.
- 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.
- 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 and 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 bottles have a peel off label with the batch number to use with paper based patient 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.
- 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.

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

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FLEBOGAMMA[®] 5% DIF INFUSION RATES

- Follow health service protocols where available.
- Not for use in neonates or children < 5 years, see pg 1.
- 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.

FLEBOGAMMA[®] 5% DIF INFUSION RATES

Start slowly, increase rate incrementally, only if tolerated.

NOTE: RATES[#] below are in mL/kg/hr:

1.0 mL/kg/hr for 30 minutes

2.0 mL/kg/hr for 30 minutes

3.0 mL/kg/hr for 30 minutes

4.0 mL/kg/hr for 30 minutes

5.0 mL/kg/hr final rate until complete (max. 500 mL/hr)[#]

Routine use of higher rates is not recommended.

[#]Lower max. rate of up to 4 mL/kg/hr (max. 300 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 info 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 the preceding vial 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 the 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 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. See PI, health service procedures & consult treating doctor.

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