Varicella Zoster Immune Globulin (Varlg) VariZIG® Supplier: KI BioPharma LLC ^A

INDICATIONS:

Varlg is recommended for post-exposure prevention of varicella in the following high-risk clients who cannot receive varicella vaccine and who are at increased risk of severe varicella disease:

- Immunocompromised clients (congenital or acquired) due to treatment or disease, including some clients receiving high doses of corticosteroids. ^B Clients receiving monthly IVIG may not require VarIg. ^c
- Newborn infants whose mothers develop varicella disease 5 days before or 48 hours after delivery.
- Hematopoietic stem cell transplant (HSCT) recipients.
- Infants and children in neonatal or pediatric intensive care settings, as determined by infectious disease/infection control specialist.
- Susceptible pregnant individuals.

DOSES AND SCHEDULE:

Give VarIg IM as soon as possible following exposure to varicella or zoster, and ideally within 96 hours after first exposure for maximal benefit. If more than 96 hours but less than 10 days has elapsed since the last exposure, VarIg may still be given but may attenuate rather than prevent disease.

All indications: Given as 125 IU/10 kg of body weight IM.

The minimum dose is 125 IU (1 vial) and the maximum dose is 625 IU (5 vials).

ADMINISTRATION:

- Each vial contains a minimum potency of 125 IU in 1.2 mL.
- This product is ready to use. No reconstitution or dilution required.
- Do not use if the solution is cloudy or contains particulates.
- The preferred site for the IM administration of Varlg is the deltoid area. Use the vastus lateralis in infants and children up to 5 years of age.
- See <u>Immune Globulin Preparations (HBIg, Ig, TIg, VarIg, Rablg)</u> for administration information and maximum volume to be administered per site according to age.
- VarIg contains no preservatives. Vials are single dose use. Once entered, discard any unused contents.

BOOSTER DOSES:

None.

^A This product may also be supplied by Saol Therapeutics Research Limited.

^B A dose of ≥ 2 mg/kg/day of prednisone or equivalent, or > 20 mg/day, particularly when given for > 2 weeks.

^c Patients receiving monthly infusions of \geq 400 mg/kg of IVIG and whose most recent infusion was within 3 weeks of exposure do not require Varlg.

Varicella Zoster Immune Globulin (Varlg) VariZIG® Supplier: KI BioPharma LLC

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any immune globulin product or any component of VariZIG®.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80. Other components: maltose.

PRECAUTIONS:

- Human Ig products are among the safest blood-derived products available. The method of
 preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV;
 therefore, the risk of transmission is extremely low. However, it is possible that unknown
 infectious agents may be present in such products.
- Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, VarIg should only be given to such persons if the expected benefits outweigh the risks, and should be administered in an emergency room setting.
- Special measures should be considered when administering IM injections to people with bleeding disorders. A smaller gauge needle (23 gauge or smaller) should be used and steady, firm pressure should be applied to the injection site for 5 minutes. If there is concern that the injection may stimulate bleeding, the client should connect with their medical specialist.

SPECIAL CONSIDERATIONS:

- To obtain Varlg, contact Transfusion Medicine (Blood Bank) at the nearest hospital.
- Document receipt of VarIg in the client's electronic record (e.g., Panorama, PARIS) and/or chart. The following information must be recorded: trade name of product, date, lot number, dosage, route and site(s).
- Provide a written record to individuals who receive any immune globulin product.
- Regarding VarIg and the administration of live vaccines, see <u>Immune Globulin Preparations</u> or Blood: <u>Timing Intervals for Vaccines Containing Live Measles</u>, <u>Mumps</u>, <u>Rubella</u>, or <u>Varicella Virus</u>.
- If a 2nd varicella exposure occurs more than 3 weeks after a dose of Varlg, another dose of Varlg should be given.



Varicella Zoster Immune Globulin (Varlg) VariZIG® Supplier: KI BioPharma LLC

ADVERSE EVENTS:

Local: pain. **Systemic:** chills, headache, rash, nausea, myalgia, fatigue, flushing.

A potential increased risk of thrombosis (blood clots) has been observed within 24 hours of receipt of immune globulin products, especially when given in large doses (i.e., more than 10 mL). Additional risk factors include: age 45 years and older, history of thrombosis, or those with risk factors for thrombosis (e.g., obesity, high blood pressure, diabetes, prolonged periods of immobilization, use of estrogens, a history of heart disease, blood clotting disorders, indwelling central vascular catheters, or diseases that thicken the blood). ^{A, B}

^A Daniel GW, Menis M, Sridhar G, et al. Immune globulins and thrombotic events as recorded in a large administrative database in 2008 through 2010. Transfusion. 2012; 52:2113-2121.

^B Menis M, Sridhar G, Selvam N, et al. Hyperimmune globulins and same-day thrombotic adverse events as recorded in a large healthcare database during 2008-2011. Am. J. Hematol. 2013; 88:1035-1040.