Get back to **Living** your life. Guarded by **Privigen**.

For people with primary immunodeficiency (PI)

**Your Guide to**

**PI Treatment With Privigen**

Please see full Important Safety Information on pages 12–13 and full prescribing information for Privigen, including boxed warning, in pocket.
A proven treatment for people with PI

Welcome to treatment with Privigen!

Privigen is an intravenous immunoglobulin treatment (IVIg) for people who have PI. Privigen has protected many against infections that would have interfered with their daily living. **Privigen is the #1 IVIg used in US hospitals since 2010.**

This booklet contains information to help you make the most of your Privigen treatment. Here, you’ll learn what you can expect with Privigen therapy. You’ll also find background information on PI to help you understand what you may be going through and how Privigen can help.

Read on! Learning about PI and this important treatment option is a big first step toward taking control of the disease.

Important Safety Information

**WARNINGS:**

- Thrombosis (blood clotting) can occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, a history of blood clotting or hyperviscosity (thick blood), use of estrogens, installed vascular catheters, and cardiovascular risk factors.
- In predisposed patients, kidney malfunction and acute kidney failure, potentially fatal, can occur with the administration of human immune globulin intravenous (IGIV) products. Kidney problems occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.
- If you are at high risk of thrombosis or kidney problems, your doctor will prescribe and administer Privigen at the minimum dose and infusion rate practicable, and will monitor you for signs and symptoms of thrombosis and viscosity, as well as kidney function. Always drink sufficient fluids before administration.

What is PI?

Primary immunodeficiency (PI) is a disorder of the immune system. Your immune system works to keep you healthy by fighting off germs.

In PI, the immune system does not work correctly, and so infections are common; they may come back often or not go away—even when antibiotics are taken. People who have PI may have frequent ear infections and colds that are severe, long lasting, and hard to cure.

The following are common symptoms of PI. If you or a loved one has 2 or more of them, PI may be the cause.

- 4 or more new ear infections within 1 year
- 2 or more serious sinus infections within 1 year
- 2 or more months on antibiotics with little effect
- 2 or more cases of pneumonia within 1 year
- Failure of an infant to gain weight or grow normally
- Recurrent, deep skin or organ abscesses
- Persistent thrush (yeast infection) in mouth or fungal infection on skin
- Need for intravenous antibiotics to clear infections
- 2 or more deep-seated infections, including septicemia (blood poisoning)
- A family history of PI
Privigen provides clinically proven protection against infections

For more than 12 years, Privigen has been helping people overcome the effects of PI

Privigen was evaluated in 2 clinical trials: a 1-year study plus an extension that lasted 2½ years.

While taking Privigen, study participants averaged less than one acute serious bacterial infection per year, such as pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.

In 1-year study

<table>
<thead>
<tr>
<th>Infections/Year</th>
<th>Acute Serious Bacterial Infections/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.55</td>
<td>0.08</td>
</tr>
</tbody>
</table>

In 2½-year study

<table>
<thead>
<tr>
<th>Infections/Year</th>
<th>Acute Serious Bacterial Infections/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.60</td>
<td>0.02</td>
</tr>
</tbody>
</table>

What is Privigen?

Privigen is an IVIg therapy that contains antibodies—essential proteins in your immune system that identify and destroy bacteria and viruses that cause disease. The primary antibody found in Privigen, immunoglobulin G, is the main type of antibody made by your immune system.

- Your doctor may refer to your Privigen treatment as “Ig,” “intravenous Ig,” or “IVIg”

By raising levels of IgG, Privigen helps boost your immune system to prevent serious and recurring infections and other complications.

You can feel well while taking Privigen. In the clinical studies, participants recorded how they felt every day. On average, the participants reported feeling “well.”

Important Safety Information

Treatment with Privigen might not be possible if your doctor determines you have hyperprolinemia (too much proline in the blood) or are IgA-deficient with antibodies to IgA and a history of hypersensitivity. Tell your doctor if you have previously had a severe allergic reaction (including anaphylaxis) to the administration of human immune globulin. Inform your physician if you notice early signs of hypersensitivity reactions to administration of Privigen, including hives, tightness of the chest, wheezing, or shock.

Please see full Important Safety Information on pages 12–13 and full prescribing information for Privigen, including boxed warning, in pocket.
Studies showed
tolerability with Privigen

In the Privigen clinical studies, most side effects occurred with the first infusion. Side effects became less common as infusions continued.

Most of the side effects with Privigen were not serious: 97% in the 1-year study and 96% in the 2½-year study. And most side effects were of mild or moderate intensity.

Most common* Privigen side effects
- Headache
- Fatigue
- Nausea
- Fever
- Chills
- Vomiting
- Back pain

Serious side effects in the 1-year study all occurred in one subject, one of three who withdrew from the study due to adverse reactions. In the long-term study, one subject withdrew because of a mild case of hives.

These are not the only side effects possible; see the full prescribing information, including boxed warning, for a complete list of adverse reactions possible with treatment for each condition.

Call your doctor if you experience any side effects, or if you have any other questions or concerns.

*Occurring in more than 5% of people in the clinical trials.

Think about PI treatment only once a month!

Privigen is administered once every 3 or 4 weeks. The average infusion for PI takes about 2 hours.

A trained nurse administers your Privigen treatment

Privigen is given through a needle into a vein. You can receive Privigen at the hospital, in an infusion clinic, at the doctor’s office, or in your own home.

WARNING: Blood clotting, kidney malfunction, and acute kidney failure, potentially fatal, can occur with immune globulin products, including Privigen. If you are at high risk for these conditions, your doctor will administer Privigen at the minimum dose and infusion rate practicable, and will monitor you for signs and symptoms. Always drink sufficient fluids before administration. See your doctor for a full explanation of complete boxed warning in prescribing information and see complete Important Safety Information included in this brochure.

Important Safety Information

Immediately report to your physician the following symptoms, which could be signs of serious adverse reactions to Privigen:
- A decrease in urine output, sudden weight gain, fluid retention, and/or shortness of breath following infusion (possible symptoms of kidney problems)
- Pain and/or swelling or discoloration of an arm or leg, shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, and numbness or weakness on one side of the body (possible symptoms of a blood clot)
- Headache; a stiff neck; excessive drowsiness or fatigue; fever; sensitivity to light or painful eye movements; nausea; increased heart rate; yellowing of the skin or eyes, and/or dark-colored urine (possible symptoms of other conditions that may require treatment)
Virus Inactivation
pH 4 incubation

Virus Reduction
Depth filtration

Virus Removal
Virus filtration

**Innovative manufacturing steps help make Privigen safe**

**Heritage of safety and excellence**

CSL Behring, the maker of Privigen, has a 65-year track record of safety and excellence in therapies derived from plasma (part of the blood). Our quality controls are among the most rigorous in the business, and our products meet exacting standards.

The process used to make Privigen includes a 3-step virus inactivation/removal process. The risk of transmission of infectious agents, including viruses, cannot be completely eliminated.

**Ig IsoLo® for added safety**

Privigen goes through an additional filtration process, called Ig IsoLo®. This step removes other antibodies that may cause serious side effects in some people.

**Important Safety Information**

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

Before receiving any vaccine, tell the immunizing physician if you have had recent therapy with Privigen, as the effectiveness of the vaccine could be compromised.

Privigen may be considered for people who have diabetes, latex allergies, or sensitivity to preservatives.

The way Privigen is made helps it to be safe for people who have special needs. Privigen is the first and only IVIg therapy that is made stable with proline.

**What is proline?**

Proline is a natural amino acid that is made in your body. Amino acids are the building blocks of proteins. Certain foods found in a normal diet also contain proline, such as meat, dairy products, and eggs.

After extensive study, proline was carefully chosen to be the stabilizer in Privigen. As a result, Privigen can be stored at room temperature and is always ready to use right off the shelf.

Treatment with Privigen might not be possible if your doctor determines that you have hyperprolinemia (too much proline in the blood).

**Important Safety Information**

In clinical trials of Privigen, headache was the most common side effect seen in all conditions treated (PI, ITP, and CIDP). Other common side effects that can be seen with treatment include fatigue, nausea, fever, and high blood pressure. These are not the only side effects possible; see the full prescribing information for a complete list of adverse reactions possible with treatment for each condition. Alert your physician to any side effect that bothers you or does not go away.
IgIQ provides complete support in one place

CSL Behring is committed to making sure you have the best experience possible with Privigen. That’s why CSL Behring offers a comprehensive set of services to help make Ig therapy accessible and affordable.

IgIQ provides several resources to help you.

- **Protection if you lose your insurance**—CSL Behring is the only IV Ig manufacturer to offer a loyalty program. CSL Behring AssuranceSM can allow you to continue receiving Privigen even if you have a lapse in your insurance coverage.
- **Financial Assistance**—The Patient Assistance Program helps provide therapy to qualified people who are uninsured, underinsured, or unable to afford their prescription.
- **Referral Triage**—IgIQ can also coordinate patient referral to specialty pharmacies.
- **Patient Support**—Trained nurses are available by phone to answer your questions and provide helpful resources as well as product information*.

*IgIQ personnel are not medical experts; medical questions should be directed to your doctor (or other healthcare professional) or your specialty pharmacy.

Where can I go for more information about PI?

As someone living with PI, you may feel you need additional support and information. You can visit the organizations below to learn more about your condition and how to manage it.

- Immune Deficiency Foundation
- The Jeffery Modell Foundation
- American Autoimmune Related Diseases Association
- International Patient Organisation for Primary Immunodeficiencies

Your single source for Ig solutions

Call 1-877-355-IGIQ (4447)
Monday–Friday, 8 AM to 8 PM ET

Please see full Important Safety Information on pages 12–13 and full prescribing information for Privigen, including boxed warning, in pocket.
Important Safety Information

Privigen is approved to:

- Treat types of primary immunodeficiency (PI).
- Treat chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. Talk with your doctor about the length of your therapy.
- Raise platelet counts in patients over 15 with chronic immune thrombocytopenic purpura (ITP).

WARNINGS:

- Thrombosis (blood clotting) can occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, a history of blood clotting or hyperviscosity (thick blood), use of estrogens, installed vascular catheters, and cardiovascular risk factors.
- In predisposed patients, kidney malfunction and acute kidney failure, potentially fatal, can occur with the administration of human immune globulin intravenous (IGIV) products. Kidney problems occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.
- If you are at high risk of thrombosis or kidney problems, your doctor will prescribe and administer Privigen at the minimum dose and infusion rate practicable, and will monitor you for signs and symptoms of thrombosis and viscosity, as well as kidney function. Always drink sufficient fluids before administration.

See your doctor for a full explanation, and the full prescribing information for complete boxed warning.

Treatment with Privigen might not be possible if your doctor determines you have hyperprolinemia (too much proline in the blood) or are IgA-deficient with antibodies to IgA and a history of hypersensitivity. Tell your doctor if you have previously had a severe allergic reaction (including anaphylaxis) to the administration of human immune globulin. Inform your physician if you notice early signs of hypersensitivity reactions to administration of Privigen, including hives, tightness of the chest, wheezing, or shock.

Immediately report to your physician the following symptoms, which could be signs of serious adverse reactions to Privigen:

- A decrease in urine output, sudden weight gain, fluid retention, and/or shortness of breath following infusion (possible symptoms of kidney problems)
- Pain and/or swelling or discoloration of an arm or leg, shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, and numbness or weakness on one side of the body (possible symptoms of a blood clot)
- Headache; a stiff neck; excessive drowsiness or fatigue; fever; sensitivity to light or painful eye movements; nausea; increased heart rate; yellowing of the skin or eyes, and/or dark-colored urine (possible symptoms of other conditions that may require treatment)

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

Before receiving any vaccine, tell the immunizing physician if you have had recent therapy with Privigen, as the effectiveness of the vaccine could be compromised.

In clinical trials of Privigen, headache was the most common side effect seen in all conditions treated (PI, ITP, and CIDP). Other common side effects that can be seen with treatment include fatigue, nausea, fever, and high blood pressure. These are not the only side effects possible; see the full prescribing information for a complete list of adverse reactions possible with treatment for each condition. Alert your physician to any side effect that bothers you or does not go away.

Please see accompanying full prescribing information for PRIVIGEN.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You can also report side effects to CSL Behring’s Pharmacovigilance Department at 1-866-915-6958.
Get back to **Living** your life.

Guarded by **Privigen**.

**Proven protection** for people with PI

Privigen is an intravenous immune globulin (IVIg) used to treat adults who have primary immunodeficiency (PI).

- Clinically proven to protect against infections
- Administered once a month by a nurse
- Manufactured for quality and safety
- Treatment protection if you lose your insurance—and more through IgIQ®

Learn more at Privigen.com.

**WARNING:** Blood clotting, kidney malfunction, and acute kidney failure, potentially fatal, can occur with immune globulin products, including Privigen. If you are at high risk for these conditions, your doctor will administer Privigen at the minimum dose and infusion rate practicable, and will monitor you for signs and symptoms. Always drink sufficient fluids before administration. See your doctor for a full explanation of complete boxed warning in prescribing information and see complete Important Safety Information included in this brochure.

Privigen is manufactured by CSL Behring AG and distributed by CSL Behring LLC. Privigen® is a registered trademark of CSL Behring AG. Biotherapies for Life®, IgIQ®, and Ig IsoLo® are registered trademarks of CSL Behring LLC. CSL Behring Assurance™ is a service mark of CSL Behring LLC.

©2020 CSL Behring LLC
1020 First Avenue, PO Box 61501, King of Prussia, PA 19406-0901 USA
www.CSLBehring.com www.Privigen.com
PVG-0255-MAR20

Please see full Important Safety Information on pages 12–13 and full prescribing information for Privigen, including boxed warning, in pocket.