



gamunex-c

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



THERE'S
MORE
TO YOU

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

**YOUR GUIDE TO UNDERSTANDING
THE TREATMENT OF CIDP***

*CIDP, chronic inflammatory demyelinating polyneuropathy.

Please see Important Safety Information on pages 12 and 13, and refer to accompanying full Prescribing Information for GAMUNEX-C.

GRIFOLS

WHAT IS CIDP?

CIDP is a rare and progressive autoimmune disease in which the body's own immune system attacks the nerves in the arms and legs.¹ The most common symptoms of CIDP are^{1,2}:

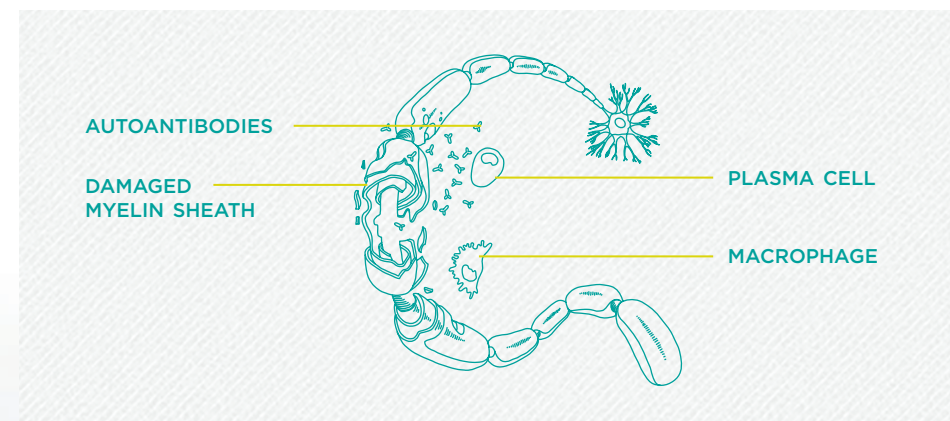
- Weakness
- Numbness
- Tingling in the legs, arms, fingers, and hands

Other symptoms include fatigue, pain, balance issues, and impairment of ability to walk.^{1,2}

The symptoms of CIDP usually occur on both sides of the body at the same time. But sometimes only one side is involved. These symptoms can be mild, moderate, or severe and can change in severity over time.^{2,3}

WHAT CAUSES CIDP?

CIDP occurs when myelin, the protective covering of the peripheral nerves (nerves located outside of the brain and spinal cord), is damaged by the body's own immune system.^{4,5}



Damage to nerves and their myelin covering means that messages from the brain to various parts of the body get disrupted, and this can cause weakness and gradual loss of sensations and reflexes. Over time, this damage may lead to disability in the arms and legs, and can have a negative impact on quality of life.⁶

HOW IS CIDP TREATED?

While there is no known cure for CIDP, it can be treated and symptoms may be reversed if caught early enough. It is critical to talk to a neurologist immediately because permanent nerve damage cannot be reversed.^{4,7}

There are 4 main treatments for CIDP

1. IVIG*: Healthy proteins called immunoglobulins are infused into your blood. They block the immune system from attacking myelin^{4,6}
2. Corticosteroids: Medicines that decrease inflammation and slow down the immune system^{8,9}
3. Plasmapheresis: A “plasma exchange” where blood is cleaned to remove antibodies that attack myelin¹⁰
4. Immunosuppressants: Medicines that interfere with the functioning of your immune system so that the attack on your myelin is decreased¹¹

*IVIG, intravenous immunoglobulin.



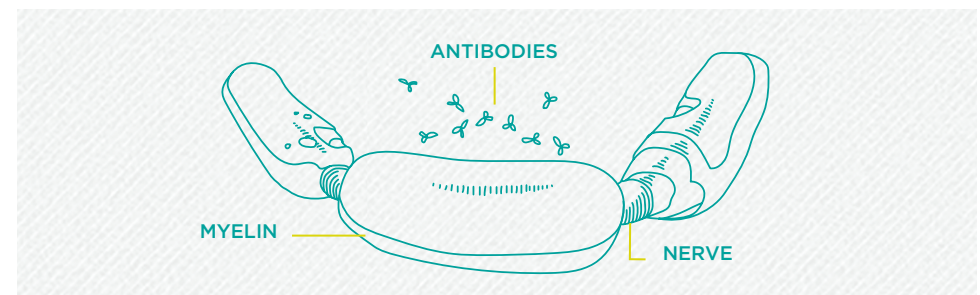
WHAT IS GAMUNEX-C?

GAMUNEX-C is an immune globulin therapy for the treatment of adult patients with CIDP. The immune globulins in GAMUNEX-C are healthy antibodies that come from donated human plasma.^{12,13}

Plasma is the liquid part of the blood and contains antibodies needed to keep you healthy.¹³

GAMUNEX-C is the #1 prescribed immune globulin therapy for CIDP¹³

In people with CIDP, it's believed that GAMUNEX-C provides healthy antibodies to block the immune and inflammatory processes that attack and destroy the protective covering around the nerve fibers.



The way in which GAMUNEX-C works in treatment of people with CIDP is not completely understood.¹⁴

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.

WHO IS GAMUNEX-C MADE FOR?

GAMUNEX-C may be an option for people with CIDP including those who have other conditions such as diabetes, heart complications, and kidney problems.¹⁵ Because of this, treatment with GAMUNEX-C may meet the needs of a variety of CIDP patient types.

An option for CIDP patients who have diabetes

Immune globulin (IG) therapies containing sugar stabilizers are more likely to interfere with diabetes treatments and cause kidney-related side effects. GAMUNEX-C contains no sugar and no preservatives.¹⁵

An option for CIDP patients who have heart conditions

Increased salt content may increase the risk of swelling, fluid overload, and congestive heart failure. GAMUNEX-C contains only trace amounts of salt.¹⁵

In a clinical study with CIDP patients who received 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.

The most serious side effect in a CIDP clinical trial was a blood clot to the lung (pulmonary embolism) in 1 patient with a history of this condition.

WILL GAMUNEX-C WORK FOR ME?

While there is no cure for CIDP, it can be treated, and many patients feel an improvement in symptoms of weakness, numbness, and poor balance after just 3 weeks. In clinical studies, GAMUNEX-C was shown to improve neuromuscular disability and impairment.

In the landmark ICE* trial—the longest IVIG study for CIDP—patients treated with GAMUNEX-C demonstrated¹⁶:

- Significant improvement in disability scores through 24 weeks
- Improved grip strength in both hands

“Oh my gosh, **I CAN ACTUALLY PICK UP** a plate and take it to a table at my restaurant.”
— Alen, treated with GAMUNEX-C



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.

*ICE, caprylate-chromatography purified immune globulin intravenous (IGIV-C) CIDP efficacy.

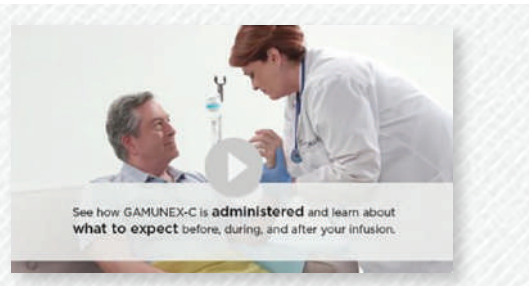
HOW IS GAMUNEX-C ADMINISTERED?

GAMUNEX-C is administered intravenously (IV) through a vein, typically in the arm. It can be taken at an infusion center, hospital, or in the convenience of the home.

Preparing for intravenous therapy

- Your first infusion of GAMUNEX-C may occur over the course of 2 days or longer. During this time, your healthcare professional will be closely monitoring your health status to ensure that you are tolerating GAMUNEX-C
 - Make sure you drink lots of fluids and increase your fluid intake 24 hours before infusion
- After your first infusion, administration of GAMUNEX-C usually takes 2 to 4 hours from start to finish
 - Consider bringing something to occupy your time, like a game, book, or tablet
- Your neurologist or infusion nurse may ask you to keep track of how you're feeling so that he/she can determine the treatment schedule that is right for you

**TO SEE A VIDEO ON
HOW GAMUNEX-C
IS ADMINISTERED,
VISIT GAMUNEX-C.COM.**



ARE THERE SIDE EFFECTS WITH GAMUNEX-C?

All medicines have risks and side effects. And, treatments for CIDP are not an exception to this. Be sure to speak with a neurologist about these common side effects of GAMUNEX-C.

The most common side effects for CIDP patients taking GAMUNEX-C were¹⁴:

- Pain in the region of the head or neck
- Raised body temperature or fever
- Abnormally high blood pressure
- Feelings of coldness and/or shivering
- Noticeable change in the texture or color of your skin such as your skin becoming scaly, bumpy, itchy, or otherwise irritated
- Sensation of unease and discomfort in the upper stomach
- Joint pain
- Abnormal physical weakness or lack of energy

Although very rare, treatment with GAMUNEX-C may cause serious side effects such as¹⁴:

- Blood clots in the lungs (pulmonary embolism)



**HAVE QUESTIONS ABOUT POTENTIAL SIDE EFFECTS?
SPEAK WITH A CERTIFIED NURSE AT GAMUNEX CONNEXIONS.**

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



YOUR TREATMENT SUPPORT PARTNER

Your dedicated Gamunex Connexions contact understands that the key to managing your CIDP is to have a strong support team behind you.



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



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)



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 PID 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 PID 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 PID), 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.

CIDP RESOURCES AND SUPPORT*

The CIDP advocacy organizations below are intended to connect you to additional educational resources about treatment.



GBS/CIDP FOUNDATION INTERNATIONAL

GBS/CIDP Foundation International provides support and assistance to patients with Guillain-Barré syndrome (GBS) and CIDP, and their families.

www.gbs-cidp.org



FOUNDATION FOR PERIPHERAL NEUROPATHY

The Foundation for Peripheral Neuropathy is the leading national nonprofit organization serving the peripheral neuropathy community.

www.foundationforpn.org

References: **1.** Chronic inflammatory demyelinating polyradiculoneuropathy. University of Rochester Medical Center website. <https://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=134&ContentID=210>. Accessed January 9, 2017. **2.** Chronic inflammatory demyelinating polyneuropathy (CIDP). University of Chicago Center for Peripheral Neuropathy website. <http://peripheralneuropathycenter.uchicago.edu/learnaboutpn/typesofpn/inflammatory/cidp.shtml>. Accessed February 16, 2017. **3.** Gorson KC, Gooch CL. The (mis)diagnosis of CIDP: the high price of missing the mark. *Neurology*. 2015;85(6):488-489. **4.** Chronic inflammatory demyelinating polyneuropathy. National Institutes of Health website. <https://medlineplus.gov/ency/article/000777.htm>. Accessed January 9, 2017. **5.** Evers R, Rinaldi S. *CIDP and the Chronic Variants*. Sleaford, UK: Guillain-Barré & Associated Inflammatory Neuropathies (GAIN); 2017. **6.** Koski CL. *CIDP: Chronic Inflammatory Demyelinating Polyneuropathy*. Narberth, PA: GBS/CIDP Foundation International; 2012. **7.** Köller H, Kieseier BC, Jander S, Hartung HP. Chronic inflammatory demyelinating polyneuropathy. *N Engl J Med*. 2005;352(13):1343-1356. **8.** Corticosteroid (oral route, parenteral route). Mayo Clinic website. <http://www.mayoclinic.org/drugs-supplements/corticosteroid-oral-route-parenteral-route/description/drg-20070491?p=1>. Accessed February 24, 2017. **9.** Steroids. NHS Choices website. [http://www.nhs.uk/conditions/corticosteroid-\(drugs\)/pages/introduction.aspx](http://www.nhs.uk/conditions/corticosteroid-(drugs)/pages/introduction.aspx). Accessed February 24, 2017. **10.** Plasmapheresis. National Multiple Sclerosis Society website. <http://www.nationalmssociety.org/Treating-MS/Managing-Relapses/Plasmapheresis>. Accessed March 10, 2017. **11.** Treating lupus with immunosuppressive medications. Johns Hopkins Medicine website. <https://www.hopkinslupus.org/lupus-treatment/lupus-medications/immunosuppressive-medications/>. Accessed February 24, 2017. **12.** National Institutes of Health. *Understanding the Immune System: How It Works*. Bethesda, MD: National Institutes of Health, US Dept of Health and Human Services; 2003. **13.** Data on file, Grifols. **14.** GAMUNEX[®]-C (immune globulin injection [human], 10% caprylate/chromatography purified) Prescribing Information. Grifols. **15.** Gelfand EW. Differences between IGIV products: impact on clinical outcome. *Int Immunopharmacol*. 2006;6(4):592-599. **16.** Hughes RAC, Donofrio P, Bril V, et al; on behalf of the ICE Study Group. Intravenous immune globulin (10% caprylate-chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial. *Lancet Neurol*. 2008;7(2):136-144.

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

gamunex[®]-c



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caprylate/chromatography purified



To learn more about GAMUNEX-C and Gamunex Connexions,
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