

## Switch to Hizentra

Manufactured by CSL Behring, maker of Vivaglobin®, Immune Globulin Subcutaneous (Human)

Feature	Vivaglobin	Hizentra
Concentration/form/administration	16% liquid SClg	20% liquid SClg
Storage	Refrigerate at 36°F – 46°F (2°C – 8°C)	Room temperature up to 77°F (25°C) for 18 months
Stabilizer	Glycine	Proline*
Infusion rate	Initial infusion at ≤ 5 mL/hr/site, as tolerated; gradually increase to 20 mL/hr/site, as tolerated	Initial infusion at ≤ 15 mL/hr/site; may be increased, as tolerated, to ≤ 25 mL/hr/site†
IgA content	≤ 1700 mcg/mL <sup>1</sup>	≤ 50 mcg/mL
IgG purity	≥ 96%	≥ 98%
Sucrose/sugars	None	None
Sodium	3 mg/mL	Trace (≤ 10 mmol/L)
Latex-free	Product and packaging	Product and packaging
Vial sizes (NDC)	3 mL (0053-7596-01) 10 mL (0053-7596-10) 20 mL (0053-7596-20)	1 g in 5 mL (44206-451-01) 2 g in 10 mL (44206-452-02) 4 g in 20 mL (44206-454-04)

\*Proline is one of 20 naturally occurring amino acids that form human proteins. It can be synthesized by the human body or obtained from dietary sources. CSL Behring chose proline as the stabilizer for Hizentra after extensive testing and analysis of other amino acids.<sup>1</sup>

†Infusion rate must not exceed 50 mL/hr for all sites combined.

### Important Safety Information

Hizentra and Vivaglobin are indicated for the treatment of patients with primary immunodeficiency (PI).

Hizentra and Vivaglobin are contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations or components of the product; they are also contraindicated in persons with selective immunoglobulin A deficiency who have known antibody against IgA.

**Please see reverse for full Important Safety Information and full Prescribing Information for Hizentra and Vivaglobin in pocket.**

**Hizentra™**  
Immune Globulin Subcutaneous  
(Human) **20% Liquid**

# Switch to Hizentra

## The first and only FDA-approved 20% SCIg therapy for the treatment of primary immunodeficiency disease

- Room temperature storage over entire 18-month shelf life
- 0 serious bacterial infections (SBIs)\* per subject year in the clinical trial
- 2.76 infections per subject year in the clinical trial
- Manufactured by CSL Behring, maker of Vivaglobin®, Immune Globulin Subcutaneous (Human)

### Dosage Forms

Grams Protein	Fill Size (mL)	NDC Number
1	5	44206-451-01
2	10	44206-452-02
4	20	44206-454-04



### IgIQ—Your single source for Ig solutions

To learn more about Hizentra resources for healthcare providers and patients, call **IgIQ**—CSL Behring's Ig resource hotline—at **1-877-355-IGIQ (1-877-355-4447)**

For more information, visit [www.Hizentra.com](http://www.Hizentra.com)

\*Defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.

**Reference: 1.** Data on file. CSL Behring LLC.

Hizentra is manufactured by CSL Behring AG and distributed by CSL Behring LLC. Hizentra is a trademark of CSL Behring AG.

Vivaglobin is manufactured by CSL Behring GmbH and distributed by CSL Behring LLC. Vivaglobin is a registered trademark of CSL Behring GmbH.

©2010 CSL Behring LLC  
 1020 First Avenue, PO Box 61501  
 King of Prussia, PA 19406-0901 USA  
[www.CSLBehring-us.com](http://www.CSLBehring-us.com) [www.Hizentra.com](http://www.Hizentra.com)  
 09-HIZ-010R 5/2010

### Important Safety Information

Hizentra and Vivaglobin are indicated for the treatment of patients with primary immunodeficiency (PI).

Hizentra and Vivaglobin are contraindicated in individuals with a history of anaphylactic or severe systemic response to immune globulin preparations or components of the product; they are also contraindicated in persons with selective immunoglobulin A deficiency who have known antibody against IgA.

Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin preparations or components of Hizentra, such as polysorbate 80. Because it contains the stabilizer L-proline, Hizentra is also contraindicated in patients with hyperprolinemia.

All IgA-deficient patients with anti-IgA antibodies are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. If hypersensitivity occurs or anaphylactic reactions are suspected, discontinue administration immediately and treat as medically appropriate.

Hizentra and Vivaglobin are derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

In separate clinical trials for Hizentra and Vivaglobin, the most frequent adverse event was injection-site reaction, consisting of mild or moderate swelling, redness, and itching. With Vivaglobin, no serious local site reactions were observed, and reactions tended to decrease substantially after repeated use. Other adverse events with Vivaglobin, irrespective of causality, included headache, gastrointestinal disorder, fever, nausea, sore throat, and rash.

The most common drug-related adverse reactions with Hizentra (observed in 5% or more of subjects in the clinical trial) were local injection-site reactions, headache, vomiting, pain, and fatigue.

Monitor patients for reactions associated with IVIg treatment that might also occur with Hizentra, including renal dysfunction/failure, thrombotic events, aseptic meningitis syndrome (AMS), hemolysis, and transfusion-related acute lung injury (TRALI).

Patients receiving Ig therapy for the first time, receiving a new product, or not having received Ig therapy within the preceding eight weeks may be at risk for developing reactions including fever, chills, nausea, and vomiting. On rare occasions, these reactions may lead to shock. Such patients should be monitored in a clinical setting during the initial administration. Ig administration can transiently impair the efficacy of live attenuated virus vaccines, such as measles, mumps and rubella. It can also lead to misinterpretation of serologic testing.

With Hizentra and Vivaglobin, no overall differences in safety or efficacy have been observed in patients over 65 or in pediatric patients. In the clinical studies for both products, desired serum IgG levels were achieved in pediatric patients without pediatric-specific dose requirements. The safety and efficacy of Vivaglobin were not studied in pediatric subjects under two years of age.

**Please see full Prescribing Information for Hizentra and Vivaglobin in pocket.**

**Hizentra™**  
 Immune Globulin Subcutaneous  
 (Human) **20% Liquid**