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CSL Behring

January 4, 2012

Subject: Hizentra™, 20%, Subcutaneous Immune Globulin (Human), 20% solution for injection

Dear Health Care Professional,

CSL Behring is pleased to inform you that Hizentra™, Subcutaneous Immune Globulin (Human) (SCIG) in 20% solution for injection will be available through Canadian Blood Services starting January, 2012.

Hizentra™, is indicated for the treatment of patients with primary immune deficiency (PID) and secondary immune deficiency (SID) who require immune globulin replacement therapy.[1]

Hizentra™, is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human normal immunoglobulin or in patients hyperprolinemia.[1]

Rarely, human normal immunoglobulin can induce anaphylactic reaction with a fall in blood pressure even in patients who had tolerated previous treatment with human normal immunoglobulin. Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment should be administered.[1]

The most common related adverse drug reactions per infusion reported in patients treated with Hizentra™ were local reactions at the site of injection (Rate: 0.056), headaches (Rate: 0.005), pruritus (Rate: 0.007) and fatigue (Rate: 0.002).[1]

Hizentra™ is an Immunoglobulin for appropriate patients who choose subcutaneous home administration or for those who are not able to be treated intravenously.[2] The Hizentra™ pivotal Phase III EU Study included Adult and Pediatric subjects while the Supportive Phase III US Study included Adult, Pediatric and Geriatric patients.

Hizentra™ will be available for your patients in 5, 10 and 20 mL vials. Each vial contains the following grams of protein (IgG):

Fill Size (mL)	Grams (IgG)
5 mL	1
10 mL	2
20 mL	4

Hizentra™ can be stored either in the refrigerator or at room temperature (up to 25°C). Hizentra™ is stable for the period indicated by the expiration date printed on the outer carton and vial label.[1]

The recommended weekly dose of Hizentra™, 20%, Subcutaneous Immune Globulin (Human), is 0.1 to 0.2 g/kg body weight administered subcutaneously. For patients who were previously on Ig replacement therapy, Hizentra™ doses are equal to the weekly equivalent doses during the subjects' previous Intravenous Immunoglobulin or Subcutaneous Immunoglobulin therapy.[1]

On account of its higher IgG concentration, the use of a 20% SCIG formulation can be expected to reduce the infusion volume and duration of infusion compared to the lower concentration SCIG preparations currently used for IgG replacement therapy.[1]

CSL Behring is a global leader in the plasma protein biotherapeutics industry. CSL Behring manufactures and markets a range of plasma-derived and recombinant products and related services. The company also operates one of the world's largest plasma collection networks, CSL Plasma. CSL Behring is a subsidiary of CSL Limited. For more information, visit www.cslbehring.ca.

For the complete risk / benefit profile as well as for the prescribing information of Hizentra™ (20% SCIG) please refer to our current Product Monograph / Prescribing Information, available on our website at www.cslbehring.ca.

If you have any questions or require additional information regarding Hizentra™ (20% SCIG), please contact your local Area Manager or Customer Service of CSL Behring at 1-866-773-7721 ext 2386.

Sincerely,

Bonaventure Agata
General Manager
CSL Behring Canada Inc.

References:

[1] Hizentra Product Monograph, 13 juillet 2011, CSL Behring Canada, Inc.
[2] Shehata et al, "The Use of Immunoglobulin Therapy for Patients With Primary Immune Deficiency: An Evidence-Based Practice Guideline", *Transfusion Medicine Reviews*, Vol24, No 1, Suppl 1 (January), 2010: pp S28-S50, specifically pp. 39, 44.