

UNDERSTANDING AND TREATING PIDD*

Information for patients and caregivers



*Primary immunodeficiency disease.

Please see Important Safety Information on pages 18 and 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.

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What is PIDD?

PIDD stands for primary humoral immunodeficiency disease. There are more than 450 different kinds of PIDD.¹ With PIDD, part of your immune system, which is what protects you from infections and fights off diseases, is missing or doesn't function properly. As a result, your body can't protect you from germs as well as it should, so you are more likely to develop infections and be sick more often.

PIDD is usually inherited, which means it is carried through the genes from your parents. That means that PIDD is not contagious. If you have the disease, you might pass it along to your children, but you won't give it to anyone else.²

If you or someone you know has PIDD, you know how difficult it can be. But there is good news, too. There are FDA-approved treatment options* available, as well as lots of support. If you have PIDD, you are certainly not alone.

*FDA, Food and Drug Administration.



About PIDD

Know the symptoms

The signs and symptoms of PIDD vary from person to person. If you or someone you know is experiencing any of the symptoms below, talk to your doctor. Early detection of PIDD can help prevent long-term problems.

The most common symptoms^{1,3}:

Infections that occur more frequently and are more severe, longer lasting, and more difficult to cure than for people with healthy immune systems

Getting sick from germs that a healthy immune system would normally be able to fight off

Autoimmune problems that happen when the immune system attacks the body's own organs and tissues instead of germs and disease-causing materials

Warning signs of PIDD*

There are warning signs that can help identify people who may have PIDD. If you or someone you know is affected by 2 or more of the following warning signs, speak to a doctor about the possible presence of PIDD.

The most common warning signs are:

- 1 Two or more **new ear infections** within 1 year (4 or more for children)
- 2 Two or more **new sinus infections** within 1 year, in absence of allergy
- 3 One **pneumonia** per year for more than 1 year (2 or more in 1 year for children)
- 4 In children, 2 or more months on **antibiotics with little effect**
- 5 In infants, **failure to gain weight or grow normally**
- 6 Chronic **diarrhea and weight loss**
- 7 Recurrent **viral infections** (colds, herpes, warts, condyloma)
- 8 Recurrent **need for intravenous antibiotics to clear infections**
- 9 Recurrent **deep abscesses of the skin** or internal organs
- 10 Persistent **thrush or fungal infection** on skin or elsewhere
- 11 Infections with normally harmless **tuberculosis-like bacteria**
- 12 A **family history** of PIDD

*Courtesy of The Jeffrey Modell Foundation.

A look inside your immune system

A healthy immune system

The immune system is an amazing collection of cells, proteins, tissues, and organs that defends against a wide variety of germs every day.³

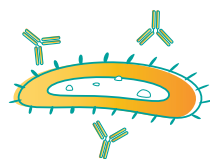
The role of antibodies



Your body's immune system makes special proteins called **antibodies**



When your body detects a threat, like **viruses and bacteria** that can make you sick, it responds by making these antibodies



Antibodies defend your body by attaching to the threat and signaling your body to destroy it

The immune system in people with PID⁴

Usually, the immune system does a great job protecting the body from threats. But in people who have PID, the immune system doesn't work correctly. And in some cases, it may not work at all. As a result, viruses and bacteria are more likely to penetrate your body's defenses.

Your treatment options

Treating PIDD isn't just about helping your body fight infections to prevent serious illnesses and hospitalizations. It's also about dealing with the underlying disease itself so you'll be less likely to get an infection in the first place. There are several treatments available to you,³ including:



Over-the-counter medicines, such as aspirin, decongestants, and/or expectorants to treat symptoms



Antibiotics, to kill infections and deal with a wide range of germs that have a greater impact on people with PIDD



Immune globulin (IG) replacement therapy that treats PIDD directly to help the immune system fight germs

In the following pages, we'll take a closer look at IG therapy



What is IG therapy?

IG stands for immune globulin. It is made up of proteins taken from human plasma and contains purified antibodies. Plasma is the liquid part of the blood. It contains antibodies needed to keep the body healthy.³

IG replacement therapy helps the immune system protect people with PI from germs and other threats. It can be given in 1 of 2 ways.

Two ways that IG therapy is given



INTRAVENOUS

Infused through a vein, typically in the arm



SUBCUTANEOUS

Infused just below the skin

If given by intravenous infusion, IG is given every 3 to 4 weeks; if given by subcutaneous infusion, it can be given daily to weekly, as desired. Also, while intravenous infusion is administered by a healthcare professional in a clinic or home, subcutaneous infusion can be self-administered conveniently at home.

GAMUNEX-C: a proven IG therapy option for people with PIDD⁵

GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is approved to treat primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older.

Fewer cases of infection

During a 9-month clinical study, patients with PIDD saw significant improvements when taking GAMUNEX-C, including^{5*}:

- ✓ No validated cases of pneumonia
- ✓ 2 times fewer sinus infections
- ✓ Fewer cases of validated infections per year

ASK YOUR DOCTOR IF GAMUNEX-C IS RIGHT FOR YOU

*GAMUNEX-C (caprylate/chromatography purified) vs Gamimune N, 10% (immune globulin intravenous [human]), solvent/detergent purified.

Do not take GAMUNEX-C if you have an allergy to immune globulin. Tell your doctor if you have had a serious reaction to other medicines that contain human immune globulin. Also tell your doctor if you have immunoglobulin A (IgA) deficiency. If you have a serious reaction while taking GAMUNEX-C, stop taking it immediately and tell your doctor.

How safe is GAMUNEX-C?

The plasma used to make GAMUNEX-C is donated at collection centers across the United States. Each center is strictly monitored by Grifols and the FDA. All plasma donors are carefully screened, and every plasma donation is tested to make sure it is safe for use. When GAMUNEX-C is made, the plasma goes through many safety steps to remove or destroy viruses.⁶

Because GAMUNEX-C 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.⁶



How therapy is administered

ADMINISTERING GAMUNEX-C

When used to treat PIDD, GAMUNEX-C is approved to be administered by either **intravenous (IV)** or **subcutaneous (SC)** infusion.⁶ You and your healthcare professional will work together to determine the treatment and schedule that is best for you.



Remember to keep track of how you are feeling, because a journal of your treatment and side effects will help you and your doctor make informed choices for your treatment plan.⁶

Write daily life considerations you'd like to discuss with your doctor here.

Please see Important Safety Information on pages 18 and 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.

Side effects⁶

What side effects can occur with GAMUNEX-C?

The most common side effects in a clinical study with PIDD patients who received subcutaneous injections of GAMUNEX-C were:

- Infusion-site reactions such as redness, swelling, and itching
- Extreme tiredness
- Pain in the region of the head or neck
- A runny nose, nasal congestion, sneezing, cough, and sputum production
- Joint pain
- Loose stools
- Sensation of unease and discomfort in the upper stomach
- Swelling of the tissue lining the sinuses
- Inflammation of the airways that carry air to your lungs
- A feeling of unhappiness, sadness, melancholy, gloom, hopelessness, or low spirits
- Red rash or bumps; itchy, swollen, and tender skin with or without blisters; or a burning feeling
- Severe headache, stiff neck, fatigue, fever, sensitivity to light, painful eye movements, nausea, and vomiting
- Muscle pain
- Familiar infectious diseases such as the common cold or flu
- Raised body temperature or fever

In clinical studies with PIDD patients who got GAMUNEX-C intravenously, the most common side effects were:

- Cough
- Irritation and inflammation of the mucous membrane inside the nose
- Sore throat caused by inflammation of the back of the throat
- Pain in the region of the head or neck
- A condition in which airways narrow and swell and produce extra mucus
- Sensation of unease and discomfort in the upper stomach
- Raised body temperature or fever
- Loose stools
- Swelling of the tissue lining the sinuses

The most serious side effect for PIDD patients taking GAMUNEX-C was:

- A flare-up of an existing type of anemia (autoimmune pure red cell aplasia)

Tell your doctor right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness, or fainting. These could be signs of a bad allergic reaction.

Tell your doctor right away if you have any of the following symptoms. They could be signs of a rare, but serious problem.

- Decreased urination, sudden weight gain, fluid retention/swelling in your legs, and/or shortness of breath. They could be signs of a serious kidney problem called renal failure
- 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. These could be signs of a blood clot in your body (thrombosis). Immediately report symptoms of thrombosis
- Severe headache, stiff neck, fatigue, fever, sensitivity to light, painful eye movements, nausea, and vomiting. These could be signs of a type of brain inflammation called aseptic meningitis
- Increased heart rate, fatigue, yellow skin or eyes, and dark-colored urine. These could be signs of a type of blood problem called hemolytic anemia
- Chest pains, trouble breathing, blue lips or extremities, and fever. These could be signs of a lung problem called TRALI (transfusion-related acute lung injury)
- Fever over 100°F (37.8°C). This could be a sign of an infection

Tell your doctor about any side effects that concern you. You can ask your doctor to give you the full Prescribing Information available to healthcare professionals.

Tell your doctor about any side effects that concern you

If you are 65 years of age older or have type 2 diabetes or kidney problems; use estrogens; or have a blood clotting disorder, hardening of the arteries, or heart disease, be sure to tell your doctor prior to starting any IG therapy. Your doctor should be able to decide what is best for you.

Because GAMUNEX-C 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.⁶

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.

Gamunex Connexions® offers dedicated support throughout treatment



We understand that as a patient or caregiver you may have questions and concerns about the cost of therapy.

At Gamunex Connexions, we're committed to helping you start and stay on therapy.

Dedicated savings and financial support

COPAY SUPPORT

- GAMUNEX-C offers copay assistance for eligible patients*
- With copay support, you may be eligible to pay as little as \$0 out of pocket
- Get help managing
 - Deductibles
 - Copayment
 - Coinsurance

PATIENT ASSISTANCE PROGRAM

- You may be qualified to receive GAMUNEX-C at no cost in the event that you lose insurance coverage

*Subject to terms and conditions.

A single, dedicated point of contact

We understand that having a strong support team behind you can help throughout your journey with PI and treatment with GAMUNEX-C.

COVERAGE AND RESOURCES PARTNER

- Helps identify the best available benefits coverage for GAMUNEX-C
- Provides educational information and resources to address your healthcare needs

ONGOING SUPPORT

- Answers questions about GAMUNEX-C, how it works, what to expect, and much more
- Provides information and support to help you manage your condition and make informed decisions about your treatment

**Call the Gamunex Connexions team
at 1-888-MYGAMUNEX (1-888-694-2686)**

for support and financial needs

Monday through Friday (8 AM to 8 PM ET)



Helpful organizations

CONNECTING YOU TO SUPPORT AND RESOURCES

There are many organizations dedicated to helping you manage PIDD and learn more about the condition.

THE IMMUNE DEFICIENCY FOUNDATION (IDF)

www.primaryimmune.org

THE JEFFREY MODELL FOUNDATION (JMF)

www.info4pi.org

THE INTERNATIONAL PATIENT ORGANISATION FOR PRIMARY IMMUNODEFICIENCIES (IPOPI)

www.ipopi.org

THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

www.niaid.nih.gov

These websites are provided as a resource only and do not constitute an endorsement by Grifols of any particular content. Grifols does not review or control the content of non-Grifols websites.

**Get more information on
support and resources through
Gamunex Connexions®.**



References: **1.** What is PI? Immune Deficiency Foundation website. <https://primaryimmune.org/understanding-primary-immunodeficiency/what-is-pi>. Accessed December 20, 2023. **2.** Breaking down common terms in the immune deficiency space. Immune Deficiency Foundation website. <https://primaryimmune.org/resources/news-articles/breaking-down-common-terms-immune-deficiency-space>. Accessed December 20, 2023. **3.** Ballou M, Epland K, Heimall J, et al, eds. *Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases*. 6th ed. Towson, MD: Immune Deficiency Foundation; 2019. **4.** Immune system and PI. Immune Deficiency Foundation website. <https://primaryimmune.org/understanding-primary-immunodeficiency/what-is-pi/immune-system-and-pi>. Accessed November 17, 2023. **5.** Roifman CM, Schroeder H, Berger M, et al. Comparison of the efficacy of IGIV-C, 10% (caprylate/chromatography) and IGIV-SD, 10% as replacement therapy in primary immune deficiency: a randomized double-blind trial. *Int Immunopharmacol*. 2003;3(9):1325-1333. **6.** GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) Prescribing Information. Grifols.



IMPORTANT SAFETY INFORMATION

GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is approved to treat primary humoral immunodeficiency disease (PID) in patients 2 years of age and older. If you have PID, you may take GAMUNEX-C under the skin (subcutaneously) or in a vein (intravenously). GAMUNEX-C is also approved to treat idiopathic thrombocytopenic purpura (ITP) in adults and children and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. If you have ITP or CIDP, you may only take GAMUNEX-C intravenously.

If you take GAMUNEX-C or a similar immune globulin product, you could experience a serious and life-threatening blood clot (thromboembolism), which 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. You are more likely to develop a blood clot if you have a history of hardening of the arteries (atherosclerosis), stroke, heart attack, or heart failure (low volume of blood pumped by the heart). You may also be more likely to get a blood clot if you are elderly, if you have a blood clotting disorder, if you are inactive for long periods of time (such as long bed rest), if you use estrogens, or if you have thickening of your blood. For patients at risk, GAMUNEX-C should be administered at the lowest dose and slowest infusion rate that is practical. However, blood clots may occur in the absence of any of the known risk factors. Patients should be well hydrated by drinking enough water before GAMUNEX-C is administered. Tell your doctor immediately if your medical history is similar to what is described here, and especially if you start having any of these symptoms while taking GAMUNEX-C.

If you take GAMUNEX-C or a similar immune globulin product intravenously, you could experience serious kidney disease and death. You may have symptoms of decreased urination, sudden weight gain, swelling in your legs (edema), or shortness of breath. You are more likely to develop serious kidney disease if you already have a kidney problem, have Type II diabetes mellitus, or are older than 65. You are more likely to develop serious kidney disease if you are dehydrated, have a blood infection (sepsis), have high protein content in your blood, or if you are receiving other medicines that are harmful to your kidneys. Tell your doctor immediately if your medical history is similar to what is described here, and especially if you start having any of these symptoms while taking GAMUNEX-C.

You are more likely to develop serious kidney disease if you take an intravenous immune globulin product that contains sugar (sucrose). GAMUNEX-C does not contain sugar. If your situation makes you more likely to experience serious kidney disease, you should take GAMUNEX-C at the lowest concentration available and the slowest infusion rate that is practical.

Do not take GAMUNEX-C if you have an allergy to immune globulin. Tell your doctor if you have had a serious reaction to other medicines that contain human immune globulin. Also tell your doctor if you have immunoglobulin A (IgA) deficiency. If you have a serious reaction while taking GAMUNEX-C, stop taking it immediately and tell your doctor.

Periodic monitoring of kidney function and urine output is particularly important in patients more likely to experience severe kidney disease.

You could experience other serious and life-threatening problems due to immune globulin. You could get aseptic meningitis (a type of brain inflammation with symptoms of severe headache, stiff neck, fatigue, fever, sensitivity to light, painful eye movements, nausea, and vomiting), a blood problem called hemolytic anemia (common symptoms include increased heart rate, fatigue, yellow skin or eyes, and dark-colored urine), and/or a lung problem called transfusion-related acute lung

injury (commonly referred to as TRALI). TRALI is a condition where you build up fluid in the lungs (called pulmonary edema) that is not the result of heart failure.

If you have higher than normal body fluid volumes or if you have a condition where increasing body fluid volume may be a concern, a higher dose, such as 1g/kg for 1-2 days, is not recommended.

Because GAMUNEX-C 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.

You may not take GAMUNEX-C subcutaneously if you have ITP. **If you have ITP and take GAMUNEX-C subcutaneously, you could experience a very serious and life-threatening black and blue wound (hematoma, which is a pocket of blood within a tissue).**

After you take GAMUNEX-C, your blood antibody levels may rise, which could cause some blood antibody tests to give false results.

The most common side effects in a clinical study with PIDD patients who got subcutaneous injections of GAMUNEX-C were infusion-site reactions such as redness, swelling, and itching; extreme tiredness; pain in the region of the head or neck; a runny nose, nasal congestion, sneezing, cough, and sputum production; joint pain; loose stools; a sensation of unease and discomfort in the upper stomach; swelling of the tissue lining the sinuses; inflammation of the airways that carry air to your lungs; a feeling of unhappiness, sadness, melancholy, gloom, hopelessness, or low spirits; red rash or bumps, itchy, swollen, and tender skin with or without blisters or a burning feeling; a severe throbbing pain or a pulsing sensation, usually on just one side of the head; muscle pain; familiar infectious diseases such as the common cold or flu; and raised body temperature or fever. In clinical studies with PIDD patients who got GAMUNEX-C intravenously, the most common side effects were cough; irritation and inflammation of the mucous membrane inside the nose; sore throat caused by inflammation of the back of the throat; pain in the region of the head or neck; a condition in which your airways narrow and swell and produce extra mucus; a sensation of unease and discomfort in the upper stomach; raised body temperature or fever; loose stools; and swelling of the tissue lining the sinuses. In a clinical study with CIDP patients who got GAMUNEX-C intravenously, the most common side effects were pain in the region of the head or neck; raised body temperature or fever; abnormally high blood pressure; feelings of coldness accompanied by shivering; a noticeable change in the texture or color of your skin such as your skin becoming scaly, bumpy, itchy, or otherwise irritated; a sensation of unease and discomfort in the upper stomach; joint pain; and abnormal physical weakness or lack of energy. In clinical trials with ITP patients who got GAMUNEX-C intravenously, the most common side effects were pain in the region of the head or neck; a discoloration of the skin resulting from bleeding underneath, typically caused by bruising; vomiting, fever, nausea, rash, abdominal pain, back pain, and a pain or an uncomfortable feeling in the upper middle part of your stomach.

The most serious side effects in clinical studies were a blood clot to the lung (pulmonary embolism) in 1 patient with a history of this condition (in CIDP), a flare-up of an existing type of anemia (autoimmune pure red cell aplasia) in 1 patient (in PIDD), and heart inflammation (myocarditis) in 1 patient (in ITP).

Please see accompanying full **Prescribing Information** for GAMUNEX-C.

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.



gamunex[®]-C
 immune globulin injection (human), 10%
caprylate/chromatography purified



To learn more about **GAMUNEX-C**
and Gamunex Connexions, visit **GAMUNEX-C.com**.

Please see Important Safety Information on pages 18 and 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.

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