CSL Behring

Product fact sheet

Indications

Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid, 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.

Please see Important Safety Information on page 3 and full prescribing information for Hizentra including boxed warning.

Healthcare Systems

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

Product information

Brand name	Hizentra
Generic name	Immune globulin subcutaneous (human), 20% liquid
WAC price (per 5 mL)	$227.39
HCPCS J-code	J1559

NDCs

Package size (g)	NDC number
Single-dose prefilled syringe	
1 g	44206-456-21
2 g	44206-457-22
4 g	44206-458-24
10 g	44206-455-25

Storage and handling

- Store the Hizentra prefilled syringe in its original carton to protect it from light
- Each prefilled syringe label contains a peel-off strip with the prefilled syringe size and product lot number for use in recording doses in a patient treatment record
- When stored at room temperature (up to 25 °C [77 °F]), Hizentra is stable for up to 30 months, as indicated by the expiration date printed on the outer carton of the prefilled syringe label
- Do not shake the Hizentra prefilled syringe
- Do not freeze. Do not use product that has been frozen
- Discard any unused product and all used disposable supplies after each infusion

How supplied

Hizentra is supplied in a prefilled syringe containing 0.2 grams of protein per mL of preservative-free liquid. The HIZENTRA packaging components are not made with natural rubber latex.

Hizentra is available as a 0.2 g per mL (20%) protein solution for subcutaneous infusion.

The product presentation includes a package insert and a single-dose prefilled syringe (1 g, 2 g, 4 g, or 10 g).

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; WAC=wholesale acquisition cost.

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Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid

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.

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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