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.

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

*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.
Improved functional ability

Overall response rates were 61% and 73% in PRIMA and PATH, respectively.1

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

Recommended dosing and infusion rates for CIDP‡

<table>
<thead>
<tr>
<th>Loading Dose</th>
<th>Initial Infusion Rate</th>
<th>Maintenance Dose</th>
<th>Maintenance Infusion Rate (if tolerated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 g/kg (20 mL/kg)</td>
<td>0.5 mg/kg/min</td>
<td>1 g/kg (10 mL/kg) administered in 1 to 2 infusions on consecutive days, every 3 weeks</td>
<td>Increase to 8 mg/kg/min (0.08 mL/kg/min)</td>
</tr>
</tbody>
</table>

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

Recommended dosing and infusion rates for CIDP‡

- 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 IV Ig 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 IsoLot® 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, hyperprolincemia, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IVIG) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG 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.
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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. Hyperprolinemia, 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 occurred in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, chest pain, 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.

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