When treating primary immunodeficiency disease...

Switch to Privigen.

Privigen delivers IVIg therapy that is:

Simple.
- Ready-to-use 10% liquid IVIg
- Room temperature storage up to 36 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. The most common adverse reactions were headache, pain, nausea, pyrexia/hyperthermia, fatigue, and chills
- 3-step virus inactivation/removal process, including nanofiltration to 20 nanometers, reduces the risk of pathogen transmission

For more information about Privigen, visit www.Privigen.com.

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. 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 IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

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) may occur 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.
Intravenous (Human), 10% Liquid

**1. INDICATIONS AND USAGE**
Privigen is an immune globulin intravenous (IGIV) product, 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/failure, administer Privigen at the minimum infusion rate practicable (see Dosage and Administration [2.3], Warnings and Precautions [5.2]).

**2. CONTRAINDICATIONS**

**3. DOSAGE FORMS AND STRENGTHS**
Privigen is a liquid solution containing 10% IgG (0.1 g/mL) for intravenous infusion.

**4. CONTRAINDICATIONS**

**5. WARNINGS AND PRECAUTIONS**

**5.1 Hypersensitivity**

Hypersensitivity reactions may occur (see Contraindications [4]). 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 (≤0.25 mg/mL) (see Description [11]). Patients with known antibodies to IgA may have a greater risk of developing potentially serious hypersensitivity and anaphylactic reactions. Privigen is contraindicated in patients with antibodies against IgA and a history of hypersensitivity reaction (see Contraindications [4]).

**5.2 Renal Failure**

Ensure that patients are not volume depleted before administering Privigen. Periodic monitoring of renal function and urine output is particularly important in patients judged to be at 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 and at appropriate intervals thereafter. If renal function deteriorates, consider discontinuing 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 hyponatremia may occur in patients receiving Privigen and other IGIV product treatments. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia with concomitant decreased calculated serum osmolality or elevated osmolar gap, because treatment aimed at decreasing serum free water in patients with pseudohyponatremia 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. Patients at risk include those with a history of attherosclerosis, 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 hypercoagulability, including those with cryoglobulins, fasting chylostenolemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients judged to be at risk of developing thrombotic events, administer Privigen at the minimum infusion rate of clinical study (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 Necrosis Syndrome (AMS)**

AMS may occur infrequently with Privigen (see Adverse Reactions [6, 6.1]) and other IGIV product treatments. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.4 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 [17]). Additional clinical and laboratory findings (CSF) studies are frequently associated with pleocytosis up to several thousand cells per cubic millimeter, predominantly from the granulocytic series, and with elevated protein levels up to several hundred mg/dl. Conduct a brain imaging neurological examination to further evaluate such signs and symptoms, including CSF studies, to rule out other causes of meningeal.

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.5,6 Hemolytic anemia can develop subsequent to Privigen therapy due to enhanced RBC sequestration and/or intravascular RBC destruction.7 Hemolytic anemia, possibly intravascular, occurred in two subjects treated with Privigen in the ITP study (see Adverse Reactions [6, 6.1]). These cases resolved uneventfully. Six other subjects experienced hemolysis in the ITP study as documented from clinical laboratory data. Monitor patients for clinical signs and symptoms of hemolysis (see Patient Counseling Information [17]). If these are present after Privigen infusion, perform appropriate confirmatory laboratory testing. If transfusion is indicated for patients who develop hemolysis with clinically compromising anemia after receiving IGIV, perform adequate cross-matching to avoid exacerbating ongoing hemolysis.

**5.7 Transfusion-Related Acute Lung Injury (TRALI)**

Noncardiogenic pulmonary edema may occur in patients following IGIV treatment.8 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. Privigen is indicated for patients for pulmonary adverse reactions (see Patient Counseling Information [17]). If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and the patient’s serum. Should TRALI occur, management may be achieved using oxygen therapy with adequate ventilatory support.

**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]).

**5.9 Transmissible Infectious Agents**

Privigen is made from human plasma. Based on effective donor screening and product manufacturing processes (see Description [11]), Privigen carries a very 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 disease (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 1-866-915-6958. Before prescribing Privigen, the physician should discuss the risks and benefits of its use with the patient (see Patient Counseling Information [17]).

**5.10 Monitoring: Laboratory Tests**

**5.11 Interference With Laboratory Tests**

**6. ADVERSE REACTIONS**

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

**6.1 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

**7. PATIENT COUNSELING INFORMATION**

Privigen is a nonagoner, open-label, single-blind, multicenter clinical study. 80 subjects with PI (with a diagnosis of XLA or CVID) received Privigen intravenously every 3 or 4 weeks for up to 12 months (see Clinical Studies [14, 15]). All subjects had been on regular IVIG replacement therapy for at least 6 months prior to participating in the study. Subjects ranged in age from 3 to 63; 57.5% were male and 42.5% were female. The safety analysis included all 80 subjects, 16 on the 3-week schedule and 64 on the 4-week schedule. The median duration of Privigen infusion was intravenously 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
Table 3: Adverse Events Occurring in >5% Subjects With Chronic ITP.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Subjects (%) [n=57]</th>
<th>Infusions (%) [n=114]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>37 (64.9)</td>
<td>41 (36.0)</td>
</tr>
<tr>
<td>Pyrexia/hyperthermia</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 increased</td>
<td>6 (10.5)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Blood conjugated bilirubin increased</td>
<td>5 (8.8)</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td>Blood total bilirubin increased</td>
<td>4 (7.0)</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>Hematocrit decreased</td>
<td>3 (5.3)</td>
<td>3 (2.6)</td>
</tr>
</tbody>
</table>

Three subjects experienced three serious AEs, one of which (aspetic meningitis) was related to the infusion of Privigen. One subject withdrew from the study due to gingival bleeding, which was not related to Privigen. Eight subjects, all of whom had a positive DAT, experienced transient drug-related hemolytic reactions, which were associated with elevated bilirubin, elevated lactate dehydrogenase, and a decrease in hemoglobin level within two days after the infusion of Privigen. Two of the eight subjects were clinically anemic but did not require clinical intervention. Four other subjects with active bleeding were reported to have developed anemia without evidence of hemolysis. In this study, there was a decrease in hemoglobin after the first Privigen infusion (median decrease of 1.2 g/dL by Day 8) followed by a return to near baseline by Day 29. Fifty-six of the 57 subjects in this study had a negative DAT at baseline. Of these 56 subjects, 12 (21.4%) developed a positive DAT during the 29-day study period.

6.2 Postmarketing Experience

Because postmarketing reporting of adverse events is voluntary and from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to product use. Evaluation and interpretation of these postmarketing reactions is confounded by underlying diagnosis, concomitant medications, pre-existing conditions, and inherent limitations of passive surveillance.

Privigen Postmarketing Experience

Adverse reactions reported during worldwide postmarketing use of Privigen do not differ from what has been observed in clinical studies with Privigen and from what is known for IGIV products.

General

The following mild to moderate reactions may occur with the administration of IGIV products: headache, dizziness, tachycardia, fever, fatigue, dizziness, malaise, chills, flushing, skin rash, wheezing, urticaria, vomiting, rigors, back pain, chest pain, myalgia, arthralgia, and changes in blood pressure. Immediate hypersensitivity and anaphylactic reactions are also a possibility.

The following adverse reactions have been identified and reported during the post-approval use of IGIV products: 17

- Aneur: Acute renal dysfunction/failure, osmotic nephropathy
- Respiratory: Apnea, Acute Respiratory Distress Syndrome (ARDS), TRALI, cyanosis, hypoxemia, pulmonary edema, dyspnea, bronchospasm
- Cardiovascular: Cardiac arrest, thromboembolism, vascular collapse, hypotension
- Neurological: Coma, loss of consciousness, seizures, tremor, aseptic meningitis syndrome
- Integumentary: Stevens-Johnson syndrome, epidermolysis, erythema multiforme, bullous dermatitis
- Hematological: Pancoastopia, leukopenia, hemolytic, positive direct antiglobulin (Coombs) test
- Musculoskeletal: Back pain
- Gastrointestinal: Hepatic dysfunction, abdominal pain
- General/Body as a Whole: Pyrexia, rigors

7. DRUG INTERACTIONS

Passive transfer of antibodies may transiently interfere with the immune response to live virus vaccines such as measles, mumps, and rubella. 18 The immunizing physician should be informed of recent therapy with Privigen so that appropriate measures may be taken (see [Patient Counseling Information (17)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C.

Animal reproduction studies have not been conducted with Privigen. It is not known whether Privigen can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Privigen should be given to pregnant women only if clearly needed. Immunoglobulins cross the placenta from maternal circulation increasingly after 30 weeks of gestation. 14,15

8.3 Nursing Mothers

Use of Privigen in nursing mothers has not been evaluated.

8.4 Pediatric Use

Treatment of Primary Humoral Immuno deficiency

Privigen 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 Privigen have not been established in pediatric patients with PI who are under the age of 3.

Treatment of Chronic Immune Thrombocytopenic Purpura

Safety and effectiveness of Privigen have not been established in pediatric patients with chronic ITP who are under the age of 15. 15

8.5 Geriatric Use

Clinical studies of Privigen did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects.

Use caution when administering Privigen to patients age 65 and over who are judged to be at increased risk of developing renal insufficiency (see Boxed Warning, Warnings and Precautions (5.2)). Do not exceed recommended doses, and administer Privigen at the minimum infusion rate practicable.

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- CD4
- CD8
- CD25
- CD40L
- CD127/IL7R
- Follicular Helper T Cell (Tfh)
- GITR

**TReg**
- GITRL
- IL-17
- IL-23 Receptor
- IL-33
- IFNγ

**T1 Cells**
- IFNγ
- IL-2
- IL-12
- IL-23
- TGFβ

**TLRs**
- TLR1
- TLR2
- TLR4
- TLR5
- TLR6
- TLR7
- TLR8
- TLR9

**Proinflammatory Cytokines**
- IL-1
- IL-12
- IFNγ
- TNFα

**MHC II**
- CD80/86

**Other**
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- CD8 T cell
- TH1
- TH2
- TH17
- T regulatory (Treg)

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- IL-23 Receptor
- IL-33
- INKT
- FOXP3
- FOXP3α2
- GPR83
- ROGR/ROGf (f)

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- IL7, human
- IL9, human
- IL16, human
- IL22, human
- KGF, human
- M-CSF, human
- NRG1/HRG beta 2, human
- SCF, mouse
- SF20/IL25, human
- TNF-alpha, human
- TNF-beta, human
- VEGF121, human
- VEGF165, human
Chair, Department of Microbiology and Immunology

The School of Medicine and Biomedical Sciences at The State University of New York at Buffalo (University at Buffalo; UB), invites nominations and applications for the position of Professor and Chair of the Department of Microbiology and Immunology. The new Chair will be expected to provide the scientific vision and direction to bring the Department to the next level of excellence. Appropriate resources, in the form of new Assistant to Full Professor faculty lines and start-up packages, are available to implement this growth.

DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY: Currently, there are 16 faculty members with interest in bacteriology, virology, parasitology, and immunology, and, most recently, mycology. Current faculty is collegial, committed, and ambitious and active in all aspects of academia, with a total direct cost grant portfolios over $20M. The Department (http://www.smbs.buffalo.edu/microb/Academic_Programs/) is responsible for educating students in both Medical and Dental school and health related professions, and for training of its own graduate and undergraduate students. The Department plays a major role in the Witebsky Center for Microbial Pathogenesis and Immunology, where faculty from several Departments works in contiguous space.

The University at Buffalo is entering the fifth year of implementation of the UB2020 strategic plan, with major strengths in Molecular Recognition in Biological Systems, Bioinformatics, and Health and Wellness across the Lifespan. UB is the SUNY system’s comprehensive campus; the Health Sciences complex includes the Schools of Dental Medicine, Pharmacy, Public Health and Health Professions, and Nursing in addition to Medicine and Biomedical Sciences.

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APPLICATION PROCESS: Applications should be addressed to Dr. M. L. Dubocovich, Chair, Microbiology and Immunology Search Committee, and submitted to www.ubjobs.buffalo.edu (posting # 1000474). Nominations or inquiries may be sent to mdubo@buffalo.edu. Position will be open until filled.

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