Your guide to Treatment With Privigen

For people with primary immunodeficiency (PI)

Proven protection
Designed for stability

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

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

A proven IVIg treatment

Designed with you in mind

Things to know about PI and treatment with Privigen

Welcome to treatment with Privigen! Whether you were recently diagnosed, are taking an immunoglobulin (Ig) therapy for the first time, or have switched to Privigen, you may have questions regarding your new therapy. We created this guide to provide information to help you feel confident in treatment with Privigen.

Privigen is an intravenous immunoglobulin (IVIg) therapy from CSL Behring, a company with more than 100 years of experience developing lifesaving therapies for people with rare and serious diseases.
Why am I sick so often?

If you or your loved one has 2 or more of the items below, primary immunodeficiency (PI) may be the cause of frequent infections.

- 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 in mouth or fungal infection on skin
- Need for intravenous antibiotics to clear infections
- 2 or more deep-seated infections including septicemia
- A family history of PI

What is PI?

Your immune system keeps you healthy by fighting off germs. But people living with PI have an immune system that does not work correctly. With PI, infections may not go away, or they can come back often, even with the use of antibiotics. Infections may be common—like ear infections and colds—severe, long lasting, or hard to cure. Appropriate therapy can prevent complications associated with PI, such as frequent infections or fevers.

Some examples of PI are:

- Common variable immunodeficiency (CVID)
- Selective immunoglobulin A (IgA) deficiency
- X-linked agammaglobulinemia (XLA)
- Autosomal recessive agammaglobulinemia (ARA)
- Hyper IgM (HIGM) syndrome

For additional questions about PI, talk with your healthcare professional.
How is PI treated?

How your PI is treated is based on which type of PI you have. Certain types of PI are associated with low immunoglobulin G (IgG) levels (immunoglobulins are proteins that help fight infection).

One treatment option is Ig therapy, which replaces the IgG that is not functioning properly, missing, or in low amounts. Ig therapy is:

- Made from a collection of donated plasma (part of the blood) of carefully screened donors that is manufactured and purified under strict conditions for efficacy and safety.
- Infused because it is made from plasma and cannot be put into pill form.

What is Privigen?

Privigen is an Ig therapy that helps protect the health of PI patients by supplying their immune systems with antibodies to help prevent infections.

The primary antibody found in Privigen is known as immunoglobulin G (IgG).

- An antibody is an essential part of the immune system that identifies and destroys disease-causing bacteria or viruses. IgG is the main type of antibody made by the immune system.

By boosting levels of IgG, Privigen can help prevent serious and recurring infections and other complications.

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

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.

Please see full Important Safety Information on pages 12–13 and full prescribing information for Privigen, including boxed warning, in pocket.
What can I expect with Privigen?

Privigen was proven to work in a clinical trial for PI that studied 80 patients for 12 months.

- People treated with Privigen had an average of 3.5 infections per year.
- The rate of serious bacterial infections per year was almost 0*.
  
  - This means there were hardly any cases of pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.

*The rate of serious bacterial infections was 0.08 infections per patient per year.

Is Privigen safe?

The clinical trial also showed that Privigen is safe and effective in the treatment of PI.

- 97% of the side effects people had with Privigen in the pivotal study were non-serious.
  
  - Of the 80 people who participated in the clinical trial, 1 had serious side effects.

The most common† side effects of Privigen are headache and nausea.

- Some people can have an allergic reaction to IV Ig treatments such as Privigen; let your doctor know if you have had a previous reaction to IgG or have been told you have an IgA deficiency.
- A vaccination for measles, mumps, and rubella might not work while on therapy. Before receiving any vaccination, tell the person administering the vaccine you are being treated with Privigen.
- The risk of transmission of infectious agents, including viruses, cannot be completely eliminated.

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

†Occurring in more than 10% of people in the clinical trials.
What makes Privigen special?

Privigen is the first and only IVIg therapy stabilized with proline. Privigen was specifically designed with proline to improve convenience and preservation of the Ig.

Privigen is made from human plasma (part of the blood). The process used to make Privigen involves several steps, including a 3-step virus inactivation/removal process.

What is proline?

Proline is a naturally occurring amino acid. It can be made by the body and is found in certain foods in a normal, healthy diet. The use of proline allows Privigen to be stored at room temperature, making it ready to use off the shelf.*

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

How will I receive Privigen?

Privigen comes in a small glass bottle and is given through a small needle into a vein. It is administered by a healthcare professional, such as a nurse or doctor, every 3–4 weeks—whether you’re at a hospital, clinic, physician’s office, or in your home.

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, 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)

Important Safety Information (cont.)

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.
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.

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.
What if I need support during treatment with Privigen?

CSL Behring is committed to making sure you have the best experience possible with Privigen, which is why they offer IgIQ: complete support all in one place.

İgIQ is ready to help

Financial Assistance—The patient assistance program helps provide therapy to qualified people who are uninsured, underinsured, or unable to afford their prescription.

Patient Support—Trained nurses are available by phone to answer your questions and provide helpful resources as well as product information.

CSL Behring Assurance℠—CSL Behring is the only company to offer a loyalty program for their Ig products: earn points for every month of continuous product use and redeem 3 points for a free 1-month supply of Privigen in the event of a lapse in coverage.

Referral Triage—IgIQ can also coordinate patient referral to specialty pharmacies.

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

Privigen is manufactured by CSL Behring AG and distributed by CSL Behring LLC. Privigen® is a registered trademark of CSL Behring AG. CSL Behring Assurance℠ and IgIQ℠ are service marks and Biotherapies for Life® is a registered trademark of CSL Behring LLC.

©2018 CSL Behring LLC
1020 First Avenue, PO Box 61501 King of Prussia, PA 19406-0901 USA
www.CSLBehring.com www.Privigen.com
PVG-0141-JAN18

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