Human Normal Immunoglobulin

PRIVIGEN AU®, PRIVIGEN®

5 g (50 mL), 10 g (100 mL) intravenous infusion

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Note:
This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient’s medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

If the patient has ANY adverse reaction, stop infusion and call a medical officer IMMEDIATELY (see monitoring)

This guideline should be used in conjunction with the Bloodsafe Guide to Administration

Synonyms
Gamma globulin, IVIG, IGIV, Intravenous Immunoglobulin

Dose and Indications
1 g = 1000 mg

See Criteria for Clinical Use of Immunoglobulin in Australia for comprehensive list of approved indications. Always contact Haematology for advice.

Privigen AU® - Australian Product
Privigen® - Imported Product
Approved Criteria for Clinical Use of Immunoglobulin in Australia

Neonatal alloimmune thrombocytopenia (NAIT)
Intravenous Infusion
1 g/kg as a single dose. Repeat in 24 hours if required

Hypogammaglobulinaemia, and suspected inborn errors of immunity/immunodeficiency diseases
Intravenous Infusion
Discuss clinical indications for immunoglobulin administration, dosing and follow-up with the on-call Paediatric Clinical Immunology Consultant via Women’s and Children’s Hospital Switchboard (08) 8161 7000.

Neonatal haemochromatosis (gestational alloimmune liver disease)
Intravenous Infusion
1–2 g/kg following exchange transfusion in the first 7 days, then up to 1 g/kg weekly as required

For updates refer to Criteria for Clinical Use of Immunoglobulin in Australia.
Non-approved Criteria for Clinical Use of Immunoglobulin in Australia

For any indication that do not meet eligible criteria by National Blood Authority a Jurisdictional Direct Order (JDO) is required:

- Contact Advanced Clinical Nurse Consultant, SA Immunoglobulin Program (0435 963 374) during business hours
- For after-hours requests contact hospital on call Immunologist.
- Neonatal Consultant to complete an Individual Patient Use Request (IPU) Form and submit to SA Immunoglobulin Therapy Advisory Group
- Submit the approved IPU to local Drug and Therapeutics Committee for noting only

Please note the Australian Product cannot be used for this indication (i.e. not Privigen® AU), therefore an imported product should be requested (e.g. Privigen®).

Isoimmune haemolytic disease

Intravenous Infusion
1 g/kg, may repeat in 12 to 24 hours if necessary.

There is low to very low quality of evidence to support adjunctive treatment with immunoglobulin in addition to phototherapy to reduce the need for exchange transfusion.

Severe neonatal enterovirus infection including myocarditis or hepatitis

Intravenous Infusion
2 g/kg as a single dose

Neonatal thrombocytopenia in the context of maternal immune thrombocytopenic purpura (ITP)

Intravenous Infusion
1 g/kg, may repeat in 24 hours if necessary.
Preparation and Administration

**Intravenous Infusion**

Start slowly, increase rate only if tolerated

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Rate (mL/kg/hour or mg/kg/hr)</th>
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<tr>
<td>First 30 minutes</td>
<td>0.5</td>
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<td>Next 30 minutes</td>
<td>1</td>
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<tr>
<td>Next 30 minutes</td>
<td>2</td>
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<td>To complete infusion</td>
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Use a dedicated IV line. Do not mix or co-infuse with other medications or intravenous fluids. Flush before and after with sodium chloride 0.9% or glucose 5%.

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.

Immunoglobulin does not contain any antimicrobial preservative, therefore each bottle must be administered within 6 hours from spiking.

The product should be at room or body temperature before use. The product 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 transfusion service provider. Do not shake.

**Compatible Fluids**

Sodium chloride 0.9% or glucose 5% for intravenous flush only

Diluting immunoglobulin is not recommended

**Adverse Effects**

Infusion related side effects include hypotension, tachycardia, flushing, fever, rigors, skin rash and vomiting.

Haemolytic anaemia is an uncommon but recognised adverse effect, particularly for children receiving multiple doses. It typically occurs up to a week after immunoglobulin administration.

**Infrequent**

Muscle spasms, arthralgia

**Rare**

Anaphylaxis, acute renal failure, aseptic meningitis syndrome, transfusion related acute injury, thrombosis
Monitoring

> Baseline full blood count, renal function and urine output
> Infusion site for phlebitis at 30 minutes, then at one hour then every hour until completion
> Monitor temperature, pulse rate, respiratory rate, oxygen saturation and blood pressure
  > At baseline prior to commencing infusion
  > Immediately prior to each rate change
  > Hourly once maximum rate is achieved
  > At completion of infusion
  > One-hour post completion of infusion
  > If the patient experiences new or increased symptoms.
> If the patient is unwell or there are any concerns particularly regarding the baseline observations the medical officer should be contacted before the infusion commences.
  > Vital signs should then be checked and recorded within 15 minutes after the start of the infusion, then as above frequency
> Observe for infusion related side effects (hypotension, tachycardia and flushing)
> If an adverse reaction occurs:
  > stop administration immediately
  > assess vital signs
  > notify the medical officer
  > provide emergency care
  > For minor reactions, the infusion can be restarted cautiously at a slower rate after the patient has improved clinically
  > Record any adverse events in the medical record and Blood and Blood Product Administration Record
> Adverse events should be reported locally through the hospital's reporting system (e.g. Safety Learning System (SLS)). Product related or immunologically related adverse events should also be reported to the Therapeutic Goods Administration. See National Blood Authority for further information.

Practice Points

> Immunoglobulin is available through the blood transfusion service. All immunoglobulin needs approval through BloodSTAR - https://www.blood.gov.au/bloodstar or approval through the JDO process for indication that are not eligible.
> Correct risk factors for adverse reactions e.g., dehydration prior to administration.
> The stabilising agent in Privigen AU® is L-proline. Physicians should weigh the risk/benefit of Privgen AU® in patients with hyperprolinaemia type 1 and type 2 on an individual basis.
> Normal human immunoglobulin may inhibit the immune response to live viral vaccines – see the National Immunisation Handbook. However, infants can receive rotavirus vaccine at any time before or after, or with, any blood product, including antibody-containing products.
> Ensure adequate hydration prior to initiation of infusion. The manufacturer of Privigen AU® recommends avoidance of concomitant use of loop diuretics.
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References

> Criteria for Clinical Use of Immunoglobulin in Australia, BloodSTAR, National Blood Authority Australia, v3.9.0
> Guidelines – Standard infusion rates for IVIg (intravenous immunoglobulin) replacement therapy, Australian Society of Clinical Immunology and Allergy, April 2023
> Intravenous Immunoglobulin Guideline, The Royal Children’s Hospital Melbourne, accessed 5/2023 online
> Privigen® 10% & Privigen AU® 10% Intravenous Immunoglobulin, Bloodsafe Guide to Administration, April 2023, Government of South Australia SA Health
> Zwiers C, Scheer-Rath MEA, Lopriore E et al, Immunoglobulin for alloimmune hemolytic disease in neonates (Review), Cochrane Database of Systematic Reviews 2018, Issue 3

Document Ownership & History

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