ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Hizentra®
Subcutaneous Immune Globulin (Human) 20%

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***OTHER NAMES:*** *Subcutaneous Immune Globulin, SCIG* ***Company: CSL Behring*** ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**Intermittent 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:

- Hizentra® is sterile solution of polyvalent human normal immunoglobulin manufactured by a combination of cold ethanol fractionation, octanoic acid fractionation, combined with a filter aid-assisted depth filtration, and anion exchange chromatography.
- The Hizentra® manufacturing process includes an immunoaffinity chromatography step that specifically reduces blood group A and B antibodies.
- Viral inactivation/removal steps include octanoic acid fractionation, combined with a filter aid-assisted depth filtration, virus filtration, and inactivation by pH 4 as well as additional depth filtration.
- Contains 20% protein solution (200mg of protein per mL) of which at least 98% is IgG.
- Contains no more than 50mg/L IgA.
- Solution is pale yellow to light brown and clear.
- Available in 4g and 10g vials, and 1g and 2g pre-filled syringes (200 mg/mL).
- pH is 4.8.
- Also contains L-proline.
- Preservative-free.
- Latex-free.

AVAILABILITY:

- Canadian Blood Services (CBS) provides SCIG products from multiple manufacturers at predetermined percentages. Local availability of a particular SCIG brand is based on provincial alignment with CBS availability.
- Requests for SCIG must meet approved indications. An IVIG/SCIG request form must be completed for initial approval and for renewal http://www.albertahealthservices.ca/frm-20549.pdf unless ordered through Connect Care.

INDICATIONS FOR USE:

- SCIG may be appropriate in a number of clinical indications. Refer to the Prairie Collaborative Criteria for the Clinical Use of Immune Globulin.

CONTRAINDICATIONS:

- Patients who are hypersensitive to human immune globulin, or any ingredient in the formulation or component of the container.
- IgA deficiency when the patient has antibodies against IgA and a history of hypersensitivity (can result in severe anaphylactic reaction)

WARNINGS:

- 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.
- There is clinical evidence of an association between immune globulin administration and thrombotic events. Thrombosis may occur even in the absence of known risk factors. Risk factors for thromboembolic events include: obesity, advanced age, hypertension, diabetes mellitus, history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, prolonged periods of immobilization, severe hypovolemia, diseases which increase blood viscosity, hypercoagulable conditions, use of estrogens, indwelling central venous catheters, and cardiovascular risk factors.
- May impair the efficacy of live attenuated virus vaccines. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.

DOSE:

- Use the lowest dose for the shortest duration required to achieve clinical efficacy.
- If SCIG is being used for immune replacement therapy (primary or secondary), monitoring trough levels is recommended.
- Refer to the Prairie Collaborative Criteria for the Clinical Use of Immune Globulin for dosing recommendations.
- For patients switching from intravenous treatment, divide the previous monthly IVIG dose in grams into equivalent weekly doses.
- To convert the Hizentra® dose in grams to milliliters (mL), multiply the dose by 5 (0.2 g per 1 mL).

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required (ie. trough IgG, IgA, CBC).
- Ensure any ordered premedications have been given (antihistamines, antipyretics prn).
- Perform the appropriate pre-transfusion checks per protocol.
- Report any new onset acute illness to the authorized prescriber prior to starting infusion.

Access:

- Subcutaneous injection only.

Administration Supplies:

- Infusion administration set(s) (i.e. butterflies or “multisite” sets)
- Antiseptic wipes or alcohol swabs
- Syringe(s)
- Transfer needles
- Infusion pump (if required)

Administration

- Bring Hizentra® to room temperature. Do not shake.
- Visually inspect the product prior to administration. Do not use products that are cloudy or contain particulates.
- Injection sites should be at least 2 inches apart.
- If an infusion pump is used for infusion, follow the manufacturer’s instructions.

Site Infusion Volume:

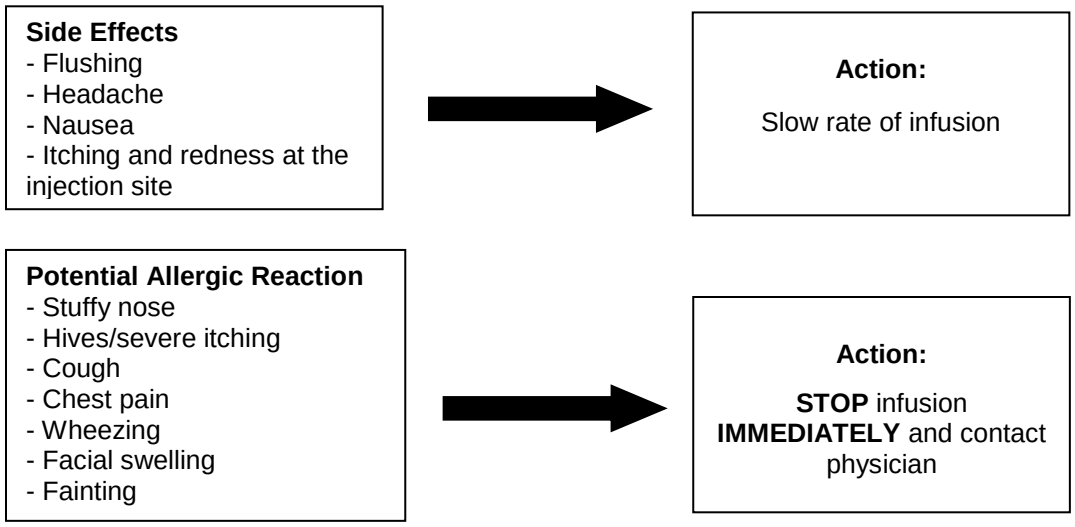
- For the first infusion, for patients not already using Hizentra®, 20mL is the maximum volume per infusion site.
- For subsequent infusions, this volume can be gradually increased as tolerated, to a maximum of 50 mL per site.

Infusion Rate:

- First infusion of Hizentra®:
  - Infuse at a maximum rate of 20 mL/h per site.
  - There is no limit to the number of injection sites used in parallel.
- Subsequent infusions:
  - Infusion rate may be gradually increased to a maximum of 50 mL/h per site as patient tolerates.
  - There is no limit to the number of injection sites used in parallel.

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.
- Aseptic meningitis syndrome, transfusion related acute lung injury (TRALI) and delayed hemolytic anemia due to blood group antibodies are associated with pooled immune globulin products.
- The most common adverse reactions to Hizentra® include local injection-site reactions (swelling, redness, and itching), headache, migraine, pain, cough, rash, pruritus, urticaria, fatigue and nasopharyngitis, and gastrointestinal disorder**.**



NURSING IMPLICATIONS:

Patient Vital Signs and Monitoring:

	Pre-transfusion	At each rate increase (to assess tolerability)	Remainder of transfusion	Post transfusion
All Patients	**Yes**	**Yes***	**q1h**	**20-30 min post, then PRN**

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

**rate increase assessment applies for initial treatment. Subsequent treatments are infused at the patient's highest tolerated rate.*

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/lab/page4240.aspx

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products Policy.*
- The transfusion documentation should be double signed to indicate infusion.
- Start and stop time of infusion and assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- 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

- Store at 2-25°C until expiry.
- Product stored by the patient for home use must comply with manufacturer's recommendations. Product issued for home use and returned will be discarded.
- In hospital/facility storage of Hizentra® must be in a Transfusion Medicine approved location.
- Do not freeze.
- Protect from light.
- Do not use expired product.

COMMENTS:

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Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Hizentra® manufacturer monograph. Available from www.cslbehring.ca

Prairie Collaborative Immune Globulin Utilization Management Framework Project. *Criteria for the clinical use of immune globulin*. Alberta Ministry of Health, Shared Health Manitoba, and Saskatchewan Ministry of Health; 2018. Available from www.ihe.ca

Canadian National Advisory Committee on Immunization