Berinert®, C1 Esterase Inhibitor (Human) is a plasma-derived concentrate of C1 Esterase Inhibitor (Human), indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adult and adolescent patients. The safety and efficacy of Berinert® for prophylactic therapy have not been established.

Berinert® is contraindicated in individuals who have experienced an anaphylactic or severe systemic reaction to C1 esterase inhibitor preparations.

On-demand means treating patients with Berinert® when an acute abdominal or facial attack occurs. For example, if a patient has 7 abdominal or facial attacks in a year, you treat the patient 7 times.

Important Safety Information

Berinert®, C1 Esterase Inhibitor (Human) is a plasma-derived concentrate of C1 Esterase Inhibitor (Human), indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adult and adolescent patients. The safety and efficacy of Berinert® for prophylactic therapy have not been established.

Berinert® is contraindicated in individuals who have experienced an anaphylactic or severe systemic reaction to C1 esterase inhibitor preparations.

Monitor patients for early signs of allergic or hypersensitivity reactions (including hives, generalized urticaria, chest tightness, wheezing, hypotension, and anaphylaxis). If hypersensitivity is suspected, immediately discontinue administration and initiate appropriate treatment. Epinephrine should be immediately available for treatment of acute severe hypersensitivity reactions.

Thrombotic events have occurred in patients receiving off-label high doses of Berinert®. Monitor patients with known risk factors for thrombotic events.

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

The most serious adverse reaction reported in subjects in clinical studies who received Berinert® is an increase in the severity of pain associated with HAE. The most common adverse reactions observed in more than 4% of subjects after Berinert® treatment were headache, abdominal pain, nausea, muscle spasms, pain, diarrhea, and vomiting.

Berinert® has not been evaluated in pregnant women or nursing mothers; benefits of treatment should be weighed against potential risks in pregnant women, and Berinert® should be given to nursing mothers only if clearly needed.

The safety and efficacy of Berinert® have not been established in children (ages 0 through 12) or in the geriatric population.

Please see Brief Summary of Prescribing Information on following pages.

Finally! On-Demand Treatment for Acute Abdominal or Facial Attacks of HAE* in Adults and Adolescents

*Hereditary angioedema.
Get Started and Prescribe Berinert® Today

Berinert® Expert Network (B.E.N.™) makes it easy for you and your patients, and helps you:

• Get access to Berinert®
• Navigate insurance issues and questions
• Offer valuable CSL Behring Assurance and Assistance Programs to your patients who need them

Berinert®, C1 Esterase Inhibitor (Human) is for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adult and adolescent patients. The safety and efficacy of Berinert® for prophylactic therapy have not been established.

Please see Brief Summary of Prescribing Information on following pages.
Berinert® [C1 Esterase Inhibitor (Human)]

Freeze-dried powder

Before prescribing, please consult full prescribing information, a brief summary of which follows. Some text and references refer to full prescribing information.

1 INDICATIONS AND USAGE

Berinert is a plasma-derived concentrate of C1 esterase Inhibitor (Human) indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adult and adolescent patients.

The safety and efficacy of Berinert for prophylactic therapy have not been established.

2 CONTRAINDICATIONS

Berinert is contraindicated in individuals who have experienced life-threatening hypersensitivity reactions, including anaphylaxis, to C1 esterase inhibitor preparations.

3 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Severe hypersensitivity reactions may occur. Epinephrine should be immediately available for treatment of acute severe hypersensitivity reaction (see Patient Counseling Information [17]). The signs and symptoms of hypersensitivity reactions may include hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and/or anaphylaxis during or after injection of Berinert.

Because hypersensitivity reactions may have symptoms similar to HAE attacks, treatment methods should be carefully considered. In case of suspected hypersensitivity, immediately discontinue administration of Berinert and institute appropriate treatment.

5.2 Thrombotic Events

Thrombotic events have been reported in association with Berinert when used off-label and at higher than labeled doses. Animal studies have confirmed the risk of thrombosis from intravenous administration of C1 esterase inhibitor products (see Overdosage [10] and Animal Toxicology and/or Pharmacology [13.2]).

5.3 Transmission of Infectious Agents

Because Berinert is made from human blood, it may contain infectious agents (eg, viruses and, theoretically, the Creutzfeldt-Jakob disease [CJD] agent) that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by processes demonstrated to inactivate and/or remove certain viruses during manufacturing (see Description [11] and Patient Counseling Information [17]).

Despite these measures, such products may still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products.

Since 1979, a few suspected cases of viral transmission have been reported with the use of Berinert outside the US, including cases of acute hepatitis C. From the incomplete information available from these cases, it was not possible to determine with certainty if the infections were or were not related to prior administration of Berinert.

The physician should discuss the risks and benefits of this product with the patient before prescribing or administering it to the patient. (See Patient Counseling Information [17.1]).

All infections thought by a physician possibly to have been transmitted by Berinert should be reported by lot number, by the physician, or other healthcare provider to the CSL Behring Pharmacovigilance Department at 1-866-915-6958.

6 ADVERSE REACTIONS

The most serious adverse reaction reported in subjects enrolled in clinical studies who received Berinert was an increase in the severity of pain associated with HAE.

The most common adverse reactions that have been reported in greater than 4% of the subjects who received Berinert in clinical studies were abdominal pain, nausea, muscle spasms, pain, diarrhea and vomiting.

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Placebo-controlled Clinical Study

In the placebo-controlled clinical study, referred to as the randomized clinical trial (RCT) (see Clinical Studies [14]), 124 subjects experiencing an acute moderate to severe abdominal or facial HAE attack were treated with Berinert (either a 10 unit per kg body weight or a 20 unit per kg body weight dose), or placebo (physiological saline solution).

The treatment-emergent serious adverse reactions/events that occurred in 5 subjects in the RCT were laryngeal edema, facial attack with laryngeal edema, swelling (shoulder and chest), exacerbation of hereditary angioedema, and laryngospasm.

Table 1: Adverse Reactions recovering up to 4 hours after initial infusion in more than 4% of subjects, irrespective of causality

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Number (% of Subjects Reporting Adverse Reactions</th>
<th>Number (% of Subjects Reporting Adverse Reactions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea‡</td>
<td>3 (7%)</td>
<td>5 (11.9%)</td>
</tr>
<tr>
<td>Diarrhea‡</td>
<td>2 (4.7%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Abdominal Pain‡</td>
<td>2 (4.7%)</td>
<td>3 (7.1%)</td>
</tr>
<tr>
<td>Vomiting‡</td>
<td>1 (2.3%)</td>
<td>3 (7.1%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>0 (0)</td>
<td>4 (9.5%)</td>
</tr>
<tr>
<td>Headache</td>
<td>0 (0)</td>
<td>2 (4.8%)</td>
</tr>
</tbody>
</table>

Table 2: Adverse Reactions occurring in more than 4% of subjects up to 72 hours after infusion of initial or rescue medication by intent-to-treat, irrespective of causality

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Number (% of Subjects Reporting Adverse Reactions</th>
<th>Number (% of Subjects Reporting Adverse Reactions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea‡</td>
<td>3 (7%)</td>
<td>11 (26.2%)</td>
</tr>
<tr>
<td>Headache</td>
<td>3 (7%)</td>
<td>5 (11.9%)</td>
</tr>
<tr>
<td>Abdominal Pain‡</td>
<td>3 (7%)</td>
<td>5 (11.9%)</td>
</tr>
<tr>
<td>Diarrhea‡</td>
<td>2 (4.7%)</td>
<td>1 (2.4%)</td>
</tr>
<tr>
<td>Vomiting‡</td>
<td>1 (2.3%)</td>
<td>7 (16.7%)</td>
</tr>
<tr>
<td>Pain‡</td>
<td>1 (2.3%)</td>
<td>4 (9.5%)</td>
</tr>
<tr>
<td>Muscle spasms‡</td>
<td>1 (2.3%)</td>
<td>4 (9.5%)</td>
</tr>
<tr>
<td>Back pain‡</td>
<td>0 (0)</td>
<td>2 (4.8%)</td>
</tr>
<tr>
<td>Facial pain‡</td>
<td>0 (0)</td>
<td>2 (4.8%)</td>
</tr>
</tbody>
</table>

Table 3: Adverse Events occurring in more than 4% of subjects 7 to 9 days after a Berinert infusion, irrespective of causality

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Number (% of Subjects Reporting Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hereditary angioedema</td>
<td>12 (11.1%)</td>
</tr>
<tr>
<td>Headache</td>
<td>12 (11.1%)</td>
</tr>
<tr>
<td>Abdominal pain‡</td>
<td>7 (6.5%)</td>
</tr>
<tr>
<td>Nausea‡</td>
<td>7 (6.5%)</td>
</tr>
<tr>
<td>Muscle spasms‡</td>
<td>6 (5.6%)</td>
</tr>
<tr>
<td>Pain‡</td>
<td>6 (5.6%)</td>
</tr>
<tr>
<td>Diarrhea‡</td>
<td>5 (4.6%)</td>
</tr>
<tr>
<td>Vomiting‡</td>
<td>5 (4.6%)</td>
</tr>
</tbody>
</table>

Extensive Study

In an interim safety analysis, of the ongoing open-label extension study, 56 subjects with 559 acute moderate to severe abdominal, facial, peripheral and/or laryngeal attacks received a 20 unit/kg body weight dose of Berinert (see Clinical Studies [14]). This study

Includes subjects in the placebo group who received Berinert 20 units/kg as rescue study medication.

‡ These symptoms were identified in the protocol as related to the underlying disease. Any increase in intensity or new occurrence of these symptoms after study medication administration was considered to be an adverse event.

§ Subjects were tested at baseline and after 3 months for possible exposure to Parvovirus B19, hepatitis B, hepatitis C, and HIV-1 and HIV-2. No subject who underwent testing evidenced seroconversion or treatment-emergent positive polymerase chain reaction testing for these pathogens.

Extension Study

In the ongoing open-label extension study, 56 subjects with 559 acute moderate to severe abdominal, facial, peripheral and/or laryngeal attacks received a 20 unit/kg body weight dose of Berinert (see Clinical Studies [14]). This study
provides additional safety data in subjects who received multiple infusions of the product for sequential HAE attacks (one infusion per attack).

Table 4 lists the adverse events that occurred in this interim safety analysis of the ongoing open-label extension study in more than 4% of subjects up to 72 hours or 9 days after the end of a Berinert infusion, irrespective of causality.

Table 4: Incidence of Adverse Events by Descending Frequency Occurring in More Than 4% of Subjects Receiving Berinert up to 72 Hours or 9 Days After Infusion, Irrespective of Causality

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Number (% of Subjects Reporting Adverse Events up to 72 hours (n=56))</th>
<th>Number (% of Subjects Reporting Adverse Events up to 9 Days (n=56))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>3 (5.4%)</td>
<td>4 (7.1%)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>3 (5.4%)</td>
<td>3 (5.4%)</td>
</tr>
<tr>
<td>Hereditary angioedema</td>
<td>2 (3.6%)</td>
<td>4 (7.1%)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2 (3.6%)</td>
<td>3 (5.4%)</td>
</tr>
</tbody>
</table>

6.2 Postmarketing Experience
Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure. Adverse reactions reported in Europe since 1979 in patients receiving Berinert for treatment of HAE include hypersensitivity/anaphylactic reactions, a few suspected cases of viral transmission, including cases of acute hepatitis C, injection-site pain, injection-site redness, chills, and fever.

The following adverse reactions, identified by system organ class, have been attributed to Berinert during post-approval use outside the US:
- Immune System Disorder: Hypersensitivity/anaphylactic reactions, and shock
- General/Body as a Whole: Pain on injection, redness at injection site, chills, and fever

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C. Animal reproduction studies have not been conducted with Berinert. It is not known whether Berinert can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Berinert should be given to a pregnant woman only if clearly needed. In a retrospective case collection study, 20 pregnant women ranging in age from 20 to 35 years received Berinert with repeated doses up to 3,500 units per attack; these women reported no complications during delivery and no harmful effects on their 34 neonates.

8.2 Labor and Delivery
The safety and effectiveness of Berinert administration prior to or during labor and delivery have not been established. Use only if clearly needed.

8.3 Nursing Mothers
It is not known whether Berinert is excreted in human milk. Because many drugs are excreted in human milk, use only if clearly needed when treating a nursing woman.

8.4 Pediatric Use
Safety and efficacy of Berinert in children (ages 0 through 12) have not been established. The clinical studies included an insufficient number of subjects in this age group to determine whether they respond differently from older subjects. The safety and efficacy of Berinert were evaluated in 5 children (ages 3 through 12) and in 8 adolescent subjects (ages 13 through 16) (see Pharmacokinetics (12.3)).

8.5 Geriatric Use
Safety and efficacy of Berinert in the geriatric population have not been established. Clinical studies with Berinert included four subjects older than 65 years. The clinical studies included an insufficient number of subjects in this age group to determine whether they respond differently from younger subjects.

15 REFERENCES

Manufactured by:
CSL Behring GmbH
35041 Marburg, Germany
US License No. 1765
Distributed by:
CSL Behring LLC
Kankakee, IL 60901 USA
Switch to Privigen.

Privigen delivers IVIg therapy that is:

**Simple.**
- Ready-to-use 10% liquid IVIg
- Room temperature storage up to 24 months

**Sophisticated.**
- First and only IVIg stabilized with proline
- Sucrose-free
- IgA ≤ 25 mcg/mL

**Safe.**
- In clinical trials, 97% of related adverse events were non-serious; 95% of 1038 infusions were administered without premedication
- 3-step virus inactivation/removal process, including nanofiltration to 20 nanometers, minimizes the risk of pathogen transmission

For more information about Privigen, visit [www.Privigen.com](http://www.Privigen.com).

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**Important Safety Information**

**Privigen** is indicated for the treatment of patients with primary immunodeficiency (PI) associated with defects in humoral immunity, including but not limited to common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

**WARNING:** Renal dysfunction, acute renal failure, osmotic nephrosis, and death may be associated with the administration of Immune Globulin Intravenous (Human) (IVIg) products in predisposed patients. Administer IVIg products at the minimum infusion rate possible. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIg products containing sucrose. Privigen does not contain sucrose. **Privigen** does not contain sucrose. **Privigen** does not contain sucrose. See full Prescribing Information for complete Boxed Warning.

**Privigen** is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin, in patients with hyperprolinemia, and in patients with selective IgA deficiency.

Privigen is manufactured by CSL Behring AG and distributed by CSL Behring LLC. Privigen is a registered trademark of CSL Behring AG.

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1020 First Avenue, P.O. Box 61501, King of Prussia, PA 19406-0901 USA


In patients at risk for developing renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine. Thrombotic events have been reported with Privigen and other IVIg treatments. Monitor patients with risk factors for thrombotic events, including a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, hypercoagulable disorders, prolonged periods of immobilization, and/or known or suspected hyperviscosity.

Aseptic meningitis syndrome (AMS) has been reported infrequently with Privigen and other IVIg treatments; AMS may occur more frequently with high doses and/or rapid infusion of IVIg. Hemolysis, hemolytic anemia, and pulmonary adverse events have also been reported. There have been reports of noncardiogenic pulmonary edema in patients administered IVIg. If transfusion-related acute lung injury is suspected, test product and patient for antineutrophil antibodies.

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

In clinical studies, the most common adverse reactions with Privigen were headache, pain, nausea, pyrexia/hyperthermia, fatigue, and chills.

Please see brief summary of full Prescribing Information on following pages.
CSL Behring
BRIEF SUMMARY OF PRESCRIBING INFORMATION
Privigen® Immune Globulin Intravenous (Human), 10% Liquid

Before prescribing, please consult full prescribing information, a brief summary of which follows. Some text and references refer to full prescribing information.

WARNING: ACUTE RENAL DYSFUNCTION/Failure

Use of Immune Globulin Intravenous (IGIV) products, particularly those containing sucrose, have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephropathy, and death. Patients at risk of acute renal failure include those with any degree of pre-existing renal insufficiency, diabetes mellitus, advanced age (above 65 years of age), volume depletion, sepsis, paraproteinemia, or receiving known nephrotoxic drugs (see Warnings and Precautions [5.2]). Privigen does not contain sucrose.

For patients at risk of renal dysfunction or failure, administer Privigen at the minimum infusion rate practicable (see Dosage and Administration [2.3], Warnings and Precautions [5.2]).

1 INDICATIONS AND USAGE

Privigen is an Immune Globulin Intravenous (Human), 10% Liquid indicated for the treatment of the following conditions.

1.1 Primary Humoral Immunodeficiency

Privigen is indicated as replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immunodeficiency in common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

1.2 Chronic Immune Thrombocytopenic Purpura

Privigen is indicated for the treatment of patients with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

2 DOSAGE AND STRENGTHS

Privigen is a liquid solution containing 10% IgG (0.1 g/ml) for intravenous infusion.

3 CONTRAINDICATIONS

Privigen is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. Because it contains the stabilizer L-proline, Privigen is contraindicated in patients with hyperprolinemia.

Privigen is contraindicated in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Severe hypersensitivity reactions may occur (see Contraindications [3.1]). In case of hypersensitivity, discontinue the Privigen infusion immediately and institute appropriate treatment. Medications such as epinephrine should be available for immediate treatment of acute hypersensitivity reactions.

Privigen contains trace amounts of IgA (250 mcg/ml) (see Description [1.1]). Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. Privigen is contraindicated in patients with antibodies against IgA and a history of hypersensitivity reaction (see Contraindications [3.4]).

5.2 Renal Failure

Ensure that patients are not volume depleted before administering Privigen. Periodic monitoring of renal function and urine output is critically important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of Privigen. Caution is therefore advised when renal function is impaired. Discontinue Privigen. For patients judged to be at risk of developing renal dysfunction, administer Privigen at the minimum infusion rate practicable (see Boxed Warning, Dosage and Administration [2.3]).

5.3 Hyperproteinemia

Hyperproteinemia, increased serum viscosity, and hyperviscosity may occur in patients receiving Privigen and other IGIV products. It is critical to clinically distinguish true hyperviscotemia from a pseudohyperviscotemia that is associated with or causally related to hyperproteinemia with concomitant decreased calculated serum osmolarity or elevated osmotic gap, because treatment aimed at decreasing serum free water in patients with pseudohyperviscotemia may lead to volume depletion, a further increase in serum viscosity, and a possible predisposition to thrombotic events.

5.4 Thrombotic Events

Thrombotic events may occur following treatment with Privigen and other IGIV products. Thrombotic events include those with a history of atherothrombosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and (or) known suspected hypercoagulability.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting hypertriglyceridemia (markedly high triglycerides), (triglycerides), or monoclonal gamopathies. For patients judged to be at risk of developing thrombotic events, administer Privigen at the minimum rate of infusion practicable (see Dosage and Administration [2.3]). Weigh the potential risks and benefits of IGIV against those of alternative therapies in all patients for whom Privigen therapy is being considered.

5.5 Aseptic Meningitis Syndrome (AMS)

AMS may occur infrequently with Privigen (see Adverse Reactions [4.6, 4.12]) and other IGIV products. Discontinuation of IGIV treatment has resulted in resolution of AMS within several days without sequelae.

AMS usually begins within several hours to 2 days following IGIV treatment.

AMS is characterized by the following signs and symptoms: severe headache, nuchal rigidity, drowsiness, fever, photophobia, painful eye movements, nausea, and vomiting (see Patient Counseling Information [1.2]). Cerebrospinal fluid (CSF) studies are frequently positive with pleocytosis up to several thousand cells per cubic millimeter and increased protein concentration from the granulocytic series, and with elevated protein levels up to several hundred mg/dL. Conduct a thorough neurological examination on patients exhibiting such signs and symptoms, including CSF studies, to rule out other causes of meningitis. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

5.6 Hemolysis

Privigen may contain blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, hemolysis. Hemolytic anemia can develop subsequent to Privigen therapy due to enhanced RBC sequestration and/or intravascular RBC destruction.

Hemolytic anemia has been reported in patients receiving Privigen in the ITP study (see Adverse Reactions [4.6, 4.17]). These cases resolved spontaneously. Six other subjects experienced hemolysis in the ITP study as documented from clinical laboratory data. Multiple serious adverse reaction signs of hemolysis (see Patient Counseling Information [1.7]). If these are present after Privigen infusion, perform appropriate confirmatory laboratory testing. If transfusion is indicated for patients who develop hemolysis, the physician should discuss the risks and benefits of this use with the patient (see Patient Counseling Information [1.7]).

5.8 Volume Overload

The high-dose regimen (1 g/kg/day for 2 days) used to treat patients with chronic ITP is not recommended for individuals with expanded fluid volumes or where fluid volume may be of concern (see Dosage and Administration [2.2]).

6 TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

Noncardiogenic pulmonary edema may occur in patients following IGIV treatment. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Symptoms typically appear within 1 to 6 hours following treatment. Monitor patients for pulmonary adverse reactions (see Patient Counseling Information [1.7]). If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and the patient’s serum.

TRALI may be managed using oxygen therapy with adequate ventilatory support.

6.4 Volume Overload

The high-dose regimen (1 g/kg/day for 2 days) used to treat patients with chronic ITP is not recommended for individuals with expanded fluid volumes or where fluid volume may be of concern (see Dosage and Administration [2.2]).

6.9 Transmammary Infectious Agents

Privigen is made from human plasma. Based on effective donor screening and product manufacturing processes (see Description [1.1]), Privigen carries an extremely remote risk of transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered to be extremely remote. No cases of transmission of viral diseases or CJD have been associated with the use of Privigen. All infections suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare professional to CSL Behring Pharmacovigilance at 1-866-913-4555.

6.10 Monitoring: Laboratory Tests

Periodic monitoring of renal function and urine output is critically important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of Privigen. Caution is therefore advised when renal function is impaired. Discontinue Privigen. For patients judged to be at risk of developing renal dysfunction, administer Privigen at the minimum infusion rate practicable (see Boxed Warning, Dosage and Administration [2.3]).

6.11 Interference With Laboratory Tests

After infusion of IgG, the rise of the variable of the transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (A, B, and D) may cause a positive direct or indirect antihemoglobin (Coombs) test.

6.12 ADVERSE REACTIONS

The most serious adverse reaction observed in clinical study subjects receiving Privigen for PI was hyperviscosity in one subject. The most common adverse reactions observed in >10% of clinical study subjects with Privigen were headache, pain, nausea, fatigue, and chill.

The most severe adverse reactions observed in clinical study subjects receiving Privigen for chronic ITP were aseptic meningitis syndrome in one subject and hemolysis in two subjects. Six other subjects in the ITP study experienced hemolysis as documented from clinical laboratory data (see Warnings and Precautions [5.4, 5.6]). The most common adverse reactions observed in >10% of clinical study subjects with chronic ITP were headache, pyrexia, hypotension, and anemia.

6.13 Clinical Trials Experience

Because different clinical studies are conducted under widely varying conditions, adverse reaction rates observed cannot be directly compared to rates in other clinical studies and may not reflect the rates observed in practice.

Treatment of Primary Humoral Immunodeficiency

In a prospective, open-label, single-arm, multicenter clinical study, 80 patients with (B) (with a diagnosis of XLA or CID) received Privigen intravenously every 3 to 4 weeks for up to 12 months (see Clinical Studies [7.4, 7.5]). All subjects had been on regular IGIV replacement therapy for at least 6 months prior to the study. Subjects ranged in age from 3 to 68; 37.5% were male and 42.5% were female. The safety analysis included all 80 subjects, 16 on a 3-week schedule and 64 on a 4-week schedule. The median doses of Privigen administered intravenously ranged from 200 to 888 mg/kg every 3 weeks (median dose 428.3 mg/kg) or 4 weeks (median dose 440.6 mg/kg). A
total of 1083 infusions of Prigven were administered. In the 4-week schedule and 766 in the 4-week schedule. Of the 1083 infusions, 435 were administrated to females and 626 to males.

Routine predmedication was not allowed. However, subjects who experienced two consecutive infusion-related adverse events (AEs) that were likely to be prevented by predmedication were permitted to receive antipyretics, antihistamines, NSAIDs, or anticholinergic agents. During the study, 8 (10%) subjects received predmedication prior to 34 (9.4%) of the 1083 infusions administrated.

Temporally associated AEs are those occurring during or within 72 hours after the end of an infusion, irrespective of causality. In this study, the upper bound of the 95% confidence interval for the proportion of Prigven infusion-related temporally associated events is 8.3%, whereas more than 5% of AEs were 23.8% (actual proportion: 20.8%). This is below the target of 40% for this safety endpoint. The total number of temporally associated AEs was 397 (a rate of 0.38 AEs per infusion), reflecting that some subjects experienced more than one AE during the observation period.

Table 2 lists the temporally associated AEs that occurred in more than 5% of subjects during a Prigven infusion or within 72 hours after the end of an infusion, irrespective of causality.

### Table 2: Adverse Events Occurring in >5% of Subjects With PI During a Prigven Infusion or Within 72 Hours After the End of an Infusion, Irrespective of Causality

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Subjects (%)</th>
<th>Infusions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>35 (41.8)</td>
<td>82 (7.9)</td>
</tr>
<tr>
<td>Pain</td>
<td>20 (25.0)</td>
<td>44 (4.2)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>13 (16.3)</td>
<td>27 (2.0)</td>
</tr>
<tr>
<td>Nausea</td>
<td>10 (12.5)</td>
<td>19 (1.8)</td>
</tr>
<tr>
<td>Chills</td>
<td>9 (11.3)</td>
<td>15 (1.4)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>7 (8.8)</td>
<td>13 (1.3)</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>6 (7.3)</td>
<td>10 (1.0)</td>
</tr>
<tr>
<td>Cough</td>
<td>5 (6.3)</td>
<td>5 (0.5)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5 (6.3)</td>
<td>5 (0.5)</td>
</tr>
<tr>
<td>Stomach discomfort</td>
<td>5 (6.3)</td>
<td>5 (0.5)</td>
</tr>
</tbody>
</table>

**Infections:**

Of the 397 temporally associated AEs reported for the 80 subjects with PI, the investigators judged 32 to be related to the infection of Prigven (including 5 serious, severe AEs described below). Of the 187 non-serious AEs related to the infection of Prigven, 91 were mild, 61 were moderate, 14 were severe, and 1 was of unknown severity. The most common temporally associated AEs judged by the investigators to be at least possibly related to the infection were headache (29% of subjects), pain (14% of subjects), nausea (11% of subjects), fatigue (11% of subjects), and chills (11% of subjects). Other AEs included musculoskeletal problems (20% experienced 41 serious, severe AEs), with the most frequently reported AEs being hypothermia, chills, fatigue, dizziness, and increased body temperature that occurred in one subject and resulted in the subject’s withdrawal from the study. Two other subjects withdrew from the study due to AEs related to Prigven treatment (chills and headache in one subject, vomiting in the other).

Seventy-seven of the 80 subjects enrolled in this study had a negative direct antigen IgM test (DAT) at baseline. Of these 77 subjects, 36 (46.8%) developed a positive DAT at some time during the study. However, no subjects showed evidence of hemolytic anemia. During this study, no subjects tested positive for infection due to human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), or HBV virus (HBV).

### Treatment of Chronic Immune Thrombocytopenic Purpura

In a prospective, open-label, single-arm, multicenter clinical study, 57 subjects with chronic ITP and a platelet count of 20 x 10^9/L or less received a total of 2 g/kg dose of Prigven administrated as 1 g/kg intravenous infusions daily for 2 consecutive days (see Clinical Studies [4.2.2]). Subjects ranged in age from 15 to 69: 50% of them were female and 40% were male.

Concomitant medications affecting platelets or other treatments for chronic ITP were not allowed. Thirty-two (56.1%) subjects received predmedication with acetaminophen and/or an antihistamine.

### Table 3: Adverse Events Occurring in >5% of Subjects With Chronic ITP During a Prigven Infusion or Within 72 Hours After the End of a Treatment Cycle, Irrespective of Causality

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Subjects (%)</th>
<th>Infusions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>37 (64.9)</td>
<td>41 (36.0)</td>
</tr>
<tr>
<td>Pyrexia/hyperpyrexia</td>
<td>21 (36.8)</td>
<td>22 (19.3)</td>
</tr>
<tr>
<td>Nausea</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Blood unconjugated bilirubin</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Increased</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
</tbody>
</table>

### Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune response to live virus vaccines such as measles, mumps, and rubella. The immunizing physician should be informed of recent therapy with Prigven so that appropriate measures may be taken (see Patient Counseling Information [17]).

### Use in Specific Populations

#### 8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Prigven. It is not known whether Prigven can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Prigven should be given to pregnant women only if clearly needed, immunoglobulins cross the placenta from maternal circulation increasing after 10 weeks of gestation.

#### 8.3 Nursing Mothers

Use of Prigven in nursing mothers has not been evaluated.

### Pediatric Use

Treatment of Primary Hemolytic Immunodeficiency

Prigven was evaluated in 31 pediatric subjects (19 children and 12 adolescents) with PI. There were no apparent differences in the safety and efficacy profiles as compared to those in adult subjects. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels. The safety and effectiveness of Prigven have not been established in pediatric patients with PI who are under the age of 3.

### 8.5 Geriatric Use

Clinical studies of Prigven did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. The use of Prigven in elderly subjects should be at increased risk of developing renal insufficiency (see Boxed Warning, Warnings, and Precautions [5.2]). Do not exceed recommended doses, and administer Prigven at the minimum infusion rate practicable.

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Important Safety Information

Immune Globulin Subcutaneous (Human), Hizentra, is indicated as replacement therapy for patients with primary humoral immunodeficiency (PI). This includes but is not limited to the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin preparations or components of Hizentra, such as polysorbate 80. Because it contains the stabilizer L-proline, Hizentra is contraindicated in patients with hyperprolinemia. Hizentra is also contraindicated in patients with immunoglobulin A deficiency who have known antibody against IgA and a history of hypersensitivity.

All IgA-deficient patients with anti-IgA antibodies are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. If hypersensitivity occurs or anaphylactic reactions are suspected, discontinue administration immediately and treat as medically appropriate.

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

The most common drug-related adverse reactions (observed in 5% or more of subjects in the clinical trial) were local reactions (ie, swelling, redness, heat, pain, and itching at the injection site), headache, vomiting, pain, and fatigue.

Monitor patients for reactions reported to occur with IVIg treatment that might also occur with Hizentra, including renal dysfunction/failure, thrombotic events, aseptic meningitis syndrome (AMS), hemolysis, and transfusion-related acute lung injury (TRALI).

Ig administration can transiently impair the efficacy of live attenuated virus vaccines, such as measles, mumps and rubella. It can also lead to misinterpretation of serologic testing.

No overall differences in safety or efficacy were observed in patients over 65 or in pediatric patients. In the clinical study, desired serum IgG levels were achieved in pediatric patients without pediatric-specific dose requirements.

Please see brief summary of full Prescribing Information on next page.

*Primary immunodeficiency disease.
†Subcutaneous immunoglobulin.
Hizentra is contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity (see Description [11]). Hizentra is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin or to components of Hizentra, such as polysorbate 80. Hizentra is contraindicated in patients with hyperprolinemia because it contains the stabilizer L-proline (see Description [11]). Hizentra is contraindicated in patients with hyperlipidemia (e.g., high cholesterolemia, high triglycerides, or monoclonal gammopathies). For patients judged to be at risk of developing potentially severe hypersensitivity and anaphylactic reactions with administration of Hizentra, Hizentra contains 50 mg/mL IgA (see Description [11]).

5.2 Reactions Reported to Occur With IGIV Treatment
The following reactions have been reported to occur with IGIV treatment and may occur with IGSC treatment.

<table>
<thead>
<tr>
<th>Renal Dysfunction/Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local reactions (i.e., swelling, redness, heat, pain, and itching at the injection site), headache, vomiting, paresthesia, and fatigue.</td>
</tr>
</tbody>
</table>

5.3 Transmissible Infectious Agents
Because Hizentra is made from human plasma, it may carry a risk of transmitting infectious agents (e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease [CJD] agent). The risk of infectious agent transmission has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current virus infections, and including virus inactivation/removal steps in the manufacturing process for Hizentra. Report all infections thought to be possibly transmitted by Hizentra to CSL Behring Pharmacovigilance at 1-866-915-6958.

6 ADVERSE REACTIONS
The most common adverse reactions (ARs), observed in 15% of subjects receiving Hizentra, were local reactions (i.e., swelling, redness, heat, pain, and itching at the injection site), headache, vomiting, paresthesia, and fatigue.

6.1 Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, AR rates observed in clinical studies of a product cannot be directly compared to rates in the clinical studies of another product and may not reflect the rates observed in clinical practice. The safety of Hizentra was evaluated in a clinical study for 15 months in subjects with PI who had been treated previously with IGIV every 3 or 4 weeks. The ITT population consisted of all subjects who received at least one dose of Hizentra. Subjects were treated with Hizentra at weekly doses ranging from 66 to 331 mg/kg body weight during the wash-in/wash-out period and from 72 to 379 mg/kg during the efficacy period. Subjects were treated with Hizentra at weekly doses ranging from 66 to 331 mg/kg body weight during the wash-in/wash-out period and from 72 to 379 mg/kg during the efficacy period. The 49 subjects received a total of 2264 weekly infusions of Hizentra.

6.2 Incidence of Subjects With Adverse Events (AEs)* (Experienced by 4 or More Subjects) and Rate per Infusion, Irrespective of Causality (ITT Population)

Table 2: Incidence of Subjects With Adverse Events (AEs)* (Experienced by 4 or More Subjects) and Rate per Infusion, Irrespective of Causality (ITT Population)

<table>
<thead>
<tr>
<th>AE (4 Subjects)</th>
<th>All AEs*</th>
<th>AEs* Occurring During or Within 72 Hours of Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%) of Subjects (n=49)</td>
<td>Number (Rate¹) of AEs (n=2264 Infusions)</td>
<td>Number (%) of Subjects (n=49)</td>
</tr>
<tr>
<td>Local reactions¹</td>
<td>49 (100)</td>
<td>1340 (0.592)</td>
</tr>
</tbody>
</table>
Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure.

6.2 Postmarketing Experience

The following adverse reactions have been identified and reported during the postmarketing use of IG products:

- **Infection reactions:** Hypersensitivity (e.g., anaphylaxis), headache, tachycardia, fever, fatigue, dizziness, malaise, chills, flushing, urticaria or other skin reactions, wheezing or other chest discomfort, nausea, vomiting, rigors, back pain, myalgia, arthralgia, and changes in blood pressure.
- **Renal:** Acute renal dysfunction/failure, osmotic nephropathy
- **Respiratory:** Apnea, Acute Respiratory Distress Syndrome (ARDS), TRAU, cyanosis, hypoxemia, pulmonary edema, dyspnea, bronchospasm
- **Cardiovascular:** Cardiac arrest, thromboembolism, vascular collapse, hypertension
- **Neurological:** Coma, loss of consciousness, seizures, tremor, aseptic meningitis syndrome
- **Integumentary:** Stevens-Johnson syndrome, epidermolysis, exfoliation, multiforme, dermatitis (e.g., bullous dermatitis)
- **Hematologic:** Panhypothyroidism, leukopenia, hemolysis, positive direct antiglobulin (Coombs') test
- **Gastrointestinal:** Hepatic dysfunction, abdominal pain
- **General/Body as a Whole:** Pyrexia, rigors

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

7 DRUG INTERACTIONS

7.1 Live Virus Vaccines

The passive transfer of antibodies with immunoglobulin administration may interfere with the response to live virus vaccines such as measles, mumps, rubella, and varicella (see Patient Counseling Information [17]).

7.2 Serological Testing

Various passively transferred antibodies in immunoglobulin preparations may lead to misinterpretation of the results of serological testing.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Hizentra. It is not known whether Hizentra can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hizentra should be given to pregnant women only if clearly needed.

8.3 Nursing Mothers

Hizentra has not been evaluated in nursing mothers.

8.4 Pediatric Use

Hizentra was evaluated in 10 pediatric subjects (3 children and 7 adolescents) with PI. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels. Hizentra was not evaluated in neonates or infants.

8.5 Geriatric Use

Of the 49 subjects evaluated in the clinical study of Hizentra, 6 subjects were 65 years of age or older. No overall differences in safety or efficacy were observed between these subjects and younger subjects.

15 REFERENCES


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- CXCL1
- IL31
- CXCL10/IP10
- IL33
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- CXCL2
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- Fractalkine
- MIP-3 alpha/CCL20
- GCSF
- MIP-3/CCCL23
- GH1
- MIP-4/CCL18
- GM-CSF
- MIP-5/CCL15
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- NAP-2/CXCL7
- IFN beta 1b
- Noggin
- IFN gamma
- NR1
- IFNg1
- NT4
- IFGFBP3
- RANTES
- IL1 alpha
- SCF
- IL1 beta
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- IL4
- VEGF

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- IL2
- IL3
- IL4
- IL11
- IL33
- LIX/CXCL5
- MCP2
- Noggin
- SDF-1 beta
- SF20
- TNF alpha
- VEGF

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- SDF-1b/CXCL12

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