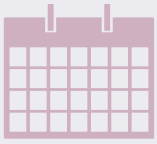
Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

Optimizing the Transition to Hizentra for CIDP Patients

Chronic Inflammatory Demyelinating Polyneuropathy

Consider this information when starting Hizentra therapy

Initiate therapy with Hizentra 1 week after the last IVIg infusion



Monitor your patients and adjust dosing as needed

- Recommended subcutaneous dose is 0.2 g/kg body weight per week*
  - A dose of 0.4 g/kg body weight per week was also safe and effective
- If CIDP symptoms worsen on 0.2 g/kg consider increasing to 0.4 g/kg per week*
- Most patients remained relapse-free on either dosing option, with the 0.4 g/kg dose showing a lower rate of relapse†‡
  - If CIDP symptoms worsen on the 0.4 g/kg dose, consider reinitiating therapy with IVIg

*Administered in 1 or 2 sessions over 1 or 2 consecutive days.
†CIDP relapse was defined as a ≥1 point increase in adjusted Inflammatory Neuropathy Cause and Treatment [INCAT] score compared with baseline.
‡Statistical tests between the two doses were not conducted.

Proactively Optimize Infusion

- Volume and rate can be adjusted after initial infusion as tolerated, which may decrease infusion time and number of sites
- Consider changing one variable at a time (eg, rate, volume, ancillary supplies, site) to help achieve ideal treatment for your patient
- Hizentra may be infused up to 8 infusion sites simultaneously, depending on the volume
- In a clinical study, site reactions were common and reports decreased in frequency over time

Administration Parameters

	Infusion parameters§	1st infusion	Subsequent infusions
CIDP Weekly	Volume (mL/site)	≤20	≤50
	Rate (mL/hr/site)	≤20	≤50

§As tolerated.

Indication

Hizentra is indicated for:

- Treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years and older.
- Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.
  - Limitation of Use: Maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only.

Important Safety Information

WARNING: Thrombosis may occur with immune globulin products, including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

For patients at risk of thrombosis, administer Hizentra 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.

Important Safety Information continues on back cover. Please see full prescribing information for Hizentra, including boxed warning, attached.

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Dosing Chart

Weight		Dose	Total weekly volume	# sites*	Time per infusion*
Pounds (lbs)	Kilograms (kgs)				
132 lb	60 kg	0.2 g/kg	60 mL	2	~1 hour
		0.4 g/kg	120 mL	3	
176 lb	80 kg	0.2 g/kg	80 mL	2	
		0.4 g/kg	160 mL	4	
198 lb	90 kg	0.2 g/kg	90 mL	2	
		0.4 g/kg	180 mL	4	

*As tolerated; the number of sites and time per infusion is based on subsequent infusions.

Personalize treatment for your patients with our dosing calculator at **Hizentra.com**

Hizentra is available in a range of vial and prefilled syringe sizes

- 5, 10, 20, and 50 mL vials
- 5, 10, and 20 mL prefilled syringes

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Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin (Ig) or components of Hizentra (eg, polysorbate 80), as well as in patients with immunoglobulin A deficiency with antibodies against IgA and a history of hypersensitivity. Because Hizentra contains L-proline as stabilizer, use in patients with hyperprolinemia is contraindicated.

IgA-deficient patients with anti-IgA antibodies are at greater risk of severe hypersensitivity and anaphylactic reactions. Thrombosis may occur following treatment with Ig products, including Hizentra.

Monitor patients for aseptic meningitis syndrome (AMS), which may occur following treatment with Ig products, including Hizentra. In patients at risk of acute renal failure, monitor renal function, including blood urea nitrogen, serum creatinine and urine output. In addition, monitor patients for clinical signs of hemolysis or pulmonary adverse reactions (eg, transfusion-related acute lung injury [TRALI]).

Hizentra is derived from human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

The most common adverse reactions (observed in ≥5% of study subjects) were local infusion-site reactions, as well as headache, diarrhea, fatigue, back pain, nausea, extremity pain, cough, upper respiratory tract infection, rash, pruritus, vomiting, upper abdominal pain, migraine, arthralgia, pain, fall, and nasopharyngitis.

The passive transfer of antibodies can interfere with response to live virus vaccines and lead to misinterpretation of serologic test results.

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To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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