YOUR GUIDE TO UNDERSTANDING THE TREATMENT OF CIDP*



*CIDP, chronic inflammatory demyelinating polyneuropathy.



What is CIDP?

CIDP is a rare, typically progressive autoimmune disease that involves nerve damage or dysfunction in the arms and legs. It occurs when the immune system malfunctions, creating an inflammatory response. The immune system attacks the peripheral nerves, which are nerves located outside the brain and spinal cord.^{1,2}

CAREGIVER TIP

If you care for someone with CIDP, you may hear them describe their symptoms as...

"a lightning storm taking place in my arms and legs."





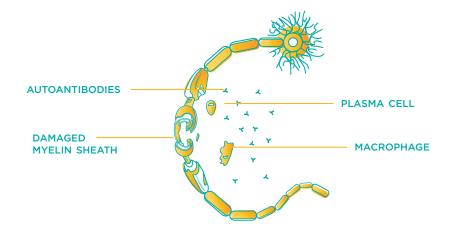


What is happening in CIDP?

In CIDP, the autoimmune process damages the protective covering of the nerves, called the myelin sheath. This impairs the ability of nerve fibers to carry signals between the brain and various parts of the body.^{2,3}

CIDP symptoms can vary from person to person and usually occur on both sides of the body at the same time. The most common CIDP symptoms are $^{2-4}$:

- · Loss of muscle strength
- Change in sensation in the feet, fingers, and hands



Symptoms of CIDP may appear in the arms and legs.



What to expect with CIDP

The symptoms of CIDP can make daily activities a challenge. Sometimes numbness and tingling in the fingers and toes can make reaching for items difficult. Climbing stairs or walking can be affected by weakness or balance issues. Fatigue and pain may occur and can be frustrating and even debilitating.



Starting treatment for CIDP
as soon as possible can help relieve
these symptoms and protect
your nerves from damage.



CIDP or something else?

CIDP can be difficult to diagnose because symptoms can vary or even resemble those of other nervous system disorders.

CIDP variations⁵

- Distal CIDP: distal sensory loss and muscle weakness predominantly in lower limbs
- Multifocal CIDP: sensory loss and muscle weakness in a multifocal pattern, usually asymmetric, upper limb predominant, in more than one limb
- Focal CIDP: sensory loss and muscle weakness in only one limb
- Motor CIDP: motor symptoms and signs without sensory involvement
- Sensory CIDP: sensory symptoms and signs without motor involvement

Other disorders that can resemble CIDP3,6

- Multiple sclerosis (MS)
- Amyotrophic lateral sclerosis (ALS)
- Guillain-Barré syndrome (GBS)

Take notes about what you or your loved one experience to share with your healthcare team so they can help you determine the right treatment.





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.^{7,8} Your healthcare provider may consider these available treatment options:

- 1. **IG***: Proteins called immunoglobulins are infused into your blood intravenously (IV) or subcutaneously (SC). They block the immune system from attacking myelin^{4,7}
- 2. Corticosteroids: Medicines that decrease inflammation and slow down your immune system⁹
- **3. Plasmapheresis**: A "plasma exchange" where blood is cleaned to remove antibodies¹⁰
- **4. Immunosuppressants:** Medicines that interfere with the functioning of your immune system so that the attack on your myelin is decreased^{2,11}

*IVIG, intravenous immunoglobulin; SCIG, subcutaneous immunoglobulin.

Please see Important Safety Information on pages 16 and 17 and refer to accompanying full Prescribing Information for GAMUNEX-C.



What are the goals of CIDP treatment?

The goals of treatment include short- and long-term goals that you and your healthcare team decide on together. Talking about your personal goals with your healthcare team can help guide decisions about your treatment. Your goals may include:

Short-term goals

- Feeling better: your symptoms and quality of life improve
- Understanding your diagnosis and what treatment will involve

Long-term goals

- Regaining and maintaining your functionality and independence
- Recognizing and addressing other quality-of-life concerns you may have
- Reducing the burden of treatment



To learn more about what to expect with CIDP treatment, call the dedicated Gamunex Connexions® team.

Call **1-888-MYGAMUNEX** (**1-888-694-2686**)

Monday through Friday (8 AM to 8 PM ET)





*Definitive Healthcare, LLC. March 2020-May 2023.



What is GAMUNEX-C?

GAMUNEX-C is an immune globulin, or IG, therapy for the treatment of adult patients with CIDP.

IG is a medicine made from proteins called antibodies taken from human plasma, the liquid part of the blood. 12,13

GAMUNEX-C blocks the autoimmune and inflammatory processes, resulting in symptom improvement and nerve protection¹⁴



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.



Will GAMUNEX-C work for me?

GAMUNEX-C works in multiple ways* to fight inflammation.¹⁵



In clinical studies, some patients felt improvement in physical functioning after just 3 weeks of treatment.¹⁵

In a landmark trial of GAMUNEX-C, the longest randomized study of IVIG in CIDP, the majority of patients¹⁵:

- Had significant improvement in disability scores through week 24 (primary endpoint)
- Experienced improved grip strength in both hands
- Who responded to treatment maintained their improvement with long-term treatment

In a clinical study of patients with CIDP 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 skin's texture or color such as scaliness, bumps, itching, or other irritation; a sensation of unease and discomfort in the upper stomach; joint pain; and abnormal physical weakness or lack of energy.

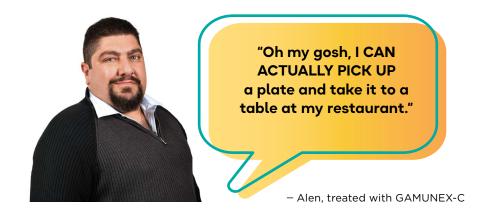
The most serious side effect in a CIDP clinical trial was a blood clot to the lung (pulmonary embolism) in 1 patient with a history of this condition.

^{*}The way in which GAMUNEX-C works in treatment of people with CIDP is not completely understood.



GAMUNEX-C is an option for a variety of patient types¹⁶

- Diabetes: GAMUNEX-C contains no sugar and no preservatives
- · Heart conditions: GAMUNEX-C contains only trace amounts of salt



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.





How is GAMUNEX-C administered?

When used to treat CIDP, GAMUNEX-C is administered intravenously (IV) through a vein, typically in the arm. It can be received at an infusion center, hospital, or in the convenience of your home.

Preparing for intravenous therapy

- Your first dose, or loading dose, of GAMUNEX-C may be split up over several days. Your healthcare professional will monitor your initial infusion closely and help with any questions you may have
- Maintenance doses of GAMUNEX-C usually take 2 to 4 hours from start to finish. Maintenance doses are given once every 3 weeks to prevent relapse
- Your neurologist or infusion nurse may ask you to keep track of how you're feeling so that he/she can evaluate your response to therapy



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.

In a clinical study, the most common side effects in patients with CIDP receiving GAMUNEX-C were:

- 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 skin's texture or color such as scaliness, bumps, itching, or other irritation
- 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 as blood clots in the lungs (pulmonary embolism).¹⁷

Have questions or concerns about potential side effects?

Talk with your healthcare team to learn what to look for.





"Gamunex Connexions was a great program. I was able to have assistance with my copays."

- Julie, treated with GAMUNEX-C

Sign up on GAMUNEX-C.com to receive more information about GAMUNEX-C





The dedicated team at Gamunex Connexions understands the importance of having support when you need it.

Financial assistance programs for eligible patients*

- Copay assistance: helps with deductibles, copayments, and coinsurance
- Patient Assistance Program: you may be qualified to receive GAMUNEX-C at no cost, in the event that you lose insurance coverage

Call the dedicated Gamunex Connexions team.

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^{*}Subject to terms and conditions. For more information, visit GAMUNEX-C.com.

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.

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

^{*}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.



References: 1. Chronic inflammatory demyelinating polyneuropathy (CIDP). University of Chicago Center for Peripheral Neuropathy website. http://peripheralneuropathycenter.uchicago.edu/learnaboutpn/typesofpn/inflammatory/ cidp.shtml. Accessed November 30, 2023. 2. Chronic inflammatory demyelinating polyradiculoneuropathy. University of Rochester Medical Center website. https://www.urmc.rochester.edu/encyclopedia/content. aspx?ContentTypeID=134&ContentID=210. Accessed November 30, 2023. 3. Gorson KC, Gooch CL. The (mis)diagnosis of CIDP: the high price of missing the mark. Neurology. 2015;85(6):488-489. 4. Koski CL. CIDP: Chronic Inflammatory Demyelinating Polyneuropathy. Narberth, PA: GBS/CIDP Foundation International; 2012. 5. Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy; report of a joint task force-second revision. Eur J Neurol. 2021;28(11):3556-3583. 6. Evers E, Hughes R, Rinaldi S. CIDP and the Chronic Variants. Sleaford, UK: Guillain-Barré & Associated Inflammatory Neuropathies (GAIN); 2017. 7. Chronic inflammatory demyelinating polyneuropathy. National Institutes of Health website. https://medlineplus.gov/ency/article/000777. htm. Accessed November 30, 2023. 8. Köller H, Kieseier BC, Jander S, Hartung HP. Chronic inflammatory demyelinating polyneuropathy. N Engl J Med. 2005;352(13):1343-1356. 9. 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 November 30, 2023. 10. Plasmapheresis. National Multiple Sclerosis Society website. https:// www.nationalmssociety.org/Treating-MS/Managing-Relapses/Plasmapheresis. Accessed November 30, 2023. 11. Treating lupus with immunosuppressive medications. Johns Hopkins Medicine website. https://www.hopkinslupus. org/lupus-treatment/lupus-medications/immunosuppressive-medications/. Accessed November 30, 2023. 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. Khoo A, Frasca J, Schultz D. Measuring disease activity and predicting response to intravenous immunoglobulin in chronic inflammatory demyelinating polyneuropathy. Biomark Res. 2019;7:3. 15. 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. 16. Gelfand EW. Differences between IGIV products: impact on clinical outcome. Int Immunopharmacol. 2006;6(4):592-599. 17. GAMUNEX®-C (immune globulin injection [human], 10% caprylate/ chromatography purified) Prescribing Information. Grifols.







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



