



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



For people with primary immunodeficiency (PI)

Your Guide to **PI Treatment With Privigen**

ITP = chronic immune thrombocytopenic purpura and CIDP= chronic inflammatory demyelinating polyneuropathy.

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

Biotherapies for Life®

CSL Behring

A proven treatment for people with PI



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 has been delivering proven protection to people since 2007.**

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.

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.

According to the Jeffrey Modell Foundation,* the following are common symptoms of PI. If you or a loved one has 2 or more of them, PI may be the cause.

*These warning signs were developed by the Jeffrey Modell Foundation Medical Advisory Board. Consultation with Primary Immunodeficiency experts is strongly suggested. ©2016 Jeffrey Modell Foundation.

- Four or more new ear infections within 1 year
- Two or more serious sinus infections within 1 year
- Two or more months on antibiotics with little effect
- Two or more pneumonias within 1 year
- Failure of an infant to gain weight or grow normally
- Recurrent, deep skin or organ abscesses
- Persistent thrush in mouth or fungal infection on skin
- Need for intravenous antibiotics to clear infections
- Two or more deep-seated infections including septicemia
- A family history of PI

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.

Privigen provides clinically proven protection against infections



For more than 14 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, defined as pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.

In 1-year study (per patient per year)

3.55	0.08
infections	acute serious bacterial infections

In 2½-year study (per patient per year)

1.60	0.02
infections	acute serious bacterial infections

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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 strengthen your immune system to prevent serious and recurring infections and other complications. The exact way that Privigen works is not completely understood.

On average, the participants reported feeling "well." In the clinical studies, participants recorded how they felt every day.*

*Based on personal assessment, patients' overall feeling of well-being score was classified as "well" on a five-point scale (1 = very well, 2 = well, 3 = fair, 4 = poor, 5 = very poor), with a mean of 2.1 ± 0.8 standard deviation.

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.

Studies showed tolerability of Privigen

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
- High blood pressure



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)

Innovative manufacturing steps help make Privigen safe

History 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 (the liquid 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.



pH 4 incubation



Depth filtration



Virus filtration

Ig IsoLo®—additional manufacturing process to help reinforce Privigen quality

Privigen goes through an additional filtration process called immunoaffinity chromatography (IAC).

IAC removes specific antibodies (anti-A and anti-B) that could otherwise lead to isoagglutination (or clumping), which may be harmful to some people. IAC binds these antibodies and removes them, while still retaining therapeutic IgG antibodies.

With IAC, Privigen is among IVIg with reduced isoagglutinin levels.

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.

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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 many people's diets also contain proline, such as meat, dairy products, and eggs.

Privigen is the first and only IVIg therapy that is made stable with proline. 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 ready to use right off the shelf.

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

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

Talk to your doctor to see if Privigen is an appropriate IVIg treatment for you.



Sugar-free



Only trace amounts of sodium



Latex- and preservative-free

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.

Privigen ConnectSM provides complete support in one place

CSL Behring is committed to helping you achieve 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.

Privigen Connect provides several resources to help you.



Assurance

CSL Behring is the only IVIg manufacturer to offer a loyalty program. This program can allow you to continue receiving Privigen even if you have a lapse in your insurance coverage.*



Patient Assistance Program

Helps provide therapy to qualified people who are uninsured or underinsured

*Enrollment required. Subject to terms and conditions. For the Assurance program, visit cslbehringassurance.com.



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

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 Jeffrey Modell Foundation
- American Autoimmune Related Diseases Association
- International Patient Organisation for Primary Immunodeficiencies



Important Safety Information

Privigen is approved to:

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

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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 Privigen ConnectSM

Learn more at Privigen.com.

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