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

Privigen CIDP Resource Guide

Chronic Inflammatory Demyelinating Polyneuropathy

Improves functional **ability**
Featuring proline for Ig **stability**

LARGEST CIDP TRIAL
PATH, 1 of 2 clinical trials,* was the largest ever CIDP study (N=207)

Indication and usage

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.

*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.

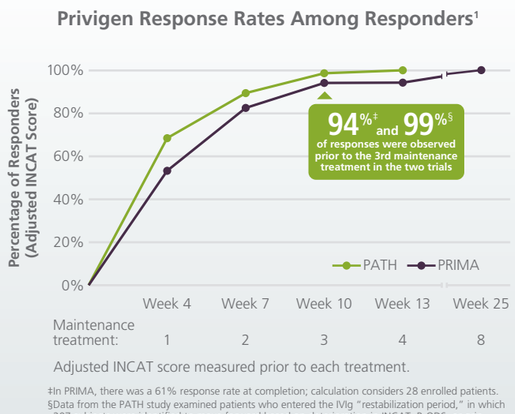
Please see full Important Safety Information on back cover and enclosed full prescribing information for Privigen, including boxed warning.

Biotherapies for Life®
CSL Behring

Improved functional ability

Overall **response rates were 61% and 73%** in PRIMA and PATH,* respectively.†

Almost all who responded† to Privigen did so after 1–2 maintenance treatments at Weeks 4 and 7*



‡In PRIMA, there was a 61% response rate at completion; calculation considers 28 enrolled patients.
§Data from the PATH study examined patients who entered the IVIg "restabilization period," in which 207 subjects were identified to move forward based on deterioration in INCAT, R-ODS, or grip strength. 151 patients were responders.

Demonstrated tolerability

CIDP clinical studies—adverse reaction study results

- 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 these clinical studies, the most common reactions, observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash

12+ Years of US Market Experience¶

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†Overall response rate was defined as percentage of subjects who experienced at least a 1-point decrease in adjusted INCAT score.
‖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.
¶Privigen was approved for use in PI and ITP in 2007, and it was approved to treat CIDP in 2017.

Administration of Privigen for CIDP

Privigen is a ready-to-use 10% liquid intravenous immunoglobulin (IVIg) with **no warming or reconstitution necessary**. It should be given by a separate infusion line and not mixed with other intravenous medications.* See the chart below to find dosing information for your patient.

*Privigen may be diluted with Dextrose Injection, USP (D5W).

Recommended dosing and infusion rates for CIDP†

Loading Dose	Initial Infusion Rate	Maintenance Dose	Maintenance Infusion Rate (if tolerated)
2 g/kg (20 mL/kg) in divided doses over 2 to 5 consecutive days	0.5 mg/kg/min (0.005 mL/kg/min)	1 g/kg (10 mL/kg) administered in 1 to 2 infusions on consecutive days, every 3 weeks	Increase to 8 mg/kg/min (0.08 mL/kg/min)

†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.

For patients at risk of thrombosis, renal dysfunction, or renal failure, administer Privigen at the minimum dose and infusion rate practicable.

Privigen is the first and only IVIg stabilized with proline²

- Enables room-temperature storage
- Reduces IgG aggregation, minimizes fragmentation, and prevents solution discoloration
- Preserves specific antibody function
- Helps reduce the formation of IgG dimers

Privigen is manufactured to maintain high quality and safety

We have developed and refined our proprietary **Integrated Safety System**:

- Advanced plasma collection, manufacturing, and distribution
- Added immunoaffinity chromatography manufacturing step, Ig IsoLo,® which produces an Ig solution with reduced levels of anti-A and anti-B antigens

Important Safety Information continued

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.

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.**

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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.

Please see enclosed full prescribing information for Privigen, including boxed warning.

References: 1. Data on file. Available from CSL Behring as DOF PVG-003. **2.** Bolli R, Woodtli K, Bärtschi M, Höfferer L, Lerch P. L-Proline reduces IgG dimer content and enhances the stability of intraveneous immunoglobulin (IVIG) solutions. *Biologicals*. 2010;38(1):150-157.

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