ALBERTA PRECISION LABORATORIES
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VariZIG®
Varicella Zoster Immunoglobulin (human)

APPLICABILITY: This document applies to all APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *VZIG, anti-VZV, VarIg* ***Company:*** *Saol Therapeutics Research Ltd.* ***Class:*** *Manufactured blood product, derived from human plasma*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

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

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- VariZIG® is a sterile solution of gamma globulin (IgG) from pooled human plasma containing antibodies to varicella zoster virus (anti-VZV) purified by anion exchange column chromatography.
- Pathogen reduction steps include filtration and solvent/detergent (S/D) treatment.
- Each vial contains approximately 125 IU of anti-VZV in 1.2mL.
- Also contains maltose and polysorbate 80.
- Preservative-free.
- Latex-free.

AVAILABILITY

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

INDICATIONS FOR USE:

- Prevention or reduction in severity of infection in susceptible individuals:
  - Susceptible pregnant women (within 4 days of exposure to varicella zoster virus);
  - Newborn infants of mothers who develop varicella from 5 days before until 48 hours after delivery;
  - Selected neonates in NICU or PICU settings;
  - Susceptible immunocompromised individuals, including susceptible HIV-infected persons and hematopoietic stem cell transplantation recipients.
- The decision to administer VariZIG should be based on fulfilling all of the following four criteria:
  1. The exposed person is susceptible* to varicella (refer to Canadian Immunization Guide for susceptibility and immunity criteria)
  2. There has been a significant exposure* to a person with varicella or herpes zoster (HZ).
  3. The exposed person is at increased risk* of severe varicella
  4. Post-exposure immunization with univalent varicella vaccine is contraindicated*.

  *Refer to the Canadian Immunization Guide definitions of susceptibility and immunity, significant exposures, persons at increased risk, and contraindications.
- Protection conferred by VariZIG® lasts approximately 3 weeks. Subsequent exposures occurring more than 3 weeks after a dose of VariZIG® require additional doses if the criteria above are met.

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic reactions to immune globulin preparations or any component of the product.
- Patients with known immunity to varicella-zoster virus.
- Patients with IgA deficiency.
- Individuals receiving replacement IVIG at a dose of 400mg/kg or higher. These individuals are considered protected and do not require VariZIG® if the last dose of IVIG was received within three weeks prior to varicella exposure.

WARNINGS:

- 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. Vaccination with live viruses should be deferred until approximately 3 months after VariZIG® administration. Patients who received VariZIG® shortly after live virus vaccination should be revaccinated 3 months after the administration of immune globulin. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.

DOSE:

- Recommended adult dose is 125 IU/10kg body weight. Minimum dose 125 IU, maximum dose 625 IU.
- The maximum dose of 625 IU should be administered for all patients greater than 40 kg in weight.
- Schedule:
  - Within 96h (preferably as soon as possible) of varicella exposure.
  - Note: benefit of administration after 96h of varicella exposure is uncertain.

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) 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: Administer by intramuscular (IM) injection or by central or peripheral venous access site. IM is preferred for patients at risk of thrombotic events.

Preferred IM sites are the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal regions should not be used routinely due to risk of injury to the sciatic nerve. If the gluteal region is used, use only the upper, outer quadrant.

Administration Supplies:

- IM administration:
  - Sterile plastic luer lock syringe (large enough to contain dose)
  - Injection Needle (appropriate size)
  - Antiseptic wipes
- Direct IV administration:
  - Sterile plastic luer lock syringe (large enough to contain dose)
  - Antiseptic wipes
  - IV administration set, as appropriate.

Administration:

- Bring VariZIG® vial(s) to room temperature.
- Visually inspect for particulate matter and discoloration.
- IM injection: Depending on the dose volume, the dose may be divided and administered IM in two or more injection sites.
- IV administration:
  - A separate infusion line should be used for IV administration.
  - Flush line with 0.9% normal saline prior to administration if a pre-existing IV line has to be used.
  - **Administration rate:**
    - Administration rate should be specified by the MRHP after patient assessment.
    - Recommended over 3-5 min.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration, on completion of dose, and as patient condition requires.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post-administration.

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 to a transfusion reaction see Transfusion Reactions | Alberta Health Services. Notify the transfusion service as soon as possible that an adverse reaction has occurred.

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products Policy.
- 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.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

Adverse Events

- 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 to VariZIG® include pain at the injection site, headache, rash, chills, fever, nausea, vomiting, allergic reactions, arthralgia, and moderate low back pain.

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	**Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**Action** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- Stored at 2-8°C
- Do not freeze.
- Do not use expired product.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

Saol Therapeutics Research Limited. Dec 2021. VariZIG® Product Monograph. Control #257271, [Accessed 20250407] https://pdf.hres.ca/dpd_pm/00064236.pdf.

Canadian Immunization Guide. Part 5 – Passive Immunization. Public Health Agency of Canada. [Accessed 20250415]. htpps://publications.gc.ca/collections/collection_2014/aspc-phac/HP40-3-5-2014-eng.pdf.

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