ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

# CUVITRU®
## Subcutaneous Immune Globulin (Human) 20%

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| **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*<br>***Company:*** *Takeda*<br>***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:**

- CUVITRU® is 20% w/v solution of purified normal immunoglobulin G (IgG), prepared from pooled human plasma by Cohn-Oncley cold alcohol fractionation, weak cation exchange chromatography, and weak anion exchange chromatography.
- Viral inactivation/removal steps include solvent/detergent treatment, nanofiltration, and incubation at low pH and elevated temperature.
- Contains 20% protein solution (200mg of protein per mL) of which at least 98% is IgG.
- Contains no more than 280 mcg/mL IgA.
- Solution is clear and colourless or pale yellow to light brown.
- Available in 1g, 2g, 4, and 8g single-dose vials.
- pH is 4.6 to 5.1
- Also contains glycine
- 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 CUVITRU® 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 AHS Transfusion Policy and Procedure.
- 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 CUVITRU® to room temperature for a minimum of 90 minutes. 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 4 inches apart.
- If an infusion pump is used for infusion, follow the manufacturer’s instructions.
- Administration should be completed within 2 hours of drawing CUVITRU® into the syringe.

**Site Infusion Volume:**

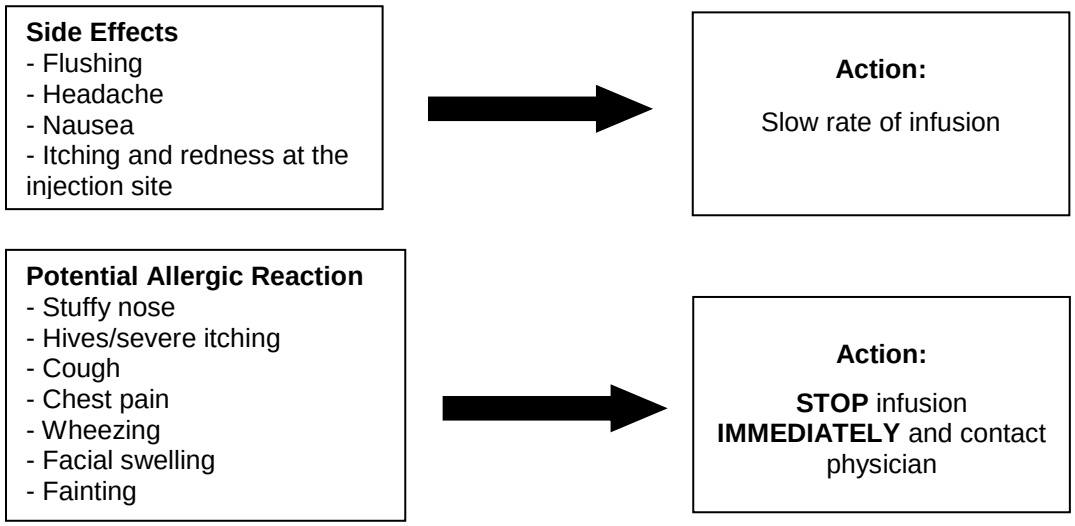
- For patients not already using CUVITRU® who weigh less than 40kg, 20mL is the maximum volume per site for the first two (2) infusions. This volume can be gradually increased as tolerated, to a maximum of 60 mL per site
- For patients who weigh at least 40kg, 60 mL is the maximum volume per site for all infusions.

**Infusion Rate:**

- First two (2) infusions of CUVITRU®:
  - Infuse at a maximum rate of 10-20 mL/h per site.
- Subsequent infusions:
  - Infusion rate may be gradually increased to a maximum of 60 mL/h per site as patient tolerates.
  - For multiple infusion sites, maximum rate is 240 mL/h for all sites combined.

**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 CUVITRU® include local injection-site reactions (swelling, redness, and itching) and headache.




**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 2 treatments. 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 also 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 CUVITRU® must follow the policies of the clinical program.

**STORAGE & STABILITY**

- Store at 2-8°C until expiry (up to 36 months from date of manufacture).
- May be stored at room temperature (not to exceed 25°C) for up to 24 months from the date of manufacture. Do not return to refrigeration once removed.
- Product stored by the patient for home use must comply with manufacturer's recommendations. Product issued for home use and returned will be discarded.
- 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**

CUVITRU® manufacturer monograph. Available from www.takeda.com

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