



gamunex-c



immune globulin injection (human), 10%
caprylate/chromatography purified

THERE'S
MORE
TO YOU

THAT'S WHY THERE'S MORE TO GAMUNEX-C

UNDERSTANDING AND TREATING PIDD*

Information for patients and caregivers

*Primary immunodeficiency disease.

Please see Important Safety Information on pages 22 and 23, and refer to accompanying full Prescribing Information for GAMUNEX-C.

GRIFOLS

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MANY INDIVIDUALS SUFFER FROM PIDD IN THE UNITED STATES

PIDD stands for primary immunodeficiency disease. This means that 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. There are more than 400 different kinds of PIDD!¹

If you or someone you know has PIDD, you know how difficult it can be. Being sick and tired all the time is very frustrating. But there is good news, too. There are FDA*-approved treatment options available, lots of support, and, if you have PIDD, you are certainly not alone.

All kinds of people can have PIDD, and the disease is usually inherited, which means it is carried through the genes from your parents. That also 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.¹

*Food and Drug Administration.

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ABOUT PIDD

Know the symptoms

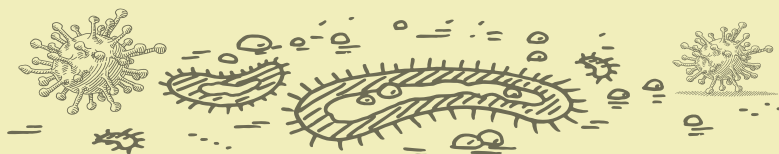
The signs and symptoms of PIDD vary from person to person. If you or someone you know is experiencing any of the symptoms below, talk to your doctor. Early detection of PIDD can prevent long-term problems.

The most common symptoms^{1,2}:

Infections that occur more frequently, are more severe, longer lasting, and harder 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

GETTING SICK FROM GERMS



Please see Important Safety Information on pages 22 and 23, and refer to accompanying full Prescribing Information for GAMUNEX-C.

WARNING SIGNS OF PIDD*

There are warning signs of PIDD that you should not ignore. 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 2 or more new **ear infections** within 1 year (4 or more for children)
- 2 2 or more serious **sinus infections** within 1 year, in the absence of allergy
- 3 In children, 2 or more months on **antibiotics with little effect**
- 4 In children, 2 or more cases of **pneumonia** within 1 year
- 5 In infants, **failure to gain weight** or **grow normally**
- 6 Recurrent **viral infections** (colds, herpes, warts, condyloma)
- 7 Recurrent, **deep skin**, or **organ abscesses**
- 8 **Persistent thrush** in mouth or on skin, after age 1
- 9 Need for **intravenous antibiotics to clear infections**
- 10 2 or more **deep-seated infections**, such as meningitis, osteomyelitis, cellulitis, or sepsis
- 11 Infection with normally harmless **tuberculosis-like bacteria**
- 12 A **family history** of PIDD

*Courtesy of The Jeffrey Modell Foundation and the American Red Cross.

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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.²

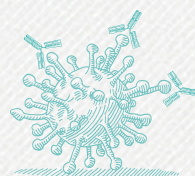
How does it work?



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



When the 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 PIDD¹

Usually, the immune system does a great job protecting the body from threats. But in people who have PIDD, 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.

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There are many components to the immune system²

These include:

TONSILS

Made up of special cells called lymphocytes that help destroy bacteria

THYMUS

Located in the upper chest.
Helps immature lymphocytes mature

LYMPH NODES

Located throughout your body.
T and B lymphocytes gather in your lymph nodes to communicate with each other

BONE MARROW

Where all cells of the immune system begin developing

LIVER

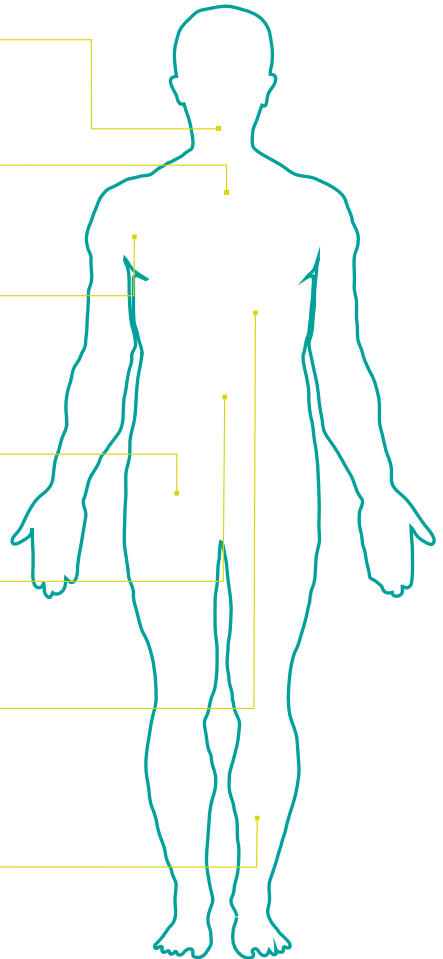
Though a part of your digestive system, it also helps ingest bacteria in the blood

SPLEEN

Serves as a blood filter and provides a place for T and B lymphocytes and monocytes to interact

BLOOD

Carries cells and proteins of the immune system from one place to another



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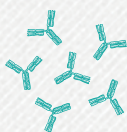
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HOW PIDD IS DIAGNOSED

4 stages of testing for PIDD³



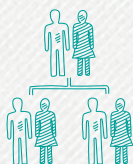
- 1 First, your doctor will look at your medical history and give you a physical examination



- 2 Next, you will receive lab tests to determine immunoglobulin levels and antibody levels



- 3 Then, your doctor will conduct additional lab tests to assess immune response, such as antibody and vaccine response



- 4 Finally, you may undergo complement screening,* have your enzymes measured, and have your family/genetics studied. In some cases, your doctor may order additional tests to more fully evaluate your condition

*Complement screening measures the activity of certain proteins in your blood. It is often used to monitor patients with an autoimmune disorder and to see if treatment is working.²

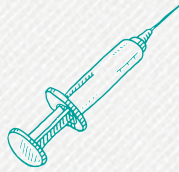
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YOUR TREATMENT OPTIONS

Treating PIDD isn't just about curing infections. It's also about dealing with the disease itself so you'll be less likely to get an infection in the first place. Luckily, there are several treatments available to you,² including:



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



Antibiotics, to kill infections and deal with a wide range of bacteria that more readily affect you if you have PIDD



Immune globulin (IG) therapy, which is recommended by most doctors and treats PIDD directly

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

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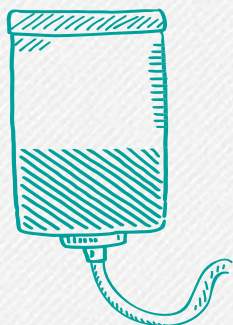


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HAVE PIDD? YOU CAN DO SOMETHING ABOUT IT

IG therapy—an effective way to take charge of PIDD

IG stands for immune globulin. It comprises healthy proteins taken from human plasma and contains purified antibodies. It is infused into your blood intravenously (in the vein) so it can help your immune system protect you from germs and other threats. In some cases, immune globulin therapy may be administered subcutaneously (under the skin).²



PLASMA

The liquid part of the blood that contains antibodies needed to keep you healthy

GAMUNEX-C: A PROVEN TREATMENT OPTION FOR PEOPLE WITH PIDD⁴

Fewer cases of infection

During a 9-month clinical study, patients with PIDD saw significant improvements when taking GAMUNEX-C including^{4*}:



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.

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.^{5,6}

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

SIDE EFFECTS⁶

What side effects can I expect 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 or older, have type 2 diabetes, kidney problems, use estrogens, 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.

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HOW THERAPY IS ADMINISTERED

There are 2 ways IG therapy can be given

ADMINISTERING GAMUNEX-C

GAMUNEX-C has been approved by the FDA to be administered by **intravenous (IV)** or **subcutaneous (sub Q)** injections.⁶ Your doctor will determine the treatment route and schedule that is best for you.



Remember to always 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.

AN IG THAT FITS YOUR LIFESTYLE

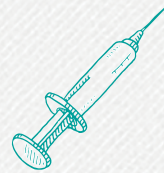
One of the benefits of GAMUNEX-C is that it can be given 2 ways, either through an IV into a vein or through a sub Q injection, which means into the skin. If administered by IV, it is given every 3 to 4 weeks; if given via sub Q injection, it is given weekly.⁶

Another benefit is that GAMUNEX-C comes ready to use, so there is no mixing and no waiting. You can begin your treatment almost immediately. If you and your doctor decide that sub Q administration is right for you, you may be able to administer it yourself at home.⁶



INTRAVENOUS

Administered through a vein, typically in your arm. It will most likely be at a doctor's office, hospital, or infusion center, or may be in your home, as determined by your treating physician



SUBCUTANEOUS

Administered through an injection, just below the skin. You can administer regular injections to yourself with a portable pump that regulates the rate of infusion. DO NOT inject GAMUNEX-C into a blood vessel or directly into a muscle

GAMUNEX-C is contraindicated in individuals with acute severe hypersensitivity reactions to immune globulin (human). It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

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LIVING WITH PIDD

Because you have a weakened immune system, it's important to protect yourself the best you can. If you or someone you know has PIDD, here are some simple steps you can take to help prevent infections:

Tips for preventing infections^{2,7}

Use proper hygiene by washing your hands with mild soap whenever using the toilet and before eating

Take care of your teeth by brushing at least 2 times a day

Eat a healthy, balanced diet to help prevent infections

Avoid exposure to people with colds or other infections and avoid crowds of people

Take your medications as prescribed to prevent infections

Check with your doctor about which vaccinations you need



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EDUCATION IS KEY

Educating yourself and others is critical to coping with PIDD so you or someone you know can get the most from treatment and live a healthier life. Here are some simple tips to help manage PIDD:

Tips for managing PIDD²



Learn all you can about PIDD



Educate others about the disease



If your child has PIDD, talk about it with his or her teachers



Teach your child about PIDD



Keep a journal and record how you feel

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YOUR TREATMENT SUPPORT PARTNER

Your dedicated Gamunex Connexions contact understands that the key to uninterrupted treatment is to have a strong support team behind you.



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connexions

Dedicated support for you during your treatment with GAMUNEX-C

- Provides educational information and support to address your healthcare needs
- Answers your questions about GAMUNEX-C
- Connects you with resources to help you manage your condition



Please see Important Safety Information on pages 22 and 23, and refer to accompanying full Prescribing Information for GAMUNEX-C.



YOUR FINANCIAL SUPPORT PARTNER

You may have questions about your treatment and the cost of therapy. At Gamunex Connexions, we're committed to helping you get and stay on therapy.

Copay Assistance Program for eligible patients*

Copay assistance up to \$10,000 per calendar year is available to help with:

- 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, effective January 1, 2022. For more information, visit GAMUNEX-C.com.



CALL THE DEDICATED GAMUNEX CONNEXIONS TEAM

Call **1-888-MYGAMUNEX (1-888-694-2686)**
Monday through Friday (8 AM to 8 PM ET)

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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

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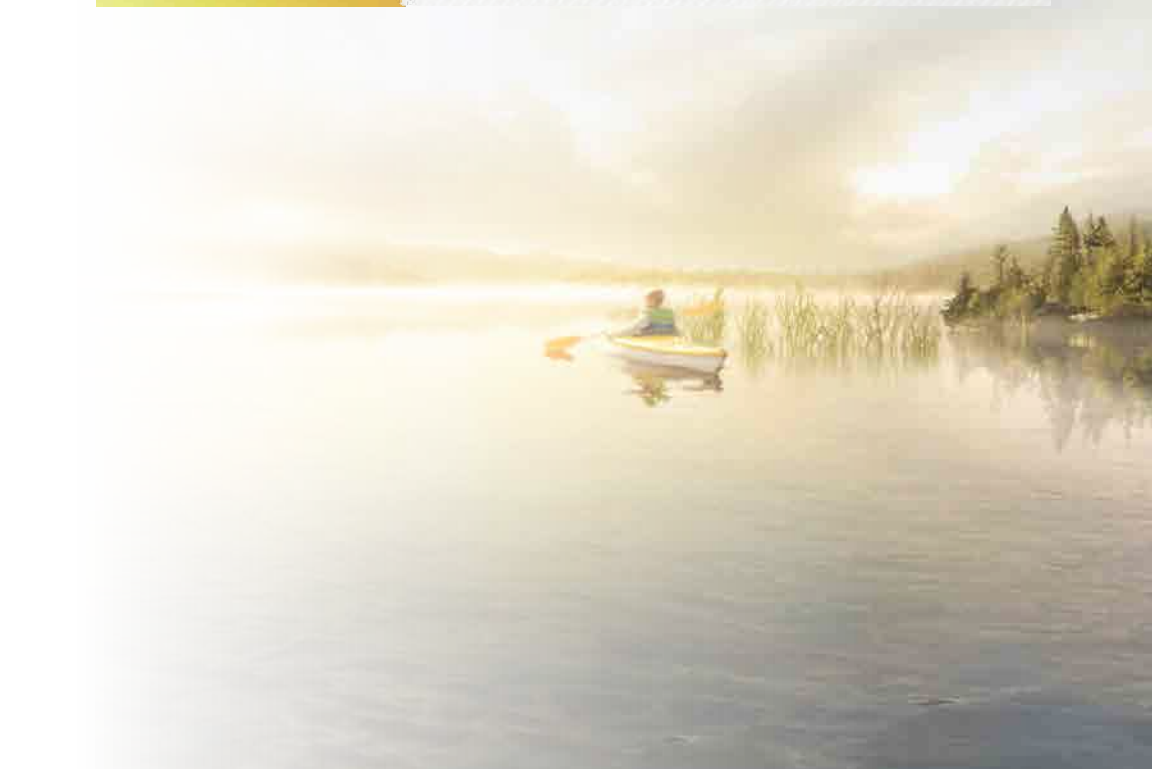


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FOR MORE INFORMATION GO TO:

GAMUNEX-C.com



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IMPORTANT SAFETY INFORMATION

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. If you have PIDD, 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.

References: **1.** About primary immunodeficiencies. Immune Deficiency Foundation website. <http://primaryimmune.org/about-primary-immunodeficiencies>. Accessed May 14, 2020. **2.** Blaes MR, Stiehm RE, Bonilla FA, Younger ME, eds. *Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases*. 5th ed. Towson, MD: Immune Deficiency Foundation; 2015. **3.** The Jeffrey Modell Foundation. 4 stages of testing for primary immunodeficiency. <http://downloads.info4pi.org/pdfs/4StagesFINAL.pdf>. Accessed May 26, 2016. **4.** 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. **5.** Data on file, Grifols. **6.** GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) Prescribing Information. Grifols. **7.** Primary immunodeficiency. Mayo Foundation for Medical Education and Research (MFMER) website. <http://www.mayoclinic.org/diseases/conditions/primary-immunodeficiency/basics/prevention/con-20031958?DSECTION=all>. Accessed May 31, 2016.

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To learn more about GAMUNEX-C and Gamunex Connexions,
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