

PATIENT GUIDE TO  
STARTING ASCENIV™

FOR PATIENTS WITH PRIMARY  
HUMORAL IMMUNODEFICIENCY (PI)

IT'S WHAT'S  
**INSIDE** THAT  
COUNTS

LEARN WHY ASCENIV  
MAY BE RIGHT FOR YOU

Please see Important Safety Information on pages  
16, 17 and 18, and [Click here](#) for Full Prescribing  
Information, including complete BOXED WARNING.



**ASCENIV™**  
IMMUNE GLOBULIN INTRAVENOUS  
(HUMAN) — sIra 10% LIQUID

### Understanding Your PI Treatment Options

- Is your PI under control?
- If you continue to experience complications while on Ig treatment, you're not alone

### Getting Started with ASCENIV™

- What is ASCENIV?
- Discover the ASCENIV difference
- Protection you can count on
- Demonstrated safety profile
- How will I receive ASCENIV?

### Resources and Support

- Steps to help prevent infections
- Savings and support made simple when starting ASCENIV
- What is PI?

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## Important Safety Information for ASCENIV™

**WARNING: RISK OF BLOOD CLOTS (THROMBOSIS), POOR KIDNEY FUNCTION, AND INABILITY TO FILTER WASTE FROM KIDNEYS. BLOOD CLOTS MAY OCCUR WITH INTRAVENOUS IMMUNE GLOBULIN PRODUCTS, INCLUDING ASCENIV.**

Before taking ASCENIV, talk to your doctor if you:

- Are of advanced age
- Are unusually sedentary (long periods of sitting down or inactive)
- Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)
- Have a permanent intravenous (IV) catheter
- Have hyperviscosity of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)
- Have cardiovascular (heart) problems or previous history of stroke

Thrombosis may occur even if you do not have any risk factors.

Serious kidney problems and death can also happen in certain patients who receive such products.

If you are at high risk of thrombosis or kidney problems, your doctor should adjust the dose of ASCENIV and will monitor you for signs and symptoms of thrombosis and viscosity, as well as kidney function.

### What is ASCENIV (immune globulin intravenous, human)?

**ASCENIV** (immune globulin intravenous, human) is a prescription medicine to help adults and adolescents (12 to 17 years old) with primary immunodeficiency fight and prevent infections.

ASCENIV is for intravenous administration only. ASCENIV is made from healthy human blood/plasma.

## Is your PI under control?

Not all Ig treatments are the same. What works for one person may not work for someone else.

When people with PI continue to suffer from respiratory tract infections it is not uncommon for their healthcare provider to recommend changing to a different Ig.



Every PI patient's experience is different and your journey is unique.

Changing Ig treatments is not unusual

**A recent survey by the Immune Deficiency Foundation** revealed that as many as **1 in 7 people with PI switched** from one Ig treatment to another in hopes of improving treatment results.\*



FINDING THE RIGHT TREATMENT IS IMPORTANT FOR YOUR OVERALL WELL BEING.

\* Immune Deficiency Foundation (IDF) survey from 2018.

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If you continue to experience complications while on Ig treatment, you're not alone

In studies, over 90% of people with PI on Ig replacement therapy continued to have opportunistic respiratory tract infections.

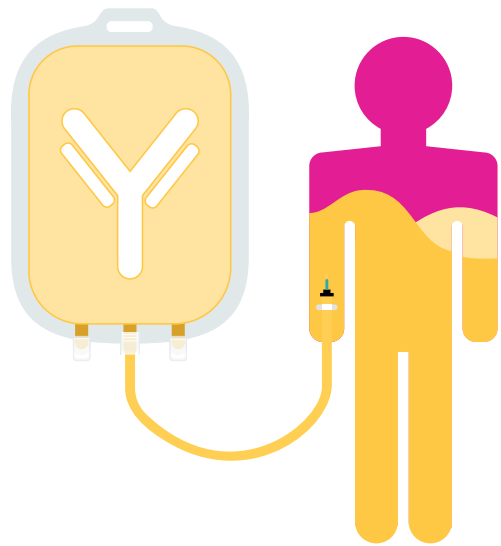


Repeated respiratory infections can make living with PI more difficult:

- Can impact your quality of life, including physical and social functioning (eg, missed school and work days)
- May lead to long-term lung issues, including, but not limited to, asthma and COPD
- Can require frequent use of antibiotics for treatment and prevention

## What is ASCENIV™?

**ASCENIV™**  
IMMUNE GLOBULIN INTRAVENOUS  
(HUMAN) — sIra 10% LIQUID



ASCENIV is an intravenous immune globulin (IVIg) for adults and adolescents (12 -17 years of age) with PI.

**ASCENIV provides proven protection against infection and has a demonstrated safety profile.**

As with other IVIg products, **ASCENIV is manufactured from plasma**, the yellow-colored liquid left over when red blood cells are removed from whole blood. Plasma is obtained from donations from people with healthy immune systems. Ig is removed from the collected plasma and purified.

## Discover the ASCENIV™ difference

### SELECT DONOR PROFILE

The only available IVIg product made with a proprietary method for donor screening AND plasma pooling

### QUALITY IN EVERY VIAL

Every vial includes a broad spectrum of antibodies, taken from plasma pooled from at least 1,000 donors

### UNIQUE IVIG COMPOSITION

Not only meets standard IVIg criteria, but also includes plasma from donors selected for their antibody levels for certain respiratory pathogens



## Important Safety Information (cont'd)

### Who should not use ASCENIV?

ASCENIV 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 ASCENIV?

**Hypersensitivity.** Severe allergic reactions may occur with immune globulin products, including ASCENIV. If you have a severe allergic reaction, stop the infusion immediately and

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get medical attention. ASCENIV contains IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions.

If you take ASCENIV or a similar immune globulin product, you could experience a serious and life-threatening blood clot (thromboembolism). This may include pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness, or weakness on one side of the body. If you are at risk, your doctor may decide to adjust the dose of ASCENIV. Your doctor will monitor you for any signs or symptoms of blood clots or poor blood flow in your arteries.

## Protection you can count on

Results from a 12-month ASCENIV™ clinical study of 59 adults and adolescents with PI:



Zero serious bacterial infections. No patient taking ASCENIV had a serious bacterial infection



Zero hospitalizations. No patient taking ASCENIV was hospitalized due to a PI-related infection



Only 1.7 missed work or school days per year

So whether ASCENIV is your first Ig or a switch from another formulation, you can think of it as an opportunity to meet your treatment goals.

## Important Safety Information (cont'd)

Always tell your doctor immediately if your medical history is similar to what is described here, and especially if you experience any of these symptoms while taking ASCENIV.

**Kidney problems or failure.** Kidney problems, kidney failure, and death may occur with use of human immune globulin products, especially those containing sucrose (sugar). ASCENIV does not contain sucrose. If you have kidney disease or diseases with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment. If your doctor determines you to be at risk, they may start your dose of ASCENIV at a safe level.

**People taking human immune globulin products, including ASCENIV, 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.**

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## Demonstrated safety profile

The most common side effects in the ASCENIV™ clinical trial were:

- Headache
- Sinus inflammation (sinusitis)
- Diarrhea
- Intestinal lining inflammation caused by virus (gastroenteritis)
- Common cold (nasopharyngitis)
- Upper respiratory tract infection
- Bronchitis
- Nausea

These are not all the possible side effects of ASCENIV. If you experience the above or any other side effects while taking ASCENIV, call your healthcare provider immediately or dial 911.

You are encouraged to report side effects of prescription drugs to ADMA Biologics at 1-800-458-4244 or the FDA. Visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.

**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 ASCENIV. 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.

**Hemolysis.** Hemolysis refers to the destruction of red blood cells. Immune globulin products, including ASCENIV, 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, which may include additional confirmation tests.

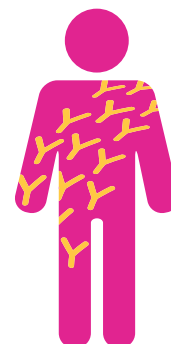
Taking intravenous human immune globulin products may cause a build up of fluid in the lungs (pulmonary edema) that is unrelated to heart problems. Your doctor should monitor you for lung-related side effects and may conduct appropriate tests that can detect the presence of certain white blood cells (anti-neutrophils) in the drug or your blood. If needed, your doctor may decide to use oxygen or other respiratory methods to help your breathing.

## How will I receive ASCENIV™?

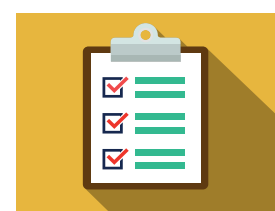
Like other IVIg treatments, ASCENIV is given by IV infusion by a medical professional. ASCENIV can be infused in a doctor's office, infusion center, or at home. It's injected into an IV infusion bag and slowly introduced to your body. The infusion typically takes about 4 hours, depending on body size.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

## How often will I receive ASCENIV?

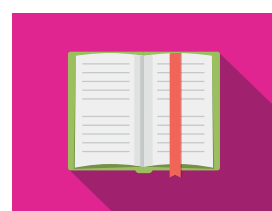
ASCENIV is usually given every 3 to 4 weeks. Fewer doses mean more treatment-free days for you! Your healthcare provider may change your dosing schedule, depending on how your body reacts to the medicine.



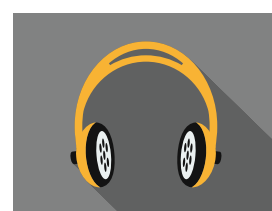
## Make the most of your infusion time



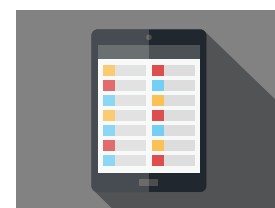
REVIEW INFUSION INSTRUCTIONS



READ BOOKS OR MAGAZINES



LISTEN TO MUSIC



PLAY GAMES ON A DEVICE



WORK ON YOUR LAPTOP



CHAT WITH OTHERS

## Important Safety Information (cont'd)

**Transmissible infectious agents.** Because ASCENIV 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 ASCENIV contains a variety of antibodies that are infused into your body, blood tests to determine antibody levels may provide misleading

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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.

 <p><b>Wash your hands regularly</b> Especially after being in public, and before eating</p>	 <p><b>Eat a healthy diet</b> Follow your doctor's recommendation for a balanced diet</p>
 <p><b>Set a sleep schedule</b> Try to get the same number of hours of sleep every night</p>	 <p><b>Stay active</b> With your doctor's approval, try light exercise – it may improve your overall health</p>
 <p><b>Practice good oral hygiene</b> Brush your teeth at least twice a day, and floss every night before bed</p>	 <p><b>Limit exposure to illness-causing germs</b> Don't give up your pandemic habits. Avoid people who are sick and practice social distancing</p>
 <p><b>Reduce stress levels</b> Consider exercising, meditating, or setting a sleep schedule. High stress levels can affect your immune system</p>	 <p><b>Ask your doctor about vaccines</b> Make sure you're up to date on the vaccinations you need</p>

interpretations. Be sure to always tell your doctor, nurse, or lab technician of any medicines you are taking and that you are using ASCENIV™.

**Interactions with medicines.** ASCENIV 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 ASCENIV.

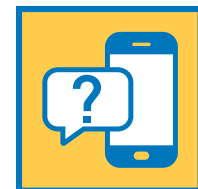
## Savings and support made simple when starting ASCENIV™

ADMA ADvantage Ig™ is a dedicated patient support hub created for eligible patients who have been prescribed ASCENIV. 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!

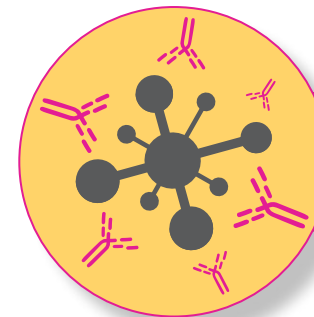
- We will help them complete all the necessary paper work, to help get you enrolled.

\*Please go to [www.ASCENIV.com](http://www.ASCENIV.com) for full terms and conditions

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## 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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**Interference with lab tests.** Because ASCENIV contains a variety of antibodies that are infused into your body, blood tests to determine antibody levels may provide misleading interpretations. Be sure to always tell your doctor, nurse, or lab technician of any medicines you are taking and that you are using ASCENIV.

**Interactions with medicines.** ASCENIV 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 ASCENIV.

### What are other possible side effects of ASCENIV?

In clinical studies of ASCENIV, some patients experienced the following:

- Headache
- Sinus inflammation (sinusitis)
- Diarrhea
- Intestinal lining inflammation caused by virus (gastroenteritis)
- Common cold (nasopharyngitis)
- Upper respiratory tract infection
- Bronchitis
- Nausea

These are not all the possible side effects of ASCENIV.

Talk to your healthcare provider about any side effect that bothers you or that does not go away.



You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please [Click here](#) for full Prescribing Information for ASCENIV.

## 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](http://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](http://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](http://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.

Learn more at [www.asceniv.com](http://www.asceniv.com)

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