gamunex®-C

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

GRIFOLS

Please see Important Safety Information on pages 8–9, and refer to accompanying full Prescribing Information for GAMUNEX-C.

Uncover CIDP diagnosis

CIDP is more common than you think[1-4]

Diagnosing CIDP is challenging[3,5]

Untreated demyelination can lead to permanent disability[6]

Early initiation of treatment is critical

COULD IT BE CIDP?

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Diagnosing CIDP can be challenging

44% **of patients with CIDP are first misdiagnosed with a different condition[7]**

SYMPTOMS CAN PRESENT IN TYPICAL AND ATYPICAL WAYS AND PATIENTS WITH ATYPICAL SYMPTOMS MAY BE MISDIAGNOSED[3,5]

- CIDP can be highly variable among patients in the early course of their disease
- Nearly 40% of patients initially present with atypical symptoms[8]

TYPICAL CIDP SYMPTOMS

- Slow onset over 8 weeks or months
- Chronic or stepwise progression
- Symmetrical symptoms
- Distal and proximal weakness
- Motor and sensory loss
- Diffusely absent reflexes
- Paresthesia

ATYPICAL CIDP SYMPTOMS

- Acute onset
- Slower onset over many months
- Relapsing and remitting
- Asymmetrical symptoms
- Only distal weakness
- Only proximal weakness
- Only sensory dominant
- Only motor loss
- Absent reflexes only in affected limbs
- Pain

It can be difficult to differentiate CIDP from DPN

THOUGH SIMILAR IN PRESENTATION, THERE ARE KEY DIFFERENCES BETWEEN TYPICAL CIDP AND DPN[10,11]*

TYPICAL CIDP	DPN
✔ Distal and proximal weakness	✔ Distal weakness mainly in the feet
✔ Motor and sensory loss	✔ Sensory loss, with no motor loss observed
✔ Reduced or absent reflexes	✔ Absent ankle jerks
✔ Symptoms evolve over months	✔ Symptoms evolve over years

*DPN, diabetic peripheral neuropathy.

When a patient with diabetes presents with weakness consider CIDP in your differential diagnosis

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THINK CIDP

Accurate diagnosis of CIDP requires a stepwise approach

USE A COMBINATION OF SUBJECTIVE AND OBJECTIVE MEASURES TO REACH A DIAGNOSIS[13]

Recognition

Patient history

- Medical history
- Family history

Physical exam

- **Motor exam:** Proximal and distal weakness in upper and lower limbs
- **Sensory exam:** Sensitivity to touch, vibration, and proprioception
- **Reflexes:** Absent or diminished reflexes
- **Gait:** Stability while standing and walking

Confirmation

- Electromyography (EMG)
- Nerve conduction study (NCS)

Additional tests:

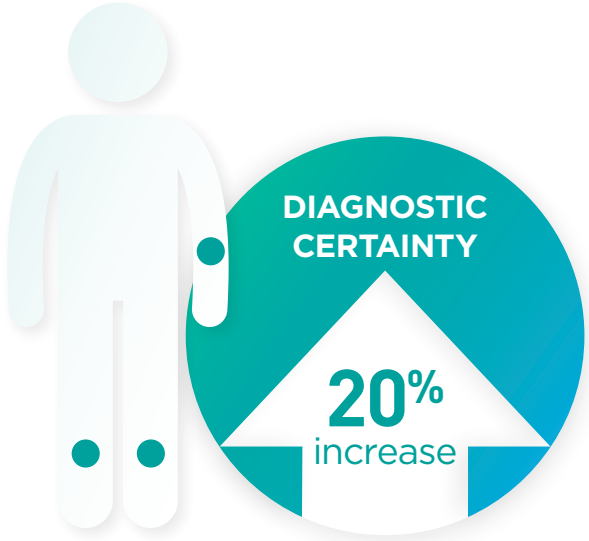
- Spinal tap
- Magnetic Resonance Imaging (MRI)

"Chronic inflammatory demyelinating polyneuropathy is clinically heterogeneous and so is best evaluated with a diverse group of assessment tools."

—Allen J et al, *JAMA Neurol*, April 2020

Electrodiagnostic testing on 3 limbs increases diagnostic accuracy of atypical CIDP

TESTING OF 2 LIMBS WAS SUFFICIENT TO DIAGNOSE 92% OF PATIENTS WITH TYPICAL CIDP, BUT ONLY 66% OF PATIENTS WITH ATYPICAL CIDP[9]



THE 4 MOST USEFUL ELECTRODIAGNOSTIC FINDINGS TO SUPPORT A CIDP DIAGNOSIS ARE:

Slow conduction velocity[10]	Delayed or absent F waves[10]	Prolonged distal latency[10]	Abnormal temporal dispersion[12]

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Important Safety Information

GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is indicated for the treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older, idiopathic thrombocytopenic purpura (ITP) in adults and children, and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

Thrombosis may occur with immune globulin products, including GAMUNEX-C. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer GAMUNEX-C at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IVIG) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose. GAMUNEX-C does not contain sucrose. For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable.

GAMUNEX-C is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Severe hypersensitivity reactions may occur with IVIG products, including GAMUNEX-C. In case of hypersensitivity, discontinue GAMUNEX-C infusion immediately and institute appropriate treatment.

Monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IVIG treatment, including GAMUNEX-C.

There have been reports of aseptic meningitis, hemolytic anemia, and noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) in patients administered with IVIG, including GAMUNEX-C.

The high-dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

Because GAMUNEX-C is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Do not administer GAMUNEX-C subcutaneously in patients with ITP because of the risk of hematoma formation.

Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of GAMUNEX-C and at appropriate intervals thereafter.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies, because of the potentially increased risk of thrombosis.

If signs and/or symptoms of hemolysis are present after an infusion of GAMUNEX-C, perform appropriate laboratory testing for confirmation.

If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient's serum.

After infusion of IgG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.

In clinical studies, the most common adverse reactions with GAMUNEX-C were headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia (in CIDP); cough, rhinitis, pharyngitis, headache, asthma, nausea, fever, diarrhea, and sinusitis with intravenous use (in PIDD) and local infusion-site reactions, fatigue, headache, upper respiratory tract infection, arthralgia, diarrhea, nausea, sinusitis, bronchitis, depression, allergic dermatitis, migraine, myalgia, viral infection, and pyrexia with subcutaneous use (in PIDD); and headache, ecchymosis, vomiting, fever, nausea, rash, abdominal pain, back pain, and dyspepsia (in ITP).

The most serious adverse reactions in clinical studies were pulmonary embolism (PE) in 1 subject with a history of PE (in CIDP), an exacerbation of autoimmune pure red cell aplasia in 1 subject (in PIDD), and myocarditis in 1 subject that occurred 50 days post-study drug infusion and was not considered drug related (in ITP).

Please see accompanying full Prescribing Information for GAMUNEX-C.

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#1 PRESCRIBED IG FOR CIDP[13]

Uncover CIDP diagnosis

RECOGNIZE, CONFIRM, AND TREAT

RECOGNIZE THE SYMPTOMS

- CIDP may be more common than you think[1-4]
- Diagnosis can be challenging with symptoms presenting in typical and atypical ways[3,5]

CONFIRM THE DIAGNOSIS

- Electrodiagnostic testing on 3 limbs increases diagnostic accuracy of atypical CIDP[9]
- Accurate diagnosis of CIDP requires a stepwise approach[13]

TREAT TO PREVENT ONGOING DAMAGE

- CIDP is a treatable neuropathy[14]
- GAMUNEX-C offers a proven formulation for a wide range of patient types[15,16]
- All GAMUNEX-C responders achieved maximal clinical response by 24 weeks[17]

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ADVERSE REACTIONS IN CIDP STUDY

In CIDP, the most common adverse reactions with GAMUNEX-C were headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia. The most serious adverse reaction was pulmonary embolism (PE) in 1 subject with a history of PE.

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