Intravenous immunoglobulin (IVIg) clinical practice guidance template

December 2025

OFFICIAL

Contents

Caveat

This information is a guide only. Health service procedures should be implemented and monitored for compliance with best practice, safety guidelines and all other requirements specific to the products available.

All health service policies/procedures should be developed and endorsed in accordance with local procedures and committee/s.

This document is correct at time of publication and will be further updated as changes occur.

General information

The National Blood Authority undertakes a tender to source imported IVIg products to supplement domestic IVIg product, ensuring adequate supply for Australian consumers.

Purpose

To provide guidance on IVIg safety and administration according to the manufacturers' instructions (product information sheets).

Indications for use

Refer to the Criteria for the Clinical Use of Immunoglobulin in Australia < https://www.criteria.blood.gov.au/>.

All requests for IVIg must be made through BloodSTAR.

BloodSTAR authorisation is needed before routine IVIg administration can occur. However, in an emergency where authorisation via BloodSTAR is delayed or not possible, a single dose may be dispensed by the pathology service provider or pharmacy. Retrospective BloodSTAR approval is still required for NBA funded IVIg.

Note that the health service may have to cover the cost of the product if the indication does not meet the current criteria.

General precautions

These general precautions apply to all IVIg products.

Aseptic meningitis syndrome (AMS)

Aseptic meningitis syndrome is an uncommon side effect which has been reported to occur in association with IVIg treatment. Discontinuation of IVIg treatment has resulted in remission of AMS within several days without sequelae.

Hypersensitivity and anaphylaxis

True hypersensitivity reactions are rare. They can occur in patients with IgA deficiency with anti-IgA antibodies.

Rarely, IVIg can induce an anaphylactic reaction, even in patients who have tolerated previous treatment with IVIg.

Thromboembolism

There is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism, and deep vein thromboses. Caution should be exercised in prescribing and infusing IVIg in patients with pre-existing risk factors for thrombotic events, such as:

- volume depletion (hypovolaemia)
- obesity
- advanced age
- hypertension
- diabetes mellitus
- a history of vascular disease or thrombotic episodes
- patients with acquired or inherited thrombophilia disorders
- patients with prolonged periods of immobilisation
- patients with diseases which increase blood viscosity
- severely hypovolaemic patients.

Patients at risk of developing thromboembolic disorders it is recommended that IVIg is administered at the minimum/slowest rate practicable.

Acute renal failure

There have been occasional reports of renal dysfunction and acute renal failure in patients receiving IVIg products. Patients at increased risk are those with:

- pre-existing renal insufficiency
- diabetes mellitus
- age greater than 65 years
- volume depletion (hypovolaemia)
- overweight
- sepsis and paraproteinaemia
- taking concomitant nephrotoxic drugs.

In all patients at risk of developing acute renal failure, intravenous immunoglobulin administration requires:

- adequate hydration prior to the initiation of the infusion of IVIg
- monitoring of urine output
- monitoring of serum creatinine levels and
- avoidance of concomitant use of loop diuretics

Haemolytic anaemia

IVIg products can contain red blood cell antibodies which may act as haemolysins that can result in a positive direct antiglobulin test (DAT/ direct Coomb's test) and, in some cases, intravascular haemolysis. Haemolytic anaemia can develop after IVIg therapy due to enhanced red blood cell (RBC) destruction or sequestration. IVIg recipients should be monitored for clinical signs and symptoms of haemolysis.

Non-cardiogenic pulmonary oedema

There have been reports of non-cardiogenic pulmonary oedema or Transfusion Related Acute Lung Injury (TRALI) in patients receiving IVIg.

Fertility, pregnancy and lactation

- No fertility studies have been reported

- Safety of IVIg has not been established in controlled trials. Clinical experience with immunoglobulins suggests that no harmful effects on the course of the pregnancy or the fetus/neonate are to be expected.
- Refer to product information.

Use in the elderly, genotoxicity and carcinogenicity

Refer to product information.

No carcinogenicity studies have been reported.

Compatibilities and drug interactions

- IVIg should be administered separately from other intravenous fluids or medications.
- The interaction of IVIg preparations with other medicines has not been established in appropriate studies.
- Immunoglobulin infusion may reduce the response to some vaccines, especially live attenuated vaccines. Administration of such vaccines, e.g., poliomyelitis or measles, rubella, mumps and varicella, should be deferred until approximately three months after IVIg administration. If the patient is having ongoing IVIg a risk-benefit assessment is needed to compare the risk of lowered vaccine efficacy against the need for protection against the vaccine preventable disease. Consider referral to immunologist. See product information for further information.

IVIg administration

Preparation for infusion

Inspection

- Immunoglobulin is a sterile, clear or slightly opalescent, colourless or pale-yellow solution for intravenous injection.
- Do not use if the solution appears cloudy, turbid or contains deposits.
- The lid, covering the rubber stopper, should be intact.

Infusion equipment

- IVIg may be administered through any vented standard IV infusion giving set directly from the bottle.
- An infusion pump may be used, follow local guidelines for use of infusion pumps.

Priming and flushing

- Lines may be primed with 0.9% normal saline or the IVIg product and flushed with 0.9% saline if needed.

Patient readiness check

- Consent to receive IVIg has been obtained and sighted.
- The IVIg prescription is consistent with the BloodSTAR authorisation.
- Baseline vital signs have been taken, recorded and if required reported to the treating medical officer.
- Any pre-infusion symptom or sign, which may be confused with an adverse reaction, has been noted.
- Patient is well hydrated.
- Any required blood tests have been taken.
- Premedication has been administered, if required.

Pre-infusion check

- Positive patient identification following usual hospital protocol.
- The right product as prescribed for this patient. It is important to verify exact product as different product names are similar. For example, Privigen versus Privigen AU.
- The right dose for this patient.
- The right date/time the infusion is due.
- The right infusion rate.

Infusion rate guide

Please refer to product information for specific infusion rates, ensuring that the correct rate is followed for the product being administered.

All IVIg product information sheets can be accessed via the Lifeblood website [Intravenous immunoglobulin (IVIg) | Australian Red Cross Lifeblood](https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/IVIg) <https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins/IVIg>

*Rate rises are at the discretion of the health care professional and as tolerated by the patient. See the product information for more detail regarding infusion rate studies for specific patient groups.

- Privigen® and Privigen AU®
  - The initial infusion rate is 0.3 mL/kg body weight/hr. If well tolerated, the rate of administration may gradually be increased to a **maximum rate of 4.8 mL/kg body weight/hr.**
- Flebogamma® 5% and 10%
  - Flebogamma 5 % DIF should be infused intravenously at an initial rate of 0.01 - 0.02 ml/kg/min for the first thirty minutes. If well tolerated, the rate of administration may be gradually increased at 30-minute intervals by 0.01mL/kg/min (equivalent to 0.6mL/kg/hr) to a maximum of 0.1ml/kg/min (6mL/kg/hr) as tolerated by the patient.
  - Flebogamma 10 % DIF should be infused intravenously at an initial rate of 0.01 ml/kg/min for the first thirty minutes. If tolerated advance to 0.02 ml/kg/min for the second thirty minutes. If tolerated advance to 0.04 ml/kg/min for the third thirty minutes. If tolerated advance to 0.06 ml/kg/min for the fourth thirty minutes. If tolerated advance to a maximum rate of 0.08 ml/kg/min, equivalent to 4.8mL/kg/hr.
- Gamunex®
  - Gamunex® should initially be infused at a rate of 0.01 mL/kg/min for the first 30 min. If well-tolerated, the rate may be increased gradually to a **maximum of 0.08 mL/kg/min (8mg/kg/min / 4.8mL/kg/hr)** at 30-minute intervals.
  - If side effects occur, the rate may be reduced, or the infusion interrupted until symptoms subside. The infusion may be resumed at the rate which is comfortable for the patient.
- Octagam®
  - Octagam® 10% should be infused at an initial rate of 0.6-1.2mL/kg/hr for 30 minutes. If well tolerated, the rate of administration may be gradually increased to **a maximum of 7.2mL/kg/hr** for the remainder of the infusion.
- Kiovig®
  - Kiovig® 10% infusion rate should start at 0.5 mL/kg/hr. If well tolerated gradually increase by a suggested rate of 0.5mL/kg/hr as per starting rate, every 30 minutes to a maximum rate of 5.0 mL/kg/hr.
  - Subsequent infusions should follow the same procedure, going to the maximum rate as tolerated in previous infusions.

Considerations for infusion rates in some patient groups

Consider running IVIg at slower rates for paediatric/neonatal patients. A consultant paediatrician may need to determine the best rate for each child/infant/neonate. The Royal Children's Hospital Melbourne has an IVIg guideline < https://www.rch.org.au/bloodtrans/about_blood_products/Intravenous_Immunoglobulin_Guideline/>. A useful resource when caring for children requiring IVIg.

Infusion rates for acutely ill, febrile, and/or elderly patients, and those with known cardiac or renal insufficiencies should be raised cautiously and may not reach the maximum rate. The patient's predisposition to circulatory overload should always be considered when selecting infusion rates. Slower infusion rates may be required in these patients.

In patients at risk of acute renal failure or thromboembolic events, IVIg products should be administered at the minimum rate of infusion and dose practicable.

Traceability

The name and batch number of every IVIg bottle administered to a patient must be recorded in the patient medical record for traceability purposes.

Observations

No specific patient observation regime is described in the product information for any IVIg product.

It is recommended that vital signs and general status are monitored regularly during the infusion and for 20 minutes post completion of the infusion for patients established on a particular IVIg product. Patients naive to IVIg, patients changing IVIg product or patients who have not received IVIg for six weeks or more should be monitored for a full hour post the IVIg infusion.

For safety ideally the patient's temperature, pulse, respiration rate and blood pressure should be taken and documented at the following intervals**:**

- prior to commencing
- prior to each rate increase and hourly once maximum rate achieved
- once completed
- observe patient for 20 minutes post completion.

Please be aware that local policies may require different observation frequencies.

Reactions to IVIg are often rate related, hence the need to closely monitor the patient throughout the infusion. More frequent observations may be required if a patient experiences an adverse reaction to IVIg.

General adverse effects

Adverse effects are often rate related, but other risk factors need to be taken into consideration.

Adverse events are commonly associated with patients who receive IVIg:

- for the first time
- when there has been a long interval since the previous infusion
- when there is a change in product.

The types of reactions that may occur during or after IVIg infusion include but are not limited to those as described in Table 1.

Table 1: Acute IVIg reactions and suggested management

Signs and symptoms of acute reactions	Management
• chest-tightness • facial flushing or pallor • erythema • hot sensations • dyspnoea or respiratory difficulty • urticaria /skin rash • rashes on hands/palms • itching • change in blood pressure • nausea or vomiting • arthralgia • dizziness • myalgia/ musculoskeletal stiffness	• STOP infusion • Notify medical staff • Following medical review and management, if the patient improves clinically, cautiously recommence at a slower rate. – Increased monitoring may be required

Table 2 Delayed IVIg reactions and suggested management

Delayed reactions	Management
May occur post infusion, normally within 24 hours • aseptic meningitis • haematological complications e.g., haemolysis • dermatological complications e.g., urticaria • other: nausea, vomiting, chest pains, rigors, dizziness, arthralgia, aching legs	Ensure: • Patient/carer knows what to look for and how to obtain assistance in the event of a delayed reaction that occurs at home/in the community, e.g. 000 for emergencies / Ambulance Victoria • Notify treating team • Other resources to consider for further advice: – Consultant haematologist

After infusion of immunoglobulin, the temporary rise of passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing. This includes passive transmission of antibodies to red blood cell antigens e.g. anti-A, anti-B, anti-D, and this may interfere with serological tests for red blood cell antibodies.

False positive viral serological findings have been reported following the passive transfer of antibodies in IVIg infusions including hepatitis, CMV and HTLV.

IVIg therapy has been associated with an increase in serum creatinine level and/or acute renal failure.

References

Flebogamma® 5% DIF, product information. Grifols Australia Pty Ltd. 2018

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Gamunex® 10%, product information. Grifols Australia Pty Ltd. 2022

Octagam®10%, product information. Octapharma Australia Pty Ltd. 2022

Kiovig®, product information, Takeda Pharmaceuticals Australia Pty Ltd, 2022

Acknowledgements

Blood Matters would like to acknowledge the Victorian Transfusion Nurse Team of the Australian Red Cross Lifeblood for their contributions to this document.

Further information

Further information can be found on the following websites:

National Blood Authority - http://www.blood.gov.au/Ig-governance

Australian Red Cross Lifeblood - https://www.lifeblood.com.au/health-professionals/products/fractionated-plasma-products/immunoglobulins

Australasian Society of Clinical Immunology and Allergy (ASCIA) - ASCIA Guidelines for standardised IVIg infusion rates for IRT - Australasian Society of Clinical Immunology and Allergy (ASCIA)

BloodSafe eLearning IVIg courses

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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

ISBN 978-1-76131-950-1 **(pdf/online/MS word)** Available at Blood Matters Program <https://www.health.vic.gov.au/patient-care/blood-matters-program>