## Considerations before infusing PRIVIGEN[1]

- Allow to **reach room temperature** before use
- **Do not shake**
- **Protect from light;** keep the bottle in the outer carton during storage
- **Do not use after expiry date**
- **Must be used immediately after opening;** contains no antimicrobial preservatives
- **Use in one patient on one occasion only;** discard any unused solution
- **Solution must be clear or slightly opalescent;** if cloudy or containing sediment, do not use
- **Always ensure patient is adequately hydrated prior to infusion;** especially for any patients that may be at risk

Refer to the New Zealand Blood service for details of access to human immunoglobulin products

**Before prescribing PRIVIGEN please review the appropriate Data Sheets for information on dosage, contraindications, precautions, interactions and adverse effects. The data sheet is on the Medsafe website at www.medsafe.govt.nz. or www.cslbehring.com.au.products/products-list.**

**Minimum Data Sheet PRIVIGEN®** Privigen® (10% (100 g/L), solution for intravenous injection.

**Indications: Replacement therapy** in primary immunodeficiency diseases (PID), myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections, symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. **Immunomodulatory therapy** in Idiopathic Thrombocytopenic Purpura in patients at high risk of bleeding or prior to surgery to correct the platelet count, Guillain-Barré Syndrome, Kawasaki disease, Chronic Inflammatory Demyelinating Polyneuropathy, Multifocal Motor Neuropathy, Myasthenia Gravis exacerbations, Lambert-Eaton Myasthenic Syndrome, Stiff Person Syndrome. **Contraindications:** Hypersensitivity to the active substance or excipients, hypersensitivity to human immunoglobulins - especially where IgA deficiency with anti-IgA antibodies. **Precautions:** Hyperprolinaemia type I or II. Adequate hydration prior to IVIg infusion. Monitor during and for the first hour after first infusion in patients that a) are naive to human normal Ig, or b) switched from an alternative Ig product, or c) with long interval since previous infusion. All other patients should be observed for at least 20 minutes after administration. Risk of certain adverse reactions may increase with a) high infusion rate, b) in hypogammaglobulinaemia or agammaglobulinaemia with or without IgA deficiency, c) receiving IVIg for the first time, d) Ig product switch, or when long interval since a previous infusion. Hypersensitivity events, haemolytic anaemia, aseptic meningitis syndrome, thromboembolism, acute renal failure and transfusion-related acute lung injury (TRALI) have been reported with immunoglobulin therapy. TRALI occurs very rarely with IVIg products including PRIVIGEN. Symptoms typically appear 1 to 6 hours post treatment; see approved product information. Ability to drive/operate machinery may be impaired by some adverse events associated with Privigen. **Pregnancy and lactation** immunoglobulin crosses placenta and is excreted in breast milk, no clinical study data therefore give with caution in pregnancy/breast-feeding. Clinical experience with immunoglobulins suggests no harmful effects. **Pathogen safety** - donor screening and dedicated viral inactivation/removal manufacturing procedures used; possibility of viral transmission cannot, however, be totally excluded. **Interactions:** May affect the response to live attenuated vaccines. May interfere with some serological tests. For all precautions, etc., review approved product information. **Adverse Effects:** Anaemia, leukopenia, haemolysis, hypersensitivity, skin disorder (including rash, pruritus, erythema, skin exfoliation), nausea/vomiting, diarrhoea, abdominal pain, headache, dizziness, hypertension, flushing, hypotension, dyspnoea (including chest pain, chest discomfort, painful respiration), pain (including arthralgia), myalgia, fever, fatigue, asthenia, influenza-like illness, hyperbilirubinaemia, Coombs' test positive, decreased haemoglobin, increased alanine aminotransferase, increased blood lactate dehydrogenase and increased aspartate aminotransferase. For all adverse events review approved product information. **Dosage & Administration:** Dose needs to be individualised for the patient. Replacement therapy: 0.2 to 0.8 g/kg/bw. Immunomodulatory therapy: 0.4 to 2g/kg/bw. Refer to PI for dosage details. **Privigen should only be administered intravenously.** Recommended initial infusion rate 0.3 mL/kg/hr which if tolerated can be gradually increased to 4.8 mL/kg/hr. **Patients at risk for acute renal failure, or thromboembolic events use minimum rate of infusion and dose practicable.** Infusion rate slowed, or stopped if adverse event occurs. Contains no preservative, use immediately after opening, discard unused portion appropriately. Do not use if cloudy or contains particulate matter. Can be diluted with glucose (5%), using aseptic technique. **Do not mix** with other medicinal products including 0.9% sodium chloride, however, infusion line may be primed/flushed with 0.9% sodium chloride. Based on PRIVIGEN Data Sheet 12 May 2020 (V 21.00).

**References: 1.** PRIVIGEN® Approved NZ Data Sheet. **2.** Stein MR, *et al. J Clin Immunol* 2009; 29:137–144. **3.** Léger J-M, *et al. J Peripheral Nervous System* 2013; 18:130–140 **4.** Sleasman JW, *et al. J Clin Immunol* 2010; 30:442–448. **5.** Robak T, *et al. Hematology* 2009; 14(4):227–236.



CSL Behring

NZBLOOD Te Ratonga Toto O Aotearoa

privigen®

Normal Immunoglobulin (Human)
10% (100 mg/mL) - Intravenous injection


# How to infuse PRIVIGEN®

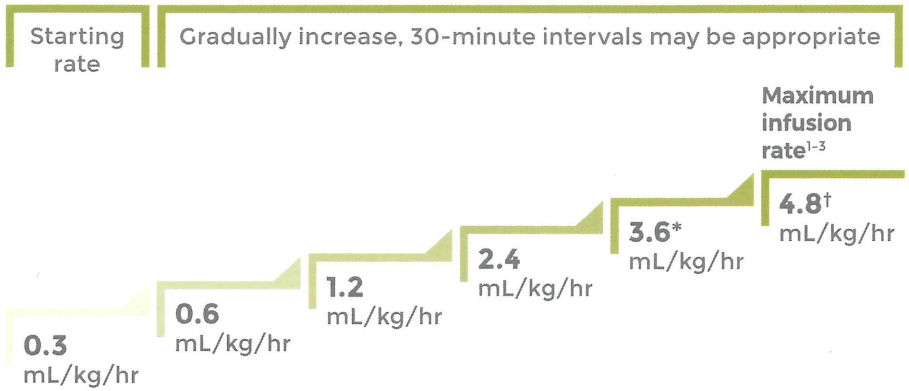
(10% human normal immunoglobulin)

CSL Behring

## What should my infusion rate be?

- The **initial infusion rate** for PRIVIGEN is **0.3 mL/kg/hr**[1]
- If the first infusion is well tolerated the rate **can be gradually increased as long as it continues to be tolerable**[1]
- A similar **step-wise approach** can then be used for **subsequent infusions**

### Example of infusion rate step-up:[2-5]




*Step rate rises used between 2.4 mL/kg/hr and 4.8 mL/kg/hr are at the discretion of the healthcare professional and as tolerated by the patient.

†In the pivotal PID study maximum rate for the first three infusions was capped at 2.4 mL/kg/hr. From the fourth infusion onwards the maximum rate was 4.8 mL/kg/hr.[2] In the extension trial to the pivotal PID study a stepwise approach was used up to a maximum rate of 4.8 mL/kg/hr in 45% of infusions and 7.2 mL/kg/hr in 36% of infusions.[4] In the pivotal ITP study the maximum rate was 2.4 mL/kg/hr (only 2 infusions given).[5]

**Infusion rate needs to be individualised to patient's risk factors, comorbidities and tolerability**

## For which patients should I consider reducing the rate of infusion?[1]

In patients that:

- are naïve to IVIg
- are at risk of thromboembolic adverse events
- are switching from an alternative IVIg
- are at risk for acute renal failure
- have not received IVIg for a long time
- have hypogammaglobulinaemia or agammaglobulinaemia with or without IgA deficiency

## What should I look out for during the infusion?[1]

- **Reactions to IVIg tend to be related to the infusion rate** (i.e., if the infusion is too rapid, there can be changes in heart ate and blood pressure) and most likely occur during the first hour of infusion
- **Monitor patient's vital signs and general status** throughout the infusion
- **If adverse reaction occurs,** depending on severity, **reduce the rate of administration or stop the infusion entirely**

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