privigen®
Normal Immunoglobulin (Human)
10% (10g/L), intravenous injection

PRIVIGEN: Product Overview

PRIVIGEN is a ready-to-use liquid immunoglobulin (IVIg) containing 100 g/L (10%) of total human plasma protein for intravenous infusion.[1]

Table 1. Product Composition[1,2,3]

Concentration of total human plasma protein	1g /10mL (10%) High purity with at least 98% being immunoglobulin G
IgA	≤ 0.025 mg/mL
Stabiliser	Proline (250 mmol/L) + pH (weakly acidic 4.8)
Sodium	Low (≤ 1mmol/L)
Osmolality	320 mOsm/kg
Carbohydrate stabiliser (e.g sucrose, etc)	None
Preservative	None

PRIVIGEN is available in a variety of presentations, including 5g, 10g and 20g[1]:

Figure 1. Colour coded packaging for three different presentations

PRIVIGEN Administration Guide

General Information[1]

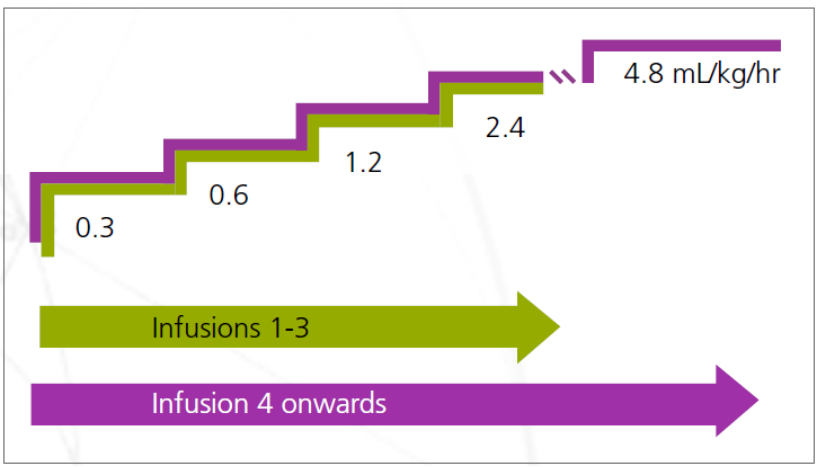
- PRIVIGEN should be at room temperature before use
- The bottle must be vented during use (by piercing the stopper at its centre, within the marked area)
- IVIg administration requires:
    - adequate hydration (avoid loop diuretics)
    - initial infusion rate of 0.3mL/kg/hr (see “infusion guide”)
    - monitor patient during and post infusion (see “monitoring”)
- If desired, PRIVIGEN can be diluted with glucose 5% solution, using aseptic technique
- Do not mix other medicinal products in the same infusion line

PRIVIGEN Infusion Guide

- The first infusion should be administered at an **initial rate of 0.3 mL/kg/hr**.[1,4-6] If the infusion is well tolerated, the rate can be increased at **30 min** intervals to a maximum rate at the discretion of the healthcare professional and as tolerated by the patient.[2-5]
- For subsequent infusions a similar **step-wise approach** can be used, as tolerated.[3-5]
- The maximum infusion rate used for PID and CIDP was 4.8 mL/kg/hr (with the exception of the first 3 infusions, where the maximum rate was 2.4 mL/kg/hr).[3,5]
- The maximum infusion rate for ITP was 2.4 mL/kg/hr as only 2 infusions were administered.[6]

In patients at risk for acute renal failure, thromboembolic adverse reactions, IVIg products should be administered at the minimum rate of infusion and dose practicable[1]

Figure 2. Example of infusion rate step-up[5-7]



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

PRIVIGEN monitoring recommendations[1]

- Monitor patient's vital signs, symptoms and general status regularly during and after PRIVIGEN infusion.
- Monitor urine output and serum creatinine

Patient Group	Is observation required during infusion?	Recommended observation time post infusion
Naïve to human Ig, switched from other Ig, long interval since previous Ig infusion	Yes	1 hour
All other patients	Yes	20 minutes

- Hypersensitivity reactions usually related to infusion rate and most likely to occur during the 1st hour of infusion
- **In case of adverse reaction, either reduce the rate of infusion or stop the infusion**
- **In case of shock administer standard medical treatment**

PRIVIGEN storage

- Store below 25°C (Do not freeze)[1]
- Do not shake[1]
- Keep the bottle in the outer carton during storage in order to protect from light[1]
- Shelf life of 36 months (3 years) when stored below 25°C[1-3,8]
- Do not use after the expiry date on the carton and the label[1]
- PRIVIGEN contains no antimicrobial preservative. After piercing rubber seal, use immediately in one patient, on one occasion only. Discard any unused solution (in an appropriate manner)[1]

References: 1. PRIVIGEN Approved Product Information/Data Sheet. Date of preparation: 24 August 2015. 2. Cramer M, et al. Vox Sang 2009; 96:219–225. 3. Berger M. Immunotherapy 2011; 3(2):163-176. 4. Leger J-M, et al. J Peripher Nerv Syst 2013; 18(2):130–140. 5. Stein MR, et al. J Clin Immunol 2009; 29:137–144. 6. Robak T, et al. Hematology 2009; 14(4):227-236. 7.CSL Behring data on file. 8. Therapeutic Goods Administration. Public Summary. Available at https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/ PublicHTML/pdfStore. Accessed August 2015.

Please review full Product Information/Data Sheet before prescribing

Minimum Data Sheet PRIVIGEN® (Human Normal Immunoglobulin [Ig] 10% (100g/100mL)) 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-Barre 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, hyperprolinaemia, hypersensitivity to homologous immunoglobulins — especially where IgA deficiency with anti-IgA antibodies. **Precautions:** 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 monitor during and at least 20 minutes post infusion. Monitor urine output and serum creatinine levels. Avoid use of loop diuretics. 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. Reported cases of hypersensitivity, haemolytic anaemia, aseptic meningitis syndrome, thromboembolism and acute renal failure. **Pregnancy and lactation** immunoglobulin crosses placenta and present in breast milk, no clinical study data, clinical experience 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:** Headache, nausea/vomiting, hypertension, back pain, urticaria/rash, chills, fever, fatigue and asthenia, influenza-like illness. 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. Immunomodulatory therapy: 0.4 to 2g/kg. Refer to full 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. Maximum infusion rate administered in PID trials was 7.2mL/kg/hour. **Patients at risk for acute renal failure, or thromboembolic events use minimum rate of infusion and dose practicable.** Infusion rate slowed, or stopped temporarily if adverse event occurs. Contains no preservative, use immediately after opening, discard unused portion. Do not use if cloudy or contains particulate matter. Do not mix other medicinal products in the same infusion line. Based on PRIVIGEN Approved Product Information/Data Sheet, Date of preparation 24 August 2015.

CSL Behring (NZ) Limited. 666 Great South Rd, Penrose, Auckland, NZ. For customer service enquiries for plasma-derived therapies email: customerservice@cslbehring.com.au, or phone: +61 3 9246 5231. For medical information enquiries for plasma-derived therapies phone: + 61 3 9389 1932. Privigen is a Registered trademark of CSL Behring AG. PVG15-09-0036a . Preparation date: October 2015.

Biotherapies for Life™ CSL Behring