



Cinryze® C1 Inhibitor (human)

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: C1 Inhibitor Company: ViroPharma Biologics Class: Manufactured blood product, derived from human plasma			
	INTRAVENOUS			OTHER		
ROUTES	DIRECT IV	IV Infusion	Continuous Infusion	SC	IM	OTHER
Acceptable Routes*	Yes**	Yes	No	No	No	N/A
<p>* Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.</p> <p>** Direct IV Administration of Blood Products may be performed by professionals per the Transfusion of Blood Components and Products Learning Module. Not to be confused with medication administration.</p>						
DESCRIPTION OF PRODUCT:						
<ul style="list-style-type: none"> ▪ Cinryze® C1 Inhibitor (human) is a sterile, stable, lyophilized preparation of C1 inhibitor derived from large pools of human plasma. ▪ Viral inactivation steps include PEG precipitation, pasteurization, nanofiltration and chromatographic procedures. ▪ Supplied in a 500 IU single-use vial. ▪ Each vial is reconstituted with 5mL sterile water for injection, resulting in a concentration of 100 IU/mL ▪ Also contains L-alanine, L-threonine, L-valine, sodium chloride, sodium citrate, and sucrose. ▪ Latex-free 						
AVAILABILITY						
<ul style="list-style-type: none"> ▪ Supplied by Canadian Blood Services. ▪ Contact your local laboratory/transfusion service regarding stock availability on site. 						
INDICATIONS FOR USE:						
<ul style="list-style-type: none"> ▪ For routine prevention of angioedema attacks in adult and adolescents with hereditary angioedema (HAE). 						
CONTRAINDICATIONS:						
<ul style="list-style-type: none"> ▪ Patients who are hypersensitive (allergic) to this blood product or any ingredient in its formulation (see description of product) 						
WARNINGS:						
<ul style="list-style-type: none"> ▪ Hypersensitivity reactions may occur. ▪ Thrombotic events have occurred in patients receiving Cinryze®. Patients with known risk factors for thrombotic events should be monitored closely. 						
DOSE (Refer to Product Insert):						
<ul style="list-style-type: none"> ▪ Dose to be determined by the most responsible health practitioner (MHRP). ▪ Consult with Hematologist or bleeding disorders clinic ▪ One IU of Cinryze® corresponds to the mean quantity of C1 inhibitor present in mL of normal fresh plasma. ▪ For routine prevention against angioedema attacks, manufacturer recommended dose is 1000 IU of Cinryze™ every 3 or 4 days. 						

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 is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per nursing protocol.

Access: Product can be given via CVAD or peripheral IV line.

Reconstitution Supplies:

- Cinryze™ Product (lyophilized powder – 2 x 500IU vials included with product)
- Sterile water for injection (2 x 5mL included with product)
- Mix2Vial® Transfer Device (not included with product) or blunt double-ended needle
 - * Mix2Vial® transfer device available for home care patients through CINRYZE Solutions® support program. Contact local bleeding disorders clinic.
- Alcohol swabs (not included with product)

Administration Supplies:

- Alcohol swabs
- Sterile plastic luer lock syringe, large enough to contain dose. Use of a silicone-free syringe is recommended.
- Syringe and Infusion set (not included with product), if required

Reconstitution:

- See [Mix2Vial® Reconstitution Instructions](#).
- Do not refrigerate after reconstitution.
- After reconstitution, Cinryze® solutions are colourless to slightly blue and clear.

Administration:

- Reconstituted solution must be used within 3 hours of reconstitution.
- Do not mix with any other medications or solutions. Separate infusion line is recommended.
- IV administration only
- Do not use solutions that are cloudy or discoloured.
- **Administration rate:**
 - Administration rate should be specified by the MRHP after patient assessment.
 - Recommended slow direct IV administration. Maximum rate 1 mL/minute.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration, on completion of dose, and as patient condition requires.

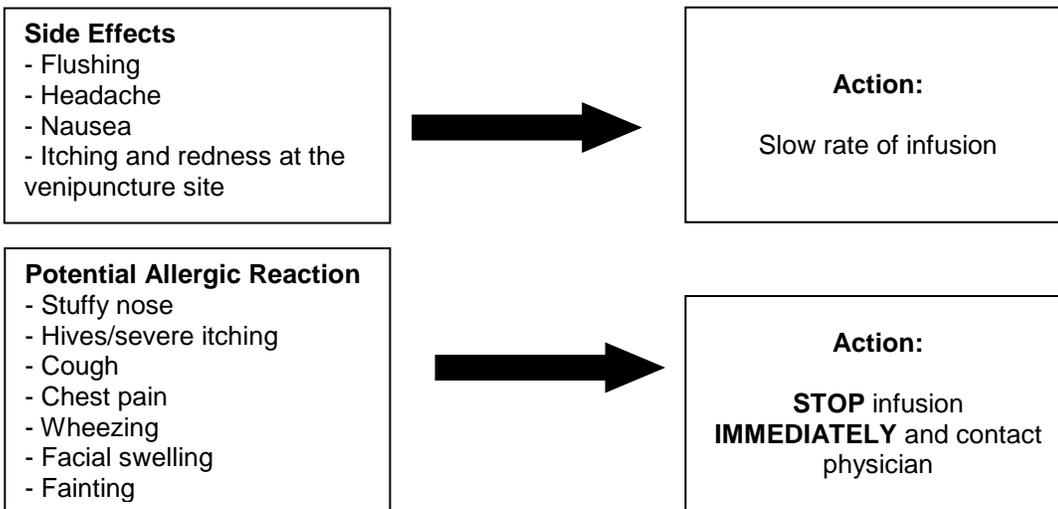
Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- 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) as required.
- Provide patient notification documentation where required.

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.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- The most commonly reported adverse reaction in patients receiving Cinryze® was development of a rash.
- Thrombotic events have been reported with the use of Cinryze®



STORAGE & STABILITY OF PRODUCT:

- Store at 2-25°C.
- Do not freeze.
- Protect from light.
- Expiration date is indicated on package.
- Do not use expired product.

CONTACT INFORMATION:

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

REFERENCES:

Cinryze® Product Monograph. Available from www.takeda.com
Betschel et al. The International / Canadian Hereditary Angioedema Guideline Allergy Asthma Clin Immunol (2019) 15:72