privigen®
Immune Globulin Intravenous
(Human), 10% Liquid

Privigen Infusion Rates

A quick reference guide to dosing and administration

Proven **Ig therapy**
Designed for **stability**

Biotherapies for Life®

CSL Behring

Please see full Important Safety Information inside and full prescribing information for Privigen, including boxed warning, in pocket.

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Proven effective

- In **PI** patients, Privigen delivered sustained, effective protection from infections and favorable tolerability. Annual rate* of serious bacterial infections† was **0.08**; annual rate* of other infections was 3.55. **97%** of adverse reactions were non-serious[1]
- In **CIDP** patients, Privigen provided rapid responses, proven efficacy, and demonstrated tolerability. Overall response rates‡ were **61%** in PRIMA and **73%** in PATH—the **largest ever CIDP study** (n=207). Almost all who responded‡ did so after 1–2 maintenance treatments at Weeks 4 and 7. In both studies, **97%** of adverse reactions were mild or moderate in intensity with 2 and 8 subjects experiencing serious adverse reactions in PRIMA and PATH, respectively§‖
- In the **ITP** clinical trial,¶ **80.7%** of subjects (46 of 57) responded to Privigen with a 150% rise in platelet count within 7 days. Adverse reactions were generally mild or moderate[2]

First and only IVIg designed with proline stabilization

- Privigen is a **ready-to-use** 10% liquid IgG preparation, requiring no reconstitution or refrigeration (for up to 36 months)
- Privigen uses **proline**, a naturally occurring amino acid, as a stabilizer[3]
- **Proprietary 3-step process** used for virus inactivation/removal#
- IgA content ≤25 mcg/mL

*Infections per subject year.
†Serious bacterial infections were defined as pneumonia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.
‡Overall response rate was defined as percentage of subjects who experienced at least a 1-point decrease in adjusted INCAT score.
§In a prospective, open-label, single-arm, multicenter clinical study (Privigen Impact on Mobility and Autonomy [PRIMA]), 28 subjects with CIDP received a Privigen loading dose of 2 g/kg followed by Privigen maintenance doses of 1 g/kg every 3 weeks for up to 21 weeks with 3-week follow-up. In a second prospective, open-label Privigen prerandomization phase of a multicenter clinical study (Polyneuropathy and Treatment with Hizentra [PATH]), 207 IVIg-pretreated subjects with CIDP received a Privigen loading dose of 2 g/kg followed by up to 4 Privigen maintenance doses of 1 g/kg every 3 weeks for up to 13 weeks.
‖Serious adverse reactions included hemolysis (2), exacerbation of CIDP (2), acute rash, diastolic increased blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine. A total of 4 patients discontinued treatment due to serious adverse reactions.
¶Study was performed on 57 subjects with chronic ITP. Each subject had a platelet count of ≤20 x 10^9/L. Dose was 1 g/kg on 2 consecutive days. Primary endpoint was elevation of platelet count to at least 50 x 10^9/L within 7 days of infusion.
#The risk of virus transmission cannot be fully eliminated.

Privigen offers 4 vial sizes, including the largest vial size of IVIg available

- 5 g (50 mL)
- 10 g (100 mL)
- 20 g (200 mL)
- 40 g (400 mL)

Important Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

See full prescribing information for complete boxed warning.

References: 1. Stein MR, Nelson RP, Church JA, et al. Safety and efficacy of Privigen®, a novel 10% liquid immunoglobulin preparation for intravenous use, in patients with primary immunodeficiencies. *J Clin Immunol.* 2009;29(1):137-144. **2.** Robak T, Salama A, Kovaleva L, et al. Efficacy and safety of Privigen®, a novel liquid intravenous immunoglobulin formulation, in adolescent and adult patients with chronic immune thrombocytopenic purpura. *Hematology.* 2009;14(4):227-236. **3.** Bolli R, Woodtli K, Bärtschi M, Höfferer L, Lerch P. L-Proline reduces IgG dimer content and enhances the stability of intravenous immunoglobulin (IVIG) solutions. *Biologicals.* 2010;38(1):150-157.

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Infusion rate calculations in mL (cc) per hour

Infusion Rate		Patient's Weight (kg)											
		10	20	30	40	50	60	70	80	90	100	110	120
		Patient's Weight (lb)											
mL/kg/min	mL/kg/h	22	44	66	88	110	132	154	176	198	220	242	264
0.005	0.3	3	6	9	12	15	18	21	24	27	30	33	36
0.010	0.6	6	12	18	24	30	36	42	48	54	60	66	72
0.015	0.9	9	18	27	36	45	54	63	72	81	90	99	108
0.020	1.2	12	24	36	48	60	72	84	96	108	120	132	144
0.025	1.5	15	30	45	60	75	90	105	120	135	150	165	180
0.030	1.8	18	36	54	72	90	108	126	144	162	180	198	216
0.035	2.1	21	42	63	84	105	126	147	168	189	210	231	252
0.040	2.4	24	48	72	96	120	144	168	192	216	240	264	288
0.045	2.7	27	54	81	108	135	162	189	216	243	270	297	324
0.050	3.0	30	60	90	120	150	180	210	240	270	300	330	360
0.055	3.3	33	66	99	132	165	198	231	264	297	330	363	396
0.060	3.6	36	72	108	144	180	216	252	288	324	360	396	432
0.065	3.9	39	78	117	156	195	234	273	312	351	390	429	468
0.070	4.2	42	84	126	168	210	252	294	336	378	420	462	504
0.075	4.5	45	90	135	180	225	270	315	360	405	450	495	540
0.080	4.8	48	96	144	192	240	288	336	384	432	480	528	576

Recommended dosage and infusion rates

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (as tolerated)
PI	200–800 mg/kg (2–8 mL/kg) every 3–4 weeks	0.5 mg/kg/min (0.005 mL/kg/min)	Increase to 8 mg/kg/min (0.08 mL/kg/min)
ITP	1 g/kg (10 mL/kg) for 2 consecutive days	0.5 mg/kg/min (0.005 mL/kg/min)	Increase to 4 mg/kg/min (0.04 mL/kg/min)
CIDP	*Loading dose*: 2 g/kg (20 mL/kg) in divided doses over 2 to 5 consecutive days *Maintenance dose*: 1 g/kg (10 mL/kg) administered in 1 to 2 infusions on consecutive days, every 3 weeks	0.5 mg/kg/min (0.005 mL/kg/min)	Increase to 8 mg/kg/min (0.08 mL/kg/min)

Monitoring patients during IVIg infusion

Monitor the patient's vital signs throughout the infusion. Slow or stop the infusion if adverse reactions occur. If symptoms subside promptly, the infusion may be resumed at a lower rate that is comfortable for the patient. Titrate based on patient tolerability.

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- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of human immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.**
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Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hyperprolinemia, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine.

Hyperproteinemia, increased serum viscosity, or hyponatremia can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Closely monitor patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimen for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Privigen is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common reactions, observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, increased diastolic blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient's response to live virus vaccines and could lead to misinterpretation of serologic testing. In patients over 65 and those at risk of renal insufficiency, do not exceed recommended dose and infuse at the minimum rate practicable.

Privigen is indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
  - Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response

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For additional details—and to get the guidance and support you need—call the IgIQ resource hotline:

IgIQ®
Your single source for Ig solutions

1-877-355-IGIQ (4447)
Monday–Friday
8 AM to 8 PM ET

For more information, visit
Privigen.com

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