When treating primary immunodeficiency disease...

Switch to Privigen.

Privigen delivers IV Ig therapy that is:

**Simple.**
- Ready-to-use 10% liquid IV Ig
- Room temperature storage up to 36 months

**Sophisticated.**
- First and only IV Ig 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.

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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) (IV Ig) products in predisposed patients. Administer IV Ig products at the minimum infusion rate possible. Renal dysfunction and acute renal failure occur more commonly in patients receiving IV Ig 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 IV Ig 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 IV Ig treatments; AMS may occur more frequently with high doses and/or rapid infusion of IV Ig. Hemolysis, hemolytic anemia, and pulmonary adverse events have also been reported. There have been reports of noncardiogenic pulmonary edema in patients administered IV Ig. 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.*
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.1 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]).

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 for 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, congenital 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.

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

- Privigen is contraindicated in patients who have had an anaphylactic or severe systemic reaction to Privigen or another IGIV product.
- 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 Hyperprolinemia

Hyperprolinemia increases serum viscosity, and hyperprolinemia may occur in patients receiving Privigen and other IGIV product treatments. It is critical to clinically distinguish true hyperprolinemia from a pseudohyperprolinemia that is associated with or causally related to hyperproteinaemia with concomitant decreased calculated serum osmolality or elevated osmolar gap, because treatment aimed at decreasing serum free water in patients with pseudohyperprolinemia may lead to volume depletion, a further increase in serum viscosity, and a possiblly predisposition to thrombotic events.2 5.4 Thrombotic Events

Thrombotic events may occur following treatment with Privigen and other IGIV products. Patients at risk for thrombotic events include those with a history of cerebrovascular disease, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and/or known/suspected hyperprocoagulability.

Consider baseline assessment of blood viscosity in patients at risk for hyperprocoagulability, including those with cryoglobulins, fasting chylomicronemia, markedly high triacylglycerols (triglycerides), or monomorphic gammapathies. 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 [6, 6.1]) and other IGIV product treatments. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.1 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]). Periodic fluid (CSF) studies are frequently performed 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 thorough neurological examination for signs such as symptoms, and 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.1,3 Hemolytic anemia can develop subsequent to Privigen therapy due to enhanced RBC sequestration and/or intravascular RBC destruction. Hemolysis, 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 on-going hemolysis.

5.7 Transfusion-Related Acute Lung Injury (TRALI)

Noncardiogenic pulmonary edema may occur in patients following IGIV treatment.3 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.

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 [2.2-2.3]).

5.9 Transmissible Infectious Agents

Privigen is made from human plasma. Based on effective donor screening and processing procedures (see Descriptions [11]), Privigen contains 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 and CJD have been associated with the use of Privigen. All infections suspected by a physician possibly have been transmitted by this product should be reported by the physician or other healthcare professional to CSL Behring Pharmacovigilance at 1-866-915-6558.

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

- Periodic monitoring of renal function and urine output is particularly important in patients judged to be at risk of developing renal dysfunction, assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of Privigen and at appropriate intervals thereafter. Because of the potentially increased risk of thrombosis, consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia, markedly high triacylglycerols (triglycerides), or monoclonal gammapathies.

- If signs and/or symptoms of hemolysis are present after an infusion of Privigen, perform appropriate laboratory testing for confirmation.

- If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and the patient’s serum.

6 ADVERSE REACTIONS

The most serious adverse reaction observed in clinical study subjects receiving Privigen for PI 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. The most serious 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 [5.5, 5.6]). The most common adverse reactions observed in >10% of clinical study subjects with chronic ITP were headache, pyrexia/hyperthermia, and anemia.

6.1 Clinical Trials Experience

Because different clinical studies are conducted under widely varying conditions, 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

Privigen was administered in 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 [14.1]). All subjects had been on regular IGIV 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 doses of Privigen 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 1038 infusions of Privigen were administered, 272 in the 3-week schedule and 766 in the 4-week schedule. Of the 1038 infusions, 435 were administered to females and 603 to males.

Routine premedication was not allowed. However, subjects who experienced two consecutive infusion-related adverse events (AEs) that were likely to be prevented by premedication were permitted to receive antiptyesics, antihistamines, NSAIDs, or antiemetic agents. During the study, 8 (10%) subjects received premedication prior to 51 (4.9%) of the 1038 infusions administered.

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 1-sided 95% confidence interval for the proportion of Privigen infusions temporally associated with one or more AEs was 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 Privigen 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 (43.8)</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 (2.6)</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 (7.5)</td>
<td>10 (0.9)</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>

*Excluding infections.

Of the 397 temporally associated AEs reported for the 80 subjects with PI, the investigators judged 192 to be related to the infusion of Privigen (including 5 serious, severe AEs described below). Of the 187 non-serious AEs related to the infusion of Privigen, 91 were mild, 81 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 infusion were headache (29% of subjects), pain (14% of subjects), nausea (11% of subjects), fatigue (11% of subjects), and chills (11% of subjects). Sixteen subjects (20%) experienced 41 serious AEs. Five of these were related severe AEs (hypersensitivity, 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 Privigen treatment (chills and headache in one subject, vomit in the other) 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 B19 virus (B19V).

9. Treatment of Chronic Immune Thrombocytopenic Purpura

In a prospective, open-label, single-arm, multicenter clinical study, 57 subjects with chronic ITP were enrolled. The investigators judged 150 to be related to the infusion of Privigen (including the one serious AE related to the infusion of Privigen). Three of the 103 non-serious AEs related to the infusion of Privigen, 103 were mild, 37 were moderate, and 9 were severe. The most common temporally associated AEs judged by the investigators to be "at least possibly" related to the infusion were headache (65% of subjects) and pyrexia/hyperthermia (35% of subjects). Three subjects experienced three serious AEs, one of which (aspecific 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 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 exposure. 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 rashes, wheezing or chest tightness, nausea, vomiting, rigor, 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: 13
- Renal: Acute renal dysfunction/failure, osmotic nephropathy
- Respiratory: Aprea, 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, aspecific meningitis syndrome
- Integumentary: Stevens-Johnson syndrome, epidermolysis, erythema multiforme, bullous dermatitis
- Hematologic: Pancytopenia, leukopenia, hemolysis, positive direct antiglobulin (Coombs') test
- 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. 13 The immunizing physician should be informed of recent therapy with Privigen so that appropriate measures may be taken (see Patient Counseling Information [77]).

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 from what has been observed in clinical studies with Privigen and from what is known for IGIV products. 13

8.2 Lactation

It is not known whether Privigen is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue use of Privigen or to discontinue nursing. 13

8.3 Nursing Mothers

Use of Privigen in nursing mothers has not been evaluated.

8.4 Pediatric Use

Treatment of Primary Humoral Immunodeficiency

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.

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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DO YOUR PART
for Vaccine Safety— Report to VAERS.

If one of your patients tells you they became ill after being vaccinated, promptly report it to the Vaccine Adverse Event Reporting System (VAERS), even if you are not sure that the vaccine caused the illness.

As an immunologist, you can help to ensure the safety of vaccines given to patients in the United States by reporting vaccine-related adverse events to VAERS.

- You may report to VAERS online at www.vaers.hhs.gov.
- You may download and complete a VAERS form and mail or fax it to:
  VAERS
  P.O. Box 1100
  Rockville, MD 20849-1100
  fax: (877) 822-7967
- For additional information on VAERS, call (800) 822-7967.

VAERS
Vaccine Adverse Event Reporting System

VAERS is a national vaccine safety surveillance program, co-sponsored by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS is a post-licensure surveillance program that collects information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the U.S.
Tenure/Tenure-Track Position in Viral Disease Immunology
Laboratory of Virology

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Intramural Research (DIR), Laboratory of Virology (LV), part of NIAID’s Rocky Mountain Laboratories (RML) in Hamilton, MT, seeks applicants for a tenure/tenure-track position (associate/assistant professor equivalent) to conduct independent research on viral agents requiring high or maximum containment.

LV conducts high-impact, innovative scientific research on viral agents requiring high or maximum containment, including arenaviruses, bunyaviruses, filoviruses, flaviviruses, and paramyxoviruses, with the goal of developing diagnostics, vaccines, and therapeutics. Research includes studies of vector/reservoir transmission, pathogenesis, pathophysiology, and host immune responses to high containment viral pathogens.

RML’s state-of-the-art facilities include an operational BSL-3 facility, a BSL-4 laboratory, and a BSL-4 animal facility that can accommodate work with both small animal and nonhuman primate models. RML also has core facilities for genomics, electron microscopy, and flow cytometry. Other RML research programs focus on prions, retroviruses, numerous pathogenic prokaryotic organisms, and pathogen transmission by arthropod vectors. RML is located in the scenic Bitterroot Valley of western Montana within easy access to some of the finest outdoor recreational opportunities in North America.

Key Requirements
- Candidates must be able to develop an independent research program in viral disease immunology, supervise staff and fellows, and collaborate with RML/DIR researchers working on other infectious diseases. A preference will be given to candidates with experience in high containment work, as outlined in CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition. An interest in and commitment to animal model studies in a biosafety level (BSL)-4 environment is essential.
- Candidates must hold a Ph.D., D.V.M., or M.D. and have a minimum of three years of relevant postdoctoral experience.
- Applicants must be U.S. citizens, resident aliens, or nonresident aliens with or eligible to obtain a valid employment-authorizing visa.
- Applicants must be able to fulfill, acquire, and maintain a favorable Access National Agency Check and Inquiries (ANACI) background investigation, Select Agent clearance, and other NIH biosecurity requirements.

Independent resources including space, support personnel, and an annual budget for services, supplies, and salaries are committed to the positions. Facilities at existing NIAID field sites in Africa and Asia may be available to the incumbents. This appointment is under Title 42, and the salary is dependent on experience and qualifications.

To apply: E-mail curriculum vitae, bibliography, and a two-to three-page description of your proposed research program to Felicia Braunstein at lvsearch@mail.nih.gov. In addition, three letters of recommendation must be sent directly from the referees to Dr. Kim Hasenkrug, Chair, NIAID Search Committee, c/o Felicia Braunstein at lvsearch@mail.nih.gov or 10 Center Drive, MSC 1356, Building 10, Room 4A30, Bethesda, MD 20892-1356. E-mail is preferred. The selected candidate may be asked for additional references.

Applications will be reviewed starting August 31, 2010, and will be accepted until the position is filled. Please refer to ad #30 on all correspondence. For additional information on this position, contact Dr. Heinz Feldmann at feldmannh@niaid.nih.gov.

Hizentra is contraindicated in IgA-deficient patients with antibodies against IgA and Aseptic Meningitis Syndrome (AMS) to be at risk of developing thrombotic events, administer Hizentra at the minimum rate practicable. High triacylglycerols (triglycerides), or monoclonal gammopathies. For patients judged to be “at least possibly related” to the administration of Hizentra. Because Hizentra is made from human plasma, it may carry a risk of transmitting infectious agents. Because Hizentra contains blood group antibodies that may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin (Coombs’) test result and hemolysis. Delayed hemolytic anemia can develop subsequent to immune globulin therapy due to enhanced RBC sequestration, and acute hemolysis, consistent with intravascular hemolysis, has been reported. Monitor recipients of Hizentra for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and patient’s serum.

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.

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.

6.2 Laboratory tests

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

6.3 Adverse Reactions

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 safety analyses included 49 subjects in the intention-to-treat (ITT) population. The ITT population consisted of all subjects who received at least one dose of Hizentra (see Clinical Studies [14]). 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.

No deaths or serious ARs occurred during the study. Two subjects withdrew from the study due to ARs. One subject experienced a severe injection-site reaction one day after the third weekly infusion, and the other subject experienced moderate myositis. Both reactions were judged to be “at least possibly related” to the administration of Hizentra.

Table 2 summarizes the most frequent adverse events (AEs) (experienced by at least 4 subjects), irrespective of causality. Included are all AEs and those considered temporally related to the administration of Hizentra, such as polysorbate 80. In case of hypersensitivity, discontinue the Hizentra infusion immediately and institute appropriate treatment.

5.1 Hypersensitivity

Severe hypersensitivity reactions may occur to human immune globulin or components of Hizentra, such as polysorbate 80. In case of hypersensitivity, discontinue the Hizentra infusion immediately and institute appropriate treatment.

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.

Renal Dysfunction/Failure

Renal dysfunction/failure, osmotic nephropathy, and death may occur with use of human immune globulin products. Ensure that patients are not volume depleted and assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of Hizentra and at appropriate intervals thereafter.

Periodic monitoring of renal function and urine output is particularly important in patients judged to have a potential increased risk of developing acute renal failure. If renal function deteriorates, consider discontinuing Hizentra. For patients judged to be at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure (such as those with diabetes mellitus or hypovolemia, those who are overweight or use concomitant nephrotoxic medicinal products, or those who are over 65 years of age), administer Hizentra at the minimum rate practicable.

Thrombotic Events

Thrombotic events may occur with use of human immune globulin products. Patients at increased risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, hypercoagulable disorders, prolonged periods of immobilization, and/or known or suspected hypercoagulability. Because of the potentially increased risk of thrombosis, consider baseline assessment of blood viscosity in patients at risk for hypercoagulability, including those with cryoglobulins, fasting chylomicronemia, markedly elevated triglycerides, or monoclonal gammapathies. For patients judged to be at risk of developing thrombotic events, administer Hizentra at the minimum rate practicable.

Aseptic Meningitis Syndrome (AMS)

AMS may occur with use of human immune globulin products. The syndrome usually begins within several hours to 2 days following IGIV treatment. AMS is characterized by signs and symptoms including severe headache, nuchal rigidity, drowsiness, fever, photophobia, painful eye movements, nausea, and vomiting. Cerebrospinal fluid (CSF) studies frequently show pleocytosis up to several thousand cells per cubic millimeter, predominantly from the granulocytic series, with elevated protein levels up to several hundred mg/dL. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

Conduct a thorough neurological examination, including CSF studies, to rule out other causes of meningitis in patients exhibiting signs and symptoms of AMS. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae.

Hemolysis

Hizentra can contain blood group antibodies that may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin (Coombs’) test result and hemolysis. Delayed hemolytic anemia can develop subsequent to immune globulin therapy due to enhanced RBC sequestration, and acute hemolysis, consistent with intravascular hemolysis, has been reported.

Monitor recipients of Hizentra for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and patient’s serum.
Most local reactions were either mild (93.4%) or moderate (6.3%) in intensity.

Table 4: Investigator Assessments* of Injection-Site Reactions by Infusion

The ratio of injections with temporally associated AEs, including local reactions, to all injections was 1338 to 2264 (59.1%; upper 95% confidence limit of 62.4%). Excluding local reactions, the corresponding ratio was 173 to 2264 (7.6%; upper 95% confidence limit of 8.9%).

Table 3 summarizes the most frequent AEs (i.e., those AEs considered by the investigators to be "at least possibly related" to Hizentra administration) experienced by at least 2 subjects.

Table 3: Incidence of Subjects With Adverse Reactions (Experienced by 2 or More Subjects) to Hizentra and Rate per Infusion (ITT Population)

The following adverse reactions have been identified and reported during the postmarketing use of IGIV products:1

1. Infusion reactions: Hypersensitivity (e.g., anaphylaxis), headache, diarrhea, 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.
2. Renal: Acute renal dysfunction/failure, osmotic nephropathy
3. Respiratory: Apnea, Acute Respiratory Distress Syndrome (ARDS), TRALI, syncope, hypoxemia, pulmonary edema, dyspnea, bronchospasm
4. Cardiovascular: Cardiac arrest, thromboembolism, vascular collapse, hypotension
5. Neurological: Coma, loss of consciousness, seizures, tremor, aseptic meningitis syndrome
6. Integumentary: Stevens-Johnson syndrome, epidermolysis, erythema multiforme, dermatitis (e.g., bullous dermatitis)
7. Hematologic: Pancytopenia, leukopenia, hemolyis, positive direct antithrombin (Coombs') test
8. Gastrointestinal: Hepatic dysfunction, abdominal pain
9. 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


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

1. Infusion reactions: Hypersensitivity (e.g., anaphylaxis), headache, diarrhea, 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.
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15 REFERENCES

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**Vivaglobin® Immune Globulin Subcutaneous (Human)**

Manufactured by: CSL Behring GmbH
39014 Marburg, Germany

Distributed by: CSL Behring LLC
Kankakee, IL 60901 USA

**CSL Behring**

**3: only**

Before prescribing, please consult full prescribing information, a brief summary of which follows:

**INDICATIONS AND USAGE**

Vivaglobin® Immune Globulin Subcutaneous (Human) is indicated for the treatment of patients with primary immune deficiency (PID).

**CONTRAINDICATIONS**

As with all immune globulin products, Vivaglobin® Immune Globulin Subcutaneous (Human) is contraindicated in individuals with a history of anaphylactic, or severe systemic reaction to immune globulin preparations and in persons with selective immunoglobulin A (IgA) deficiency (serum IgA < 0.05 g/L) who have known antibodies against IgA.

**WARNINGS**

Patients who receive immune globulin therapy for the first time, who are switched from another brand of immune globulin, or who have not received immune globulin therapy within the preceding eight weeks may be at risk for developing reactions (including fever, chills, nausea, and tingling). On rare occasions, these reactions may lead to death. Such patients should be monitored for these reactions in a clinical setting during the initial administration of Vivaglobin® Immune Globulin Subcutaneous (Human).

If anaphylactic or anaphylactoid reactions are suspected, discontinue administration immediately. Treat any acute anaphylactic reactions as medically appropriate.

Vivaglobin® is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. Because Vivaglobin® is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the CD agent. The risk that such plasma-derived products will transmit an infectious agent has been reduced by plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses during manufacture (see DESCRIPTION section for virus reduction measures). Strengthen procedures utilized at plasma collection centers, plasma-testing laboratories and fractionation facilities are designed to reduce the risk of virus transmission. The primary virus reduction steps of the Vivaglobin® manufacturing process are pasteurization (heat treatment of the aqueous solutio n of 40°C for 10 minutes) and filtration. Additional purification and inactivation procedures used in the manufacture of Vivaglobin® also potentially provide virus reduction. Despite these measures, such products may still potentially contain infectious agents. In general, it is not known if such agents can be completely eliminated in plasma that has been pasteurized to destroy the infectious agents. Only three subjects in the US and Canada study and one subject in the Europe and Brazil study discontinued due to local site reactions.

**REPRODUCTION**

Female patients: Vivaglobin® should be given to a pregnant woman only if clearly needed.

**ADVERSE REACTIONS**

In clinical studies, administration of Vivaglobin® Immune Globulin Subcutaneous (Human), has been shown to be safe and well tolerated in both adult and pediatric subjects. Reactions similar to those reported with administration of other immune globulin products may also occur with Vivaglobin®. Rarely, immune anaphylactic and anaphylactoid reactions may occur. In exceptional cases, sensitization to IgG may result in an anaphylactic reaction (see CONTRAINDICATIONS).

Should evidence of an acute hypersensitivity reaction be observed, the infusion should be stopped promptly, and appropriate treatment and supportive therapy should be administered.

In the US and Canada clinical study, the safety of Vivaglobin® was evaluated in 6 children and 4 adolescents in the US and Canada study and in 16 children and 6 adolescents in the Europe and Brazil study. Table 5 summarizes the most frequent adverse events by subject reported in the clinical study, and Table 6 summarizes the most frequent adverse events by infusion.

**Table 5: Most Frequent Adverse Events by Subject Prevalence of Causality** in the US and Canada Study

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>No. of Subjects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Injection Site Reactions</strong></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>31 (48%)</td>
</tr>
<tr>
<td>Gastrointestinal disorder</td>
<td>23 (37%)</td>
</tr>
<tr>
<td>Fever</td>
<td>16 (25%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>12 (19%)</td>
</tr>
<tr>
<td>Rash</td>
<td>7 (11%)</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>7 (11%)</td>
</tr>
<tr>
<td>Pain</td>
<td>6 (10%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>6 (10%)</td>
</tr>
<tr>
<td>Cough/hoarseness</td>
<td>6 (10%)</td>
</tr>
</tbody>
</table>

**Exclusively Adverse Events**

1 Due to missing subject diary information, values listed are estimates.

**Table 6: Most Frequent Adverse Events by Infusion Prevalence of Causality** in the US and Canada Study

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>No. of Subjects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Injection Site Reactions</strong></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>23 (37%)</td>
</tr>
<tr>
<td>Gastrointestinal disorder</td>
<td>17 (27%)</td>
</tr>
<tr>
<td>Radiating pain</td>
<td>11 (17%)</td>
</tr>
</tbody>
</table>

**Table 7: Most Frequent Related Adverse Events by Subject** in the US and Canada Study

<table>
<thead>
<tr>
<th>Related Adverse Event</th>
<th>No. of Subjects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Injection Site Reactions</strong></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>23 (37%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>7 (11%)</td>
</tr>
<tr>
<td>Rash</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Gastrointestinal disorder</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Skin disorder</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Urine abnormality</td>
<td>2 (3%)</td>
</tr>
</tbody>
</table>

**Table 8: Most Frequent Related Adverse Events by Infusion** in the US and Canada Study

| Related Adverse Event | No. of AEs (Rate %)
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Injection Site Reactions</strong></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>1787 (49%)</td>
</tr>
</tbody>
</table>

*Rate = number of reactions/infusion

In the non-IND Europe and Brazil clinical study, the safety of Immune Globulin Subcutaneous (Human), Vivaglobin® was evaluated for 10 months in adults with PID. The adverse events and rates reported in this study were similar to those reported in the US and Canada study, with two notable exceptions for the related adverse events. These events were 59 episodes of headache (11.6%) and 2 episodes of fever (0.4%) in the US and Canada study and no episodes of headache and 18 episodes of fever (0.8%) in the Europe and Brazil study.

Local (Injection Site) Reactions: Local injection site reactions consisting of mostly mild or moderate swelling, redness and itching, have been observed with the use of Vivaglobin®. No serious local site reactions were observed. The majority of injection site reactions resolved within four days. Additionally, the number of subjects reporting local injection site reactions decreased substantially after repeated use (see Figure 1). Only three subjects in the US and Canada study and one subject in the Europe and Brazil study discontinued due to local site reactions.

**Figure 1: Subjects Reporting Local Site Reactions by Infusion**

After administration, discard any unused solution and administration equipment in accordance with biohazard procedures.

**HOW SUPPLIED**

Vivaglobin® Immune Globulin Subcutaneous (Human), is supplied in single-use vials containing 100 mg IgG per mL. The following dosage forms are available:

<table>
<thead>
<tr>
<th>NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0053-796-01</td>
<td>3 mL, vial</td>
</tr>
<tr>
<td>0053-796-05</td>
<td>10 mL, vial</td>
</tr>
<tr>
<td>0053-796-10</td>
<td>10 mL, vial</td>
</tr>
<tr>
<td>0053-796-20</td>
<td>20 mL, vial</td>
</tr>
<tr>
<td>0053-796-25</td>
<td>20 mL, vial</td>
</tr>
</tbody>
</table>

**STORAGE**

Store at 2°C - 8°C (36°F - 46°F). Vivaglobin® Immune Globulin Subcutaneous (Human), is stable for the period indicated by the expiration date on its label. Do not freeze. Keep vials in storage box until use.

Based on April 2009 revision.

Table 7 summarizes the most frequent related adverse events by subject reported in the clinical study, and Table 8 summarizes the most frequent related adverse events by infusion.
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N. CHINA TOLL FREE: 10.800.711.0752
S. CHINA TOLL FREE: 10.800.110.0694
FAX: 831.457.3801
E-MAIL: asia@scbt.com

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The American Association of Immunologists
Produced in barley, these proteins are animal, bacterial, and viral free, and are ultra pure, with extremely low endotoxin.

Cell Sciences offers innovative, unique growth factors and hard-to-produce recombinant proteins, bypassing the use of bacterial or animal cell systems. These ultra pure proteins contain no contamination from other growth factors and negligible amounts of endotoxin.

Background: barley endosperm
The host organism, barley, with its specialized endosperm storage tissue, provides many unique features including proficient protein machinery, with eukaryotic folding, and a distinct route for long-term protein protection and storage. A biochemically inert environment, void of endotoxins, low protease activity and secondary metabolite content, and a simple protein profile, aid in downstream processing. Barley has also a G.R.A.S. (generally recognized as safe) status from the FDA.

Cell Sciences ultra pure growth factors and cytokines are produced for use in basic and applied medical scientific research, cell culture media and diagnostics.

- serum free
- animal, bacterial & viral free
- extremely low endotoxin (<0.005 ng/µg)
- highly biologically active
- easier regulatory clearance
- perfect for cell culture, drug development, stem cell research, animal research
- for use in all in vitro cellular studies
- for use in all in vivo animal studies

Ultra pure cytokines & growth factors
- FGF1, human
- FGF2, human
- FLT3 ligand, human
- GCSF, human
- IFNA2, human
- IFN gamma, human
- IGF1, human
- IL1-alpha, human
- IL2, human
- IL3, human
- IL4, human
- IL5, human
- IL6, human
- 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
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Program details at www.aai.org/GRIP_rd.htm

FACULTY POSITION
THE CENTER FOR COMPARATIVE MEDICINE
Schools of Medicine and Veterinary Medicine
University of California, Davis

Candidates are sought for a tenure-track position at the level of ASSISTANT or ASSOCIATE PROFESSOR/ASSISTANT or ASSOCIATE PROFESSOR IN RESIDENCE in the Center for Comparative Medicine, a research center at the University of California, Davis, co-sponsored by the Schools of Medicine and Veterinary Medicine and a relevant Instructional and Research (I&R) academic department. The center is engaged in investigative research involving animal models of human disease. We seek individuals with D.V.M and/or Ph.D. degrees or equivalent, postdoctoral experience and a record of publication in high-quality journals. We are soliciting applications from candidates who have enthusiasm for the investigation of human infectious diseases in animal models and the concepts of “One Health”. Candidates are expected to have or to establish and maintain a strong extramurally funded research program and to participate in professional and graduate education in their fields. Ample office and laboratory space is available in the Center (including access to BSL2 and BSL3 laboratory space), with state-of-the-art facilities, instrumentation, and administrative support. Center research and teaching programs interdigitate with other campus-wide programs and resources in the Schools of Medicine and Veterinary Medicine, the Mouse Biology Program, the California National Primate Research Center, and the Cancer Center. Faculty members will hold an academic appointment in the commensurate department of the School of Veterinary Medicine. The position will provide 0.5 salary support. Review of applications will commence immediately until the position is filled. Priority will be given to applications received by October 1, 2010. Submit applications with letter of interest, curriculum vita, concise statement of present and future research plans, summary of teaching experience, up to three representative reprints, and names of four references (including addresses, telephone numbers and e-mail addresses) to: Recruitment Committee Chair, c/o Center for Comparative Medicine, University of California, Davis, CA 95616. The University of California is an Equal Opportunity/Affirmative Action Employer.
The University of Louisville School of Medicine invites nominations and applications for the position of Professor and Chair of the Department of Microbiology and Immunology. The Department has 20 faculty with primary appointments and 20 faculty with joint or associate appointments. The faculty currently focus on the study of the cellular and molecular regulation of innate (inflammation) and adaptive immune responses and on bacterial and viral infections. The Center for Predictive Medicine and Emerging Infectious Diseases has been established in recently constructed facilities that support both in vitro and in vivo studies of Biohazard Level 3 organisms. In response to the Challenge for Excellence, the faculty maintain active involvement in the Center for Predictive Medicine, the Institute for Cellular Therapeutics, the James Graham Brown Cancer Center and the Center for Genetics and Molecular Medicine. The selected candidate will be expected to continue to foster and expand interdisciplinary collaborations in the focus areas of host defense, cancer, transplantation, cardiovascular disease, visual sciences, neurosciences and molecular medicine. The Department has an outstanding graduate program and provides excellent instruction to medical, dental, and graduate students. Further information on the Department and its faculty is available at www.louisville.edu/medschool/microbiology

The University of Louisville and its School of Medicine are engaged in a vigorous effort to advance research excellence and productivity. Areas of research that have been targeted for investment include oncology, genetics and molecular medicine, environmental and public health, neuroscience, and cardiovascular disease. Candidates with research programs and a vision for collaborative research activities in these areas are particularly encouraged to apply. The School of Medicine is committed to providing the financial resources necessary to attract a chair with an outstanding record of achievement and leadership.

Requirements for the position include a doctorate (or equivalent degree) in microbiology, immunology or related discipline and an outstanding academic record necessary for appointment as professor with tenure. The candidate selected will demonstrate outstanding skills in leadership and administration and will transfer a vigorous and focused research program using state-of-the-art approaches with continuous federal grant support. The selected candidate will articulate a vision for the promotion of Departmental excellence in research and teaching.

Applicants must apply online at www.louisville.edu/jobs for position # 25559 by attaching a current curriculum vitae documenting research, education and administrative experience. Applicants should also submit a cover letter describing a vision for promotion of Departmental excellence in clinical service, research and teaching, along with the names and contact information of four references, by e-mail to Ms. Carmel Mackin at carmel.mackin@louisville.edu.

Review of applications will begin August 1, 2010 and will continue until the position is filled.

The University of Louisville is an Affirmative Action, Equal Opportunity, Americans with Disabilities Employer, committed to diversity, and in that spirit, seeks applications from a broad variety of candidates.