Alberta Health Services

This document applies to all Covenant and AHS sites.

Hizentra ™

Class: *Manufactured blood product, derived from human plasma*

OTHER NAMES: Hizentra™ Subcutaneous Immune Globulin (Human), 20%

Company: CSL Behring

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	No	No	No	Yes	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

DESCRIPTION OF PRODUCT:

- A sterile, liquid, polyvalent human normal immunoglobulin G (IgG) for subcutaneous infusion.
- Viral reduction steps include octanoic acid fractionation combined with a filter aid-assisted depth filtration, virus filtration and inactivation by pH 4 incubation as well as additional depth filtration.
- Contains at least 98% IgG.
- Available in 5, 10, 20, 50 mL single-use vial sizes at a concentration of 200 mg/mL.
- Contains L-proline (nonmedicinal clinically relevant ingredient)
- **Latex-free**

AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Treatment of patients with primary immune deficiency (PID) and Secondary Immune Deficiency (SID) who require immune globulin replacement therapy.

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic response to immune globulin preparations or to components of Hizentra.

WARNINGS:

- **DO NOT** administer intravenously.
- Patients with selective immunoglobulin A (IgA) deficiency who have known antibody against IgA should only be given Hizentra™ under close medical supervision.
- Rarely, human normal immunoglobulin can induce a drop in blood pressure with anaphylactic reaction, 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.

DOSE (Refer to Product Insert):

- Dose and dosing interval may vary.
- Recommended weekly dose = 0.1-0.2 g/Kg body weight (bw)
- *Loading Dose:* If a loading dose is required: Hizentra may be given at least 0.2 to 0.5 g/Kg bw [1.0 to 2.5 mL/Kg bw] divided over several days.
- *Switching from IVIG:* For patients switching from intravenous treatment, the monthly dose is usually divided into equivalent weekly doses. Example: Divide the previous IVIG dose in grams by the number of weeks between doses (dosing interval) during the patient's IVIG treatment (i.e., 3 or 4 weeks).
- *Switching from another SCIG:* For patients already on SCIG treatment the dosing recommendation is to start with an initial weekly Hizentra dose that is equal to the previous (weekly) SCIG dose.
- To convert the Hizentra dose (in grams) to milliliters (mL), multiply the dose by 5 (0.2 g per 1 mL).

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight and height is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

Access: <u>Subcutaneous</u> injection **<u>ONLY</u>** in any four quadrants of the abdomen, or lateral aspects of the thigh and upper arm

Administration Supplies:

- Infusion administration set(s) (tubing and needle i.e.butterflies or "multisite" sets)
- Antiseptic wipes or alcohol swabs
- Syringe(s)
- Transfer needles
- Pump (If required. Be sure to follow manufacturer's instructions for use)

Administration:

- Bring Hizentra™ vial(s) to room temperature.
- **Do not shake product.**
- Visually inspect for discoloration and particulate matter. Solution should be clear and pale yellow to light brown.
- Wash hands. Ensure aseptic technique when preparing and administering Hizentra™.
- Remove cap and cleanse stopper with alcohol swab. Allow to dry.
- Using a sterile syringe and transfer needle, prepare to draw up Hizentra™ by first injecting air into the vial equal to the amount of Hizentra™ to be withdrawn. Then withdraw desired volume of Hizentra™. Repeat for each vial needed.
- Follow manufacturer's instructions to prepare pump and/or administration tubing where applicable.
- Prepare injection site.

Rate

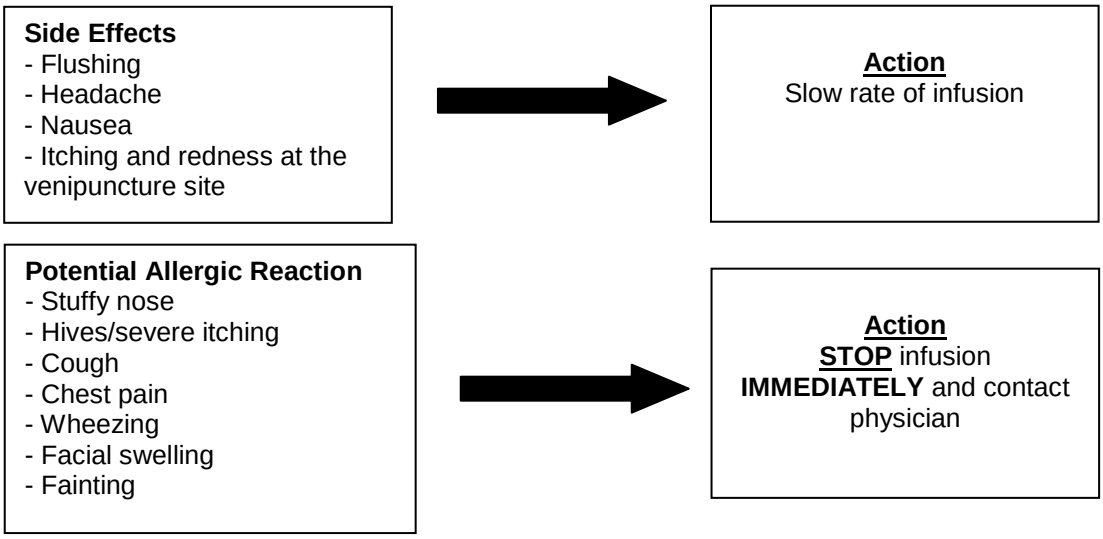
- Infuse Hizentra™, following manufacturer's instructions for the pump or by push at a rate of 1mL/min.
- For the first infusion of Hizentra, the maximum recommended flow rate is 15 mL per hour per site. For subsequent infusions, the flow rate may be increased to a maximum of 34 mL per hour per site as tolerated.

Additional Notes

- Multiple injection sites may be used and should be at least 2 inches apart. For patients not already on SCIG, volume should not exceed 15 mL per site. After fourth infusion, you may increase to 25 mL per infusion site, as tolerated.
- Ensure Hizentra™ is **<u>NOT</u>** injected into a blood vessel ("pinch an inch" to inject into fatty subcutaneous tissue). Aspirate to ensure you are not in a blood vessel, if blood flows back, discard and start again.
- **<u>Important notes:</u>**
  - In hospital/facility storage of Hizentra™ must be in an approved Blood Bank fridge. Product stored by the patient for home use must be in compliance with the manufacturer's recommendations.
  - **<u>DO NOT</u>** mix Hizentra™ with other products.
  - Discard any unused portion immediately after use.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity, from minor with no sequelae, to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted. Acute reactions need medical involvement
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.
- **The most common adverse reactions include local injection-site reactions (swelling, redness, and itching), headache, nausea, rash, asthenia, and gastrointestinal disorder.**



NURSING IMPLICATIONS (where applicable):

	Pre Transfusion Vitals?	Initial Monitoring: Stay At Patient Bedside?			Vital Signs During Transfusion		Post Transfusion Monitoring
		First 5 min	First 10 min	First 15 min	After 15 min	Remainder of transfusion	
ADULTS	**Yes**		**NO**, but must be immediately available		**Yes**	**q1h**	Set of V/S then monitor prn
PEDIATRICS	**Yes**	YES			**Yes**	**1st hour**→q 15 min **2nd and 3rd hours**→ q30 min then q1h until complete	For 30-60 minutes following
NEONATES	**Yes**				**Yes**	**q15 min** for duration of transfusion	For 30-60 minutes following

Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: http://www.albertahealthservices.ca/4240.asp

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.
- Documentation for home use of Hizentra™must follow the policies of the clinical program.

STORAGE & STABILITY OF PRODUCT:

Stored at 2-25°C.
Do not freeze.
Do not use product that has been frozen.
Product issued for home use and returned will be discarded.

COMMENTS:
Date Effective: June 2014
Version: 1.0
Next Review Date: June 2015
Approved By: Transfusion Medicine Network
Reference: Hizentra™ product monograph
For questions or concerns regarding this document contact: trevor.richardson@albertahealthservices.ca

LINK to WEBSITE for PRESCRIBING INFORMATION
Product Monograph available at:
http://www.cslbehring.ca