ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Ceprotin®

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:*** *Protein C Concentrate* ***Company: Shire*** ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	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.**
**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**
***** Although not indicated by the manufacturer monograph, the authorized prescriber may indicate subcutaneous (SC) administration due to the patient's venous access and/or condition.**

DESCRIPTION OF PRODUCT:

- Ceprotin® (protein C concentrate [human]) is a vitamin K-dependent coagulation inhibitor prepared from large pools of human plasma.
- Viral inactivation and/or removal processes include: detergent treatment, heat treatment, and immunoaffinity chromatography.
- Available in 500 IU or 1000 IU single-dose vials of sterile, preservative-free lyophilized powder.
- After reconstitution with the full volume of supplied diluent (5 mL or 10 mL sterile water for injection), human Protein C concentration is 100 IU/mL. **NOTE:** concentration will vary if using other volumes as ordered by the authorized prescriber.
- Also contains: human albumin, trisodium citrate dehydrate, and sodium chloride.
- May contain traces of mouse protein or heparin.

AVAILABILITY:

- Ceprotin® is an **unlicensed product** in Canada. Patient-specific requests must be approved by Health Canada's Special Access Programme (SAP). Authorized prescriber must contact Transfusion Medicine physician.

INDICATIONS FOR USE:

- Prevention and treatment of venous thrombosis and purpura fulminans in neonatal, pediatric and adult patients with severe congenital Protein C deficiency.

CONTRAINDICATIONS:

- Patients who are hypersensitive (allergic) to this drug or any ingredient in the formulation or container (see product monograph for complete listing).

WARNINGS:

- Simultaneous administration with tissue plasminogen activator (tPA) and/or anticoagulants may increase risk of bleeding.
- Use with caution in patients with allergic-type reactions to mouse protein or heparin.
- Use with caution in patients on low-sodium diet and/or renal impairment. Maximum daily dose Ceprotin® contains sodium >200 mg.
- Discontinue administration if heparin-induced thrombocytopenia is suspected.

DOSE and ADMINISTRATION:

Consult Stollery KidClot (North Zone, Edmonton Zone, Central Zone [Red Deer]), Pediatric Thrombosis (Calgary Zone, Central Zone [south of Red Deer]), or Pediatric Hematology (South Zone) for dose and patient-specific administration procedure and infusion rate.

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 transfusion policy and procedure.

Reconstitution Supplies:

- Vial of Ceprotin® lyophilized powder
- Sterile Water for Injection, USP (included with product)
- Double-ended transfer needle (included with product)
- Separate blunt needle (if not using full volume of supplied diluent)
- Plastic syringe (if not using full volume of supplied diluent)
- Alcohol swabs

Administration Supplies:

- Filter needle (included in packaging)
- Plastic syringe (appropriate size)
- Suitable needle, or infusion set
- Syringe pump (as appropriate)

Reconstitution:

1. Bring Ceprotin® lyophilized powder and Sterile Water for Injection (diluent) vials to room temperature.
2. Remove caps and cleanse with alcohol swabs. Allow to dry prior to use.
3. If using full volume of supplied diluent, follow Step 4. If not using full volume of supplied diluent, proceed to Step 5.
4. If using full volume of supplied diluent:
   a) On a flat surface, remove covering from one end of the double-ended transfer needle and insert through the center of the diluent stopper vial.
   b) Remove covering from the other end of the double-ended transfer needle, rapidly invert the diluent vial over the upright Ceprotin® vial and insert the free end of the needle through the center of the Ceprotin® vial.
   c) Disconnect the vials and remove the transfer needle.
   d) Proceed to Step 6.
5. If using partial volume of supplied diluent:
   a) Using a blunt needle and appropriate size plastic syringe, inject an equal amount of air as the diluent volume ordered by the authorized prescriber into the diluent vial.
   b) Draw up the ordered volume of diluent.
   c) Inject the diluent into the lyophilized Ceprotin® vial, aiming down the side of the vial to avoid foaming.
   d) Proceed to Step 6.
6. Gently swirl until dissolved. Solution should colorless to slightly yellowish, and clear to slightly opalescent, and not contain any visible particles.

Administration:

- Ceprotin must be administered within 3 hours of reconstitution.
- Draw up reconstituted Ceprotin® using filter needle and appropriate size plastic syringe.

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 suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- **Most common adverse reactions were hypersensitive or allergic reactions. In particular, lightheadedness, and itching and rash.**

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	**Action:** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, as patient condition requires
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post

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:

- The transfusion documentation should be double signed (where required) 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.
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification documentation where required.

STORAGE & STABILITY OF PRODUCT:

- Store at 2°C - 8°C.
- Do not freeze.
- Protect from light.

COMMENTS:

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Version: 1.00
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For questions or comments about this document, please contact Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Ceprotin® Product Monograph. Available from:
https://www.shirecontent.com/PI/PDFs/CEPROTINPATIENT_USA_ENG.pdf
Stollery KidClot program (Alberta Health Services)
https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.12640
https://www.ncbi.nlm.nih.gov/pubmed/24509341
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