



# cutaquig®

## Subcutaneous Immune Globulin (Human) 16.5%

<b>APPLICABILITY:</b> 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.				<b>OTHER NAMES:</b> <i>Subcutaneous Immune Globulin, SCIG</i>		
				<b>Company:</b> <i>Octapharma Canada Inc.</i>		
				<b>Class:</b> <i>Manufactured blood product, derived from human plasma</i>		
	<b>INTRAVENOUS</b>			<b>OTHER</b>		
<b>ROUTES</b>	<b>DIRECT IV</b>	<b>Intermittent Infusion</b>	<b>Continuous Infusion</b>	<b>SC</b>	<b>IM</b>	<b>OTHER</b>
<b>Acceptable Routes*</b>	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.						
<b>DESCRIPTION:</b>						
<ul style="list-style-type: none"> <li>▪ cutaquig® is a sterile liquid preparation of highly purified immunoglobulin G (IgG) prepared from pooled human plasma by cold ethanol fractionation followed by ultrafiltration and chromatography.</li> <li>▪ Pathogen reduction steps include solvent/detergent (S/D) treatment and incubation at low pH.</li> <li>▪ Contains 16.5% protein solution (165 mg of protein per mL) of which at least 96% IgG.</li> <li>▪ Solution is clear and colourless.</li> <li>▪ Available in 1g (6mL), 2g (12mL), 4g (24mL), 8g (48mL) single-use vials.</li> <li>▪ Also contains maltose and polysorbate 80.</li> <li>▪ Latex free.</li> </ul>						
<b>AVAILABILITY:</b>						
<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Requests for SCIG must meet approved indications. An IVIG/SCIG request form must be completed for initial approval and for renewal <a href="http://www.albertahealthservices.ca/frm-20549.pdf">http://www.albertahealthservices.ca/frm-20549.pdf</a> unless ordered through Connect Care.</li> </ul>						
<b>INDICATIONS:</b>						
<ul style="list-style-type: none"> <li>▪ SCIG may be appropriate in a number of clinical indications. Refer to the <a href="#">Prairie Collaborative Criteria for the Clinical Use of Immune Globulin</a>.</li> </ul>						
<b>CONTRAINDICATIONS:</b>						
<ul style="list-style-type: none"> <li>▪ Patients who are hypersensitive to human immune globulin, or any ingredient in the formulation or component of the container.</li> <li>▪ IgA deficiency when the patient has antibodies against IgA and a history of hypersensitivity (can result in severe anaphylactic reaction).</li> </ul>						
<b>WARNINGS:</b>						
<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ 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.</li> <li>▪ May impair the efficacy of live attenuated virus vaccines. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.</li> </ul>						

**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 cutaqui<sup>®</sup> dose in grams to milliliters (mL), multiply the dose by 6.

**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 cutaqui<sup>®</sup> vial(s) 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 5cm apart.
- If an infusion pump is used for infusion, follow the manufacturer’s instructions.

**Site Infusion Volume:**

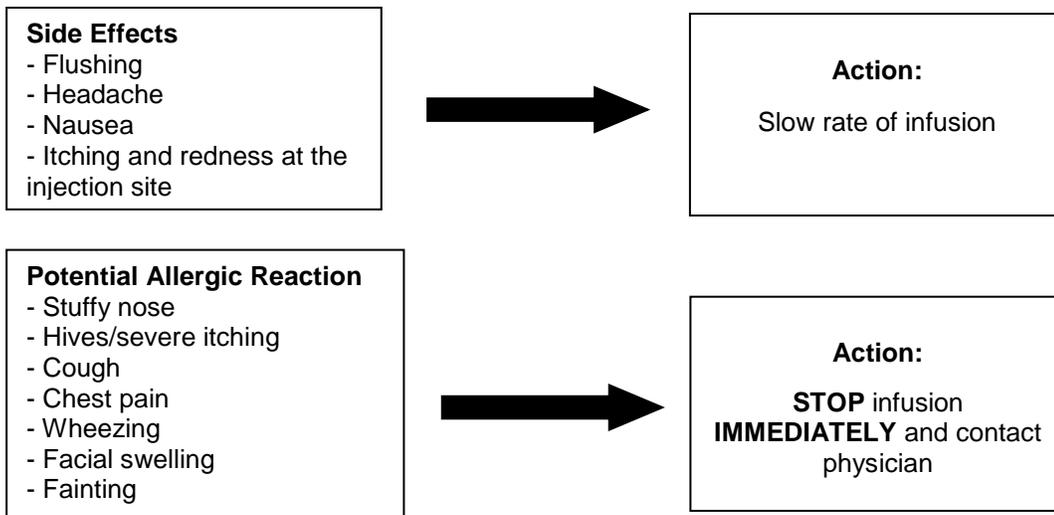
- For patients not already using cutaqui<sup>®</sup>, 25 mL is the maximum volume per infusion site for the first six (6) infusions.
- This volume can be gradually increased as tolerated, to a maximum of 40 mL per site.

**Infusion Rate:**

- First six (6) infusions of cutaqui<sup>®</sup>:
  - Infuse at a maximum rate of 15-20 mL/h per site.
  - For multiple infusion sites, maximum rate is 30 mL/h for all sites combined.
- Subsequent infusions:
  - Infusion rate may be gradually increased to a maximum of 25 mL/h per site as patient tolerates.
  - For multiple infusion sites, maximum rate is 100mL/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 cutaquig® include local injection-site reactions (swelling, redness, and itching), and pyrexia.



**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 6 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 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 cutaquig® must follow the policies of the clinical program.

**STORAGE & STABILITY**

- Stored at 2-8°C until expiry (up to 36 months from date of manufacture).
- May be stored for a period of up to 6 months within its shelf life at room temperature (not to exceed 25°C). 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.
- In hospital/facility storage of cutaquig® must be in a Transfusion Medicine approved location.

- Do not freeze.
- Protect from light
- Do not use expired product.

**COMMENTS:**

Date Effective: 15 Sept 2021

Revision #: 2.00

Approved By: APL Transfusion Medicine Discipline Council

Document Number: TM40-01.02.151

*For questions or comments regarding this document please contact: [Transfusion.SafetyTeam@aplabs.ca](mailto:Transfusion.SafetyTeam@aplabs.ca)*

**REFERENCES**

cutaquiig® manufacturer monograph. available from [www.octapharma.ca](http://www.octapharma.ca)

Home infusion resources available from [cutaquiig.ca](http://cutaquiig.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](http://www.ihe.ca)

[Canadian National Advisory Committee on Immunization](#)