

PATIENT GUIDE TO
STARTING BIVIGAM™



FOR PATIENTS WITH PRIMARY HUMORAL IMMUNODEFICIENCY (PI)

PROTECTION IS A BEAUTIFUL THING

Please see Important Safety Information on pages 13, 14 and 15, and [Click here](#) for Full Prescribing Information, including complete BOXED WARNING.



BIVIGAM[®]
IMMUNE GLOBULIN INTRAVENOUS
(HUMAN), 10% LIQUID
BY YOUR SIDE

Learn more at bivigam.com

LEARNING ABOUT PI

- What is PI?
- How is PI treated?

GETTING STARTED WITH BIVIGAM[®]

- What is BIVIGAM?
- Proven protection against serious infections
- Demonstrated safety profile
- How will I receive BIVIGAM?

RESOURCES AND SUPPORT

- Steps to help prevent infections
- Savings and support made simple when starting BIVIGAM
- Where can I get more information about PI?

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IMPORTANT SAFETY INFORMATION FOR BIVIGAM®

WARNING: RISK OF BLOOD CLOTS (THROMBOSIS), POOR KIDNEY FUNCTION, AND KIDNEY FAILURE

- Blood clots may happen with intravenous immune globulin products, including BIVIGAM. Before taking BIVIGAM, talk to your doctor if you:
 - Are of advanced age
 - Are unusually sedentary (long periods of sitting down or inactive)
 - Have a history of blood clots in the veins or arteries, cardiovascular (heart) problems or previous history of stroke
 - Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)
 - Have a permanent intravenous (IV) catheter
 - Have hyperviscosity (poor blood flow) of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)
- Kidney problems, kidney failure, and death are more common in people who are taking human immune globulin products, especially those containing sucrose (sugar). BIVIGAM does not contain sucrose. Let your doctor know if you have kidney disease or diseases with kidney involvement, have a history of diabetes, or are older than 65 years of age. Your doctor should check your hydration level, blood infection risk, protein levels, and if you are taking any drugs that may damage your kidneys.
- If you are at risk for blood clots or kidney problems, your doctor should adjust your starting dose of BIVIGAM and monitor your blood flow.

What is BIVIGAM [Immune Globulin Intravenous (Human), 10% Liquid]?

BIVIGAM [Immune Globulin Intravenous (Human), 10% Liquid] is a prescription medicine to help adults and adolescents (12 to 17 years old) with primary immunodeficiency fight and prevent infections. BIVIGAM is for intravenous administration only. BIVIGAM is made from healthy human blood/plasma.

Who should not use BIVIGAM?

BIVIGAM should not be used if you had a severe allergic reaction to human immune globulin or if you have been told by a doctor that you are immunoglobulin A (IgA) deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product.

What are possible warnings and precautions with taking BIVIGAM?

If you take BIVIGAM or a similar immune globulin product, you could experience a serious and life-threatening blood clot (thromboembolism). Thrombosis may occur even if you do not have any risk factors.

Your doctor should perform blood tests to see if you are at risk for poor blood flow (hyperviscosity). These tests will check for the presence of other proteins in the blood that might put you at risk of blood clots.

Kidney problems or failure. Kidney problems, kidney failure, and death may occur with use of human immune globulin products. If your doctor determines that you are at risk of kidney problems, they should monitor you with routine blood and urine tests.



WHAT IS PI?

PI occurs when a person's immune system doesn't work correctly or when parts of the system are missing. As a result, the immune system can't make enough antibodies to fight infections effectively.

Antibodies are small proteins that target invading germs, including bacteria and viruses.



How common is PI?

The exact prevalence of PI is unknown. In the United States, it is estimated that 1 in 2,000 children and 1 in 600 households are diagnosed with PI. **Patients with PI often get one infection after another. These infections may never really improve as expected and may recur over time.**

150,000 to 360,000

PEOPLE ARE DIAGNOSED WITH PI



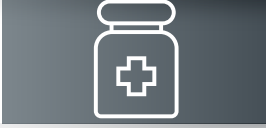







Source: Jiang F, Torgerson TR, Ayars AG. Allergy Asthma Clin Immunol. 2015.

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What causes PI?

There's no single cause. Many PI disorders are inherited, which means that the condition is passed down from one or both parents. Some immune system defects are caused by genetic factors in a person's DNA. At one time, it was thought that PI was a disease of infants and small children. Now we know the symptoms of PI can appear later in life.

The following list shows 10 warning signs of PI.
You may have experienced one or more of them.

	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 types of pneumonia within one 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	

Source: Jeffrey Modell Foundation.



HOW IS PI TREATED?

One of the most common treatments for PI is immune globulin (Ig) replacement.

Ig is a component of plasma. Plasma is the yellow-colored liquid left over when red blood cells are removed from whole blood that is donated by people with healthy immune systems. Ig is removed from the collected plasma and purified. It is then used to treat a variety of conditions, including PI.

Ig treatment can improve the health and quality of life for many patients with PI



Fewer respiratory tract (lung) infections



Less time spent in the hospital



Fewer missed work/school days

IMPORTANT SAFETY INFORMATION (cont'd)

Aseptic meningitis syndrome (AMS). Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache, which may occur with human immune globulin treatment, including BIVIGAM. AMS usually happens within a few hours to 2 days after treatment. AMS is more commonly associated with higher doses of treatment and/or after rapid infusion. Your doctor may perform a neurological exam, including spinal tap (sampling fluid which surrounds the spinal cord) to evaluate your condition and to rule out other causes of meningitis.

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WHAT IS BIVIGAM® ?

BIVIGAM is an Ig treatment indicated for patients with PI

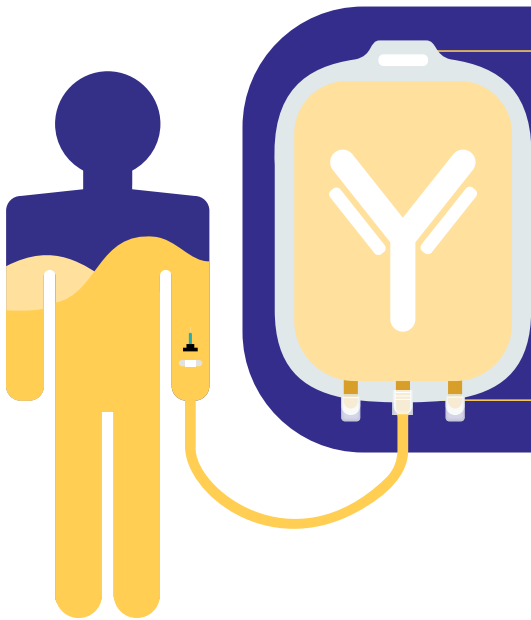
- Based on plasma pooled from more than 1,000 donors
- Administered intravenously (through the vein)

Quality you can count on inside every vial

- A wide spectrum of antibodies that help you fight infection
- Manufactured from the plasma of donors with healthy immune systems

Proven PI protection and safety

- Demonstrated protection from serious bacterial infections (SBIs)
- Reduced health-related burdens



BIVIGAM helps PI patients fight against infection by replacing antibodies their immune system cannot make.

People taking human immune globulin products, including BIVIGAM, may experience hyperproteinemia (high levels of protein in the blood), hyponatremia (low levels of sodium in the blood), and hyperviscosity (poor blood flow). Your doctor may perform certain blood tests and monitor you to minimize any of the above risks.

Hemolysis. Hemolysis refers to the destruction of red blood cells. Immune globulin products, including BIVIGAM, may contain certain antibodies that can result in the rupturing of red blood cells. Your doctor should monitor you for signs and symptoms of hemolysis. People taking human immune globulin products may experience lung-related side effects, including transfusion-related acute lung injury (TRALI). TRALI is a rare but serious syndrome characterized by sudden acute respiratory distress following transfusion. Your doctor should monitor you for lung-related side effects and may conduct tests to check for the presence of certain white blood cells (anti-neutrophils) in the drug or your blood.

PROVEN PROTECTION AGAINST SERIOUS INFECTIONS

IN A 1-YEAR STUDY OF 63 PATIENTS WITH PI, BIVIGAM MET ITS GOALS

BIVIGAM IS BY YOUR SIDE



0.37 serious bacterial infections per patient/year

0.21 days of hospitalization per patient/year

2.3 days of school or worked missed per patient/year

IMPORTANT SAFETY INFORMATION (cont'd)

Transmissible infectious agents. Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. Your doctor will report to the manufacturer any cases of suspected infections spread by the product.

Interference with lab tests. Because BIVIGAM contains a variety of antibodies that are infused into your body, blood tests may provide misleading interpretations. Be sure to tell your doctor, nurse, or lab technician that you are using BIVIGAM.

Interactions with medicines. BIVIGAM can make vaccines (like measles, mumps, rubella, and chicken pox vaccines) less effective in your body. Before you get any vaccines, tell your healthcare provider that you take BIVIGAM.

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DEMONSTRATED SAFETY PROFILE

Side effects occurring most often in BIVIGAM® clinical trial

- Headache
- Fatigue
- Infusion site reaction
- Nausea
- Sinusitis
- Increased blood pressure
- Diarrhea
- Dizziness
- Lethargy

If you experience the above or any other side effects while taking BIVIGAM, call your healthcare provider immediately or dial 911.

You are encouraged to report side effects of prescription drugs to ADMA Biologics @ 1-800-458-4244 or the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

What are other possible side effects of BIVIGAM?

In clinical studies of BIVIGAM, some patients experienced the following serious side effects:

- Vomiting
- Dehydration

The most common side effects included:

- Headache
- Fatigue
- Reaction at the site of infusion
- Nausea
- Sinus inflammation (sinusitis)
- Blood pressure increase
- Diarrhea
- Dizziness
- Loss of energy (lethargy)

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HOW WILL I RECEIVE BIVIGAM® ?

Like other IVIg treatments, BIVIGAM is given by IV infusion by a medical professional. BIVIGAM can be infused in a doctor’s office, infusion center, or at home. It’s injected into an IV infusion bag and slowly introduced to your body. The infusion typically takes about 4 hours, depending on body size. It may be given more slowly the first time to reduce the risk of side effects.

How often will I receive BIVIGAM?

BIVIGAM is usually given every 3 to 4 weeks. Fewer doses mean more treatment-free days for you! Your healthcare provider may change your dosing schedule, depending on how your body reacts to the medicine.



Make the most of your infusion time



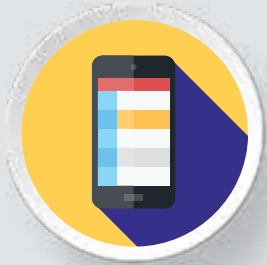
REVIEW INFUSION INSTRUCTIONS



READ BOOKS OR MAGAZINES



LISTEN TO MUSIC



PLAY GAMES ON A DEVICE



WORK ON YOUR LAPTOP



CHAT WITH OTHERS

IMPORTANT SAFETY INFORMATION (cont’d)

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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.

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STEPS TO HELP PREVENT INFECTIONS

There is no way to prevent primary immunodeficiency disorders because their causes are genetic. But you can take steps to help prevent infections that can occur due to a weakened immune system. Discuss the tips below with your doctor before giving them a try.



Wash your hands regularly

Especially after being in public, and before eating



Eat a healthy diet

Follow your doctor's recommendation for a balanced diet



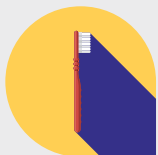
Set a sleep schedule

Try to get the same number of hours of sleep every night



Stay active

With your doctor's approval, try light exercise – it may improve your overall health



Practice good oral hygiene

Brush your teeth at least twice a day, and floss every night before bed



Limit exposure to illness-causing germs

Don't give up your pandemic habits. Avoid people who are sick and practice social distancing



Reduce stress levels

By exercising, meditating, or setting a sleep schedule. High stress levels can affect your immune system



Ask your doctor about vaccines

Make sure you're up to date on the vaccinations you need

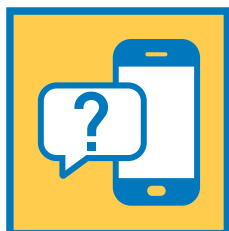
SAVINGS AND SUPPORT MADE SIMPLE WHEN STARTING BIVIGAM®

ADMA ADvantage Ig™ is a dedicated patient support hub created for eligible patients who have been prescribed BIVIGAM. Ask your doctor today about enrolling!



FINANCIAL ASSISTANCE WITH YOUR CO-PAY COSTS*

- We can help cover most of your out-of-pocket expenses, so you pay the lowest amount possible.



DEDICATED SUPPORT TO HELP YOU

- We can help you understand your insurance and medication costs.



ASK YOUR DOCTOR TODAY ABOUT ENROLLING!

- We will help them complete all the necessary paper work, to help get you enrolled.

*Please go to www.BIVIGAM.com for full terms and conditions

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WHERE CAN I FIND MORE INFORMATION ABOUT PI?

For more information about PI and its treatment, you may wish to contact the following organizations.*

Immune Deficiency Foundation (IDF). IDF is a national non-profit patient organization dedicated to improving the diagnosis and treatment of patients with PI.

 www.primaryimmune.org
 800-296-4433

United States Immunodeficiency Network (USIDNET). USIDNET is an NIH-funded research program of the IDF. Its mission is to advance scientific research in PI.

 www.usidnet.org

International Patient Organization for Primary Immunodeficiencies (IPOPI). IPOPI is an international organization that provides general information on PI and resource contacts for patients and professionals.

Primary Immune Deficiency Treatment Consortium (PIDTC). PIDTC consists of 42 centers in North America whose shared goal is to improve outcomes for patients with rare, life-threatening, inherited disorders of the immune system.

 <https://www.rarediseasesnetwork.org/cms/PIDTC>

The Jeffrey Modell Foundation. The Jeffrey Modell Foundation supports early and precise diagnosis and meaningful treatments of PI.

 www.jmfworld.com

*ADMA Biologics does not endorse and is not responsible for the content provided by these resources about treatment and patient support groups.

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