privigen®
Human Normal Immunoglobulin, 10%, Liquid

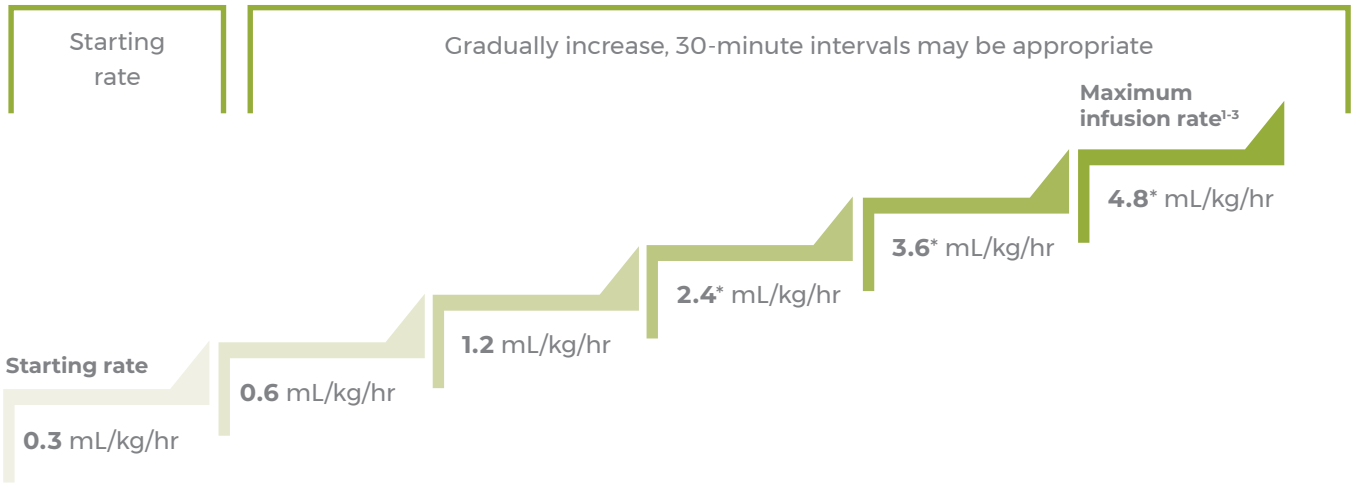
Infusion & Dosing Guide

PRIVIGEN® infusion rate

The infusion rate step-up diagram and calculator are provided as guidance only. The infusion rate needs to be individualised to patient's risk factors, comorbidities and tolerability.

- 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]



Normal Immunoglobulin (Human) 10% (100 g/L), intravenous injection Infusion Rate (mL/hr) Calculator[1–3,5,6]

Infusion rate (mL/kg/hr)	Pump rate	Patient's body weight (kg)																		
		10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
0.3	mL/hr	3	4.5	6	7.5	9	10.5	12	13.5	15	16.5	18	19.5	21	22.5	24	25.5	27	28.5	30
0.6	mL/hr	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
1.2	mL/hr	12	18	24	30	36	42	48	54	60	66	72	78	84	90	96	102	108	114	120
2.4*	mL/hr	24	36	48	60	72	84	96	108	120	132	144	156	168	180	192	204	216	228	240
3.6*	mL/hr	36	54	72	90	108	126	144	162	180	198	216	234	252	270	288	306	324	342	360
4.8*	mL/hr	48	72	96	120	144	168	192	216	240	264	288	312	336	360	384	408	432	456	480

*Step-up rate rises used between 2.4 mL/kg/hr and 4.8 mL/kg/hr are at the discretion of the health care professional and as tolerated by the patient. †In the pivotal primary immunodeficiency disease study, the 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.[3] In the extension trial to the pivotal primary immunodeficiency disease study, a step-wise 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 idiopathic thrombocytopenic purpura study, the maximum rate was 2.4 mL/kg/hr (only two infusions given).[5]

All patients should be regularly monitored throughout the infusion and for a period after.[1]
Refer to approved Product Information for full dosing and administration recommendations.

In patients at risk of acute renal failure or thromboembolic adverse reactions, IVIg products should be administered at the minimum rate of infusion and dose practicable.[1] As with all IVIgs, the patient needs to be adequately hydrated prior to infusion and should be closely monitored and observed for any symptoms during and after infusion.[1] In the case of an adverse reaction, the rate of administration must be reduced or the infusion stopped.[1]

PRIVIGEN® is indicated for:

Replacement IgG therapy in:

- Primary Immunodeficiency Diseases (PID)
- Multiple myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment

Immunomodulatory therapy for:

- Patients with Idiopathic Thrombocytopenic Purpura at high risk of bleeding or prior to surgery to correct the platelet count
- Myasthenia gravis exacerbations
- Kawasaki disease
- Guillain-Barr syndrome
- Chronic inflammatory demyelinating polyneuropathy
- Multifocal motor neuropathy
- Stiff person syndrome
- Lambert-Eaton myasthenic syndrome

Contraindicated in patients with:[1]

- hypersensitivity to the active substance of the excipient
- hypersensitivity to human immunoglobulins especially in patients with IgA deficiency and antibodies against IgA

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Refer to the New Zealand Blood Service for details of access to human immunoglobulin products. Before prescribing please review Data Sheet available at www.cslbehring.com.au/products/products-list or scan QR code

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).

IVIg: intravenous immunoglobulin.

References: 1. PRIVIGEN® Approved Data Sheet. **2.** Leger J-M, *et al. J Periph Nervous Sys* 2013; 18: 130–40. **3.** Stein MR, *et al. J Clin Immunol* 2009; 29: 137–144. **4.** Sleasman JW, *et al. J Clin Immunol* 2010; 30: 442–48. **5.** Robak T, *et al. Hematology* 2009; 14(4):227–36. **6.** CSL Behring data on file.

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