Cuvitru [Immune Globulin Subcutaneous (Human)] 20% Fact Sheet

TRADE NAME

CUVITRU
Normal Immune Globulin (Human) [SCIG] 200 mg/mL (20%) Solution for Subcutaneous Infusion

LIS ORDERING

Mnemonic: <facility specific>

PRODUCT COMPOSITION

CUVITRU is a purified, ready to use IgG liquid biologic product at 20% w/v protein concentration. This preparation is an isotonic solution containing a concentration of approximately 200 mg of protein per mL, of which at least 98% is gamma globulin, and has a pH of 4.6 to 5. The stabilizing agent is glycine and is present in the range of 0.20 to 0.30M. **The product contains no preservative. None of the nonmedicinal Ingredients are clinically relevant.**

ALTERNATIVES

Hizentra – 1g/2g vials (until Jan 2018), 1g/2g pre-filled syringes (until Sept-Oct 2018), 4g/10g (until July-Aug 2018)

DOSAGE

For subcutaneous administration only. Do not administer intravenously or intramuscularly.

- **Refer to CUVITRU product monograph for specific dosage guidelines for each clinical indication and for guidelines regarding switching from another Immune Globulin Subcutaneous (Human) treatment (pages 18 to 20/58).**
- The dose regimen should achieve a trough level of IgG (measured before the next infusion) of at least 5 to 6 g/L and aim to be within the reference interval of serum IgG for age. A loading dose of at least 0.2 to 0.5 g/kg (1 to 2.5 mL/kg) body weight may be required. This may need to be divided over several days, with a maximal daily dose of 0.1 to 0.15 g/kg. After steady state IgG levels have been attained, maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order of 0.3 to 1.0 g/kg. Each single dose may need to be injected at different anatomic sites.
- It is recommended to use an initial administration speed of 10 mL/hr/infusion site. If well tolerated (see section ADVERSE REACTIONS), the rate of administration may be increased at intervals of at least 10 minutes to a maximum of 20 mL/hr/infusion site for the initial two infusions. More than one pump can be used simultaneously. The amount of product infused into a particular site varies. In infants and children, infusion site may be changed every 5-15 mL. In adults, doses over 30 mL may be divided according to patient preference.
- CUVITRU can be administered at regular intervals from daily up to every two weeks (biweekly). Individualize the dose based on the patient's pharmacokinetic and clinical response. Monitor serum IgG trough levels regularly to guide subsequent dose adjustments and dosing intervals as needed.
- To guide dose adjustments, see section Dose Adjustments (see Table I-5), page 20/58.

ADMINSTRATION

Replacement therapy should be initiated and monitored under the supervision of a physician experienced in the treatment of immunodeficiency.

Refer to Table I-6 (page 21/58) for infusion volume and rates.

Refer to CUVITRU Product Monograph Instructions for Administration, pages 21 to 23/58.

CLINICAL/ DIAGNOSTIC MONITORING

- Vital sign monitoring as per hospital policy for any blood, blood component and other related product. <facility specific>
- In the event of an immediate or suspected transfusion reaction, refer to hospital policy and procedures. <facility specific>
- ***Monitoring and Laboratory Tests***
  - Periodic monitoring of renal function and urine output is particularly important in patients predisposed

CLINICAL/ DIAGNOSTIC MONITORING continued...

to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of CUVITRU and at appropriate intervals thereafter.

- Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies, because of the potentially increased risk of thrombosis[3, 5].
- If signs and/or symptoms of hemolysis are present after an infusion of CUVITRU, perform appropriate laboratory testing for confirmation.
- If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies and anti-HLA antibodies in both the product and patient's serum.

- Monitor patients who are at an increased risk for developing renal failure or thrombotic events. Do not exceed the recommended dose, and infuse at the minimum infusion rate practicable.
- For patients at risk of thrombosis, administer CUVITRU at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity for those at risk for hyperviscosity.

CLINICAL INDICATIONS

Indicated as replacement therapy for primary humoral immunodeficiency (PI) and secondary humoral immunodeficiency (SI) in adult and pediatric patients two years of age and older.

- Geriatrics (>65 years of age): CUVITRU was evaluated in 12 subjects 65 years of age and older. No differences in safety or efficacy were observed for this group. Monitor patients who are at an increased risk for developing renal failure or thrombotic events. Do not exceed the recommended dose, and infuse at the minimum infusion rate practicable [see warning under section Warnings and Precautions and Dosage and Administration].
- Pediatrics (≥2 years of age): The safety and efficacy profiles were similar to adult subjects. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels.

SPECIAL CONSIDERATIONS

- Administer with caution to pregnant women and breast-feeding mothers and only if clearly indicated.
- Safety and effectiveness of CUVITRU has not been evaluated in neonates or infants < 2 years old.

CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.
- Patients who have had an anaphylactic or severe systemic hypersensitivity reaction to the subcutaneous administration of human immune globulin.
- Patients with severe IgA-deficiency and a history of hypersensitivity to human immune globulin treatment.

STORAGE CONDITIONS

- Store at refrigeration temperature: 2°C to 8°C for up to 36 months or
- Room temperature: not to exceed 25°C for up to 12 months from the date of manufacture.
- In case the product is stored in a refrigerator, the unopened vials must be placed at room temperature for a minimum of 90 minutes prior to use and kept at room temperature during administration. Do not use heating devices including microwaves.
- Refer to Special Handling Instructions – page 28/58 of product monograph.

REFERENCES

CUVITRU Product Monograph, Baxalta Canada Corporation, Submission control #190451, June 30, 2017. Canadian Product Monograph may be obtained by calling Shire Pharma Canada ULC at 1-800-268-2772 or online at https://www.shirecanada.com/-/media/shire/shireglobal/shirecanada/pdffiles/product%20information/cuvitru-pm-en.pdf