Alberta Health Services

This document applies to all Covenant and AHS sites.

Beriplex® P/N Prothrombin Complex Concentrate

Class: *Manufactured prothrombin complex product, derived from human plasma*

OTHER NAMES:

Company: CSL Behring

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes	Yes	No	No	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:

- Beriplex ® P/N is a latex free manufactured prothrombin complex concentrate (PCC) that is derived from human plasma.
- Manufacturing process includes viral inactivation by pasteurisation and a nanofiltration step for virus removal.
- Two vial sizes are available: 500 IU (Beriplex ® P/N 500) and 1000 IU (Beriplex ® P/N 1000). Each vial contains a lyophilized plasma protein preparation of prothrombin complex (coagulation Factors II, VII, IX, X, and Protein C and S. See product insert for actual amounts. Factor IX is used to determine the concentration of the product.
- Also contains heparin, sodium citrate, sodium chloride and human antithrombin III and albumin.
- Diluent (sterile water for injection) vial size is 20 mL for the Beriplex® P/N 500 vial size, and 40 mL for the Beriplex® P/N 1000 vial size.

AVAILABILITY:

- Supplied by Canadian Blood Services (CBS)
- Contact your local laboratory/transfusion service regarding stock availability on site

INDICATIONS FOR USE:

- Emergent reversal of warfarin therapy or vitamin K deficiency in patients
  - i) Exhibiting serious or life-threatening bleeding manifestations
  - ii) Requiring URGENT (<6 hours) interventions with risk of bleeding

CONTRAINDICATIONS:

- Patients with history of heparin induced thrombocytopenia (HIT)
- Not Recommended for:
  - i) Patients with recent history of disseminated intravascular coagulation (DIC), thrombosis, or myocardial infarction
  - ii) Coagulopathy associated with liver dysfunction/disease
  - iii) Massive transfusions
  - iv) Reversal of anticoagulants other than Vitamin K antagonists
  - v) Treatment of elevated INRs without bleeding or need for surgical intervention
  - vi) Elective reversal of warfarin therapy pre-invasive procedure.

DOSE:

- Dosing of prothrombin complex concentrate should be based on the National Advisory Committee recommendations as found in the table below. Dosing is based on INR. If the INR is unknown or major bleeding is present, 80 mL should be administered.

	INR 1.5 - 2.9	**INR 3.0 - 5.0**	**INR greater than 5**
Dose of Beriplex ® P/N	40 mL (1000 IU)	80 mL (2000 IU)	120 mL (3000 IU)
Vitamin K1	10 (mg IV) co-administration strongly recommended if reversal is required for longer than 6 hours.		

- **If time permits, reassessment of INR at 10 - 30 minutes post dose is recommended, with additional PCC provided if the INR remains greater than 1.5 and bleeding continues. In the event sufficient product is not available to meet the above recommendations, the maximum dose available should be given with consideration for transferring the patient to another facility for additional treatment.**
- **Maximum total dose = 120 mL**

ADMINISTRATION:

Ensure informedconsent has been obtained prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion: Perform the appropriate pre-transfusion checks per *Transfusion of Blood Components and Products* policy and procedure. Ensure pertinent labs are available where possible.

Access: Beriplex ® P/N can be administered by CVC, PICC, Port-a-Cath®, or peripheral IV line.

Additional Clinical Information: can be found at:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-pcc-clinreconst-info.pdf

Reconstitution: Reconstitution directions can be found at
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-reconst-inst.pdf

Reconstitution Supplies:

- Vial of Beriplex ® P/N lyophilized powder
- Vial of Sterile Water for Injection (diluent)
- Mix2Vial™ filter transfer device (single use)
- Alcohol swabs

} Contained in box

Administration Supplies:

- **For direct IV administration:**
  - Sterile plastic Luer lock syringe large enough to contain dose
- **For IV infusion:**
  - IV administration set (either a buretrol, infusion set for syringe pump or minibag with regular infusion set)
  - IV pump or syringe pump as appropriate

Administration:

- Use immediately following reconstitution. No filter needed. Do not dilute further.
- No other drugs/solutions can be co-administered in the same line while Beriplex® P/N is being infused.

Administration Rate

- Maximum rate =8 mL/min (Pump rate: 480 mL/h).

Options for IV Infusion:

- **Direct IV:** Slow administration, not to exceed 8 mL/min**.**
- **Syringe pump:** (Microbore tubing required). Not to exceed 8 mL/min **(Pump rate: 480 mL/h).**
- **Minibag:** Remove all normal saline from a minibag sufficient in size to hold the required volume of product. Replace normal saline with product. Label minibag as per AHS *Transfusion of Blood Components and Products* procedure.Using regular IV tubing, prime line with product. Attach to closest port to patient. Infuse Beriplex® P/N. Flush line at the same rate with 35 mL normal saline at the end of Beriplex® P/N infusion to ensure entire dose has been administered.
- **Buretrol:** (In-line or 'add-a-line')
  - **Option 1:** Attach 500-mL NS bag to buretrol line. Prime tubing with 35 mL NS **(leave chamber empty)** and close clamp between NS and buretrol. Add Beriplex® P/N to chamber for infusion. Infuse Beriplex® P/N. Flush line at the same rate with 35 mL NS at the end of Beriplex® P/N infusion to ensure entire dose has been administered. **Note:** Transfusion monitoring begins when product reaches the patient (small bolus may be required to advance normal saline through tubing).
  - **Option 2 :** Prime buretrol line with Beriplex® P/N (similar to tPA process). Infuse Beriplex® P/N. Flush line at the same rate with 35 mL NS at the end of infusion.

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) should be reported to your local transfusion service.
- **Beriplex® P/N has been rarely associated with immediate allergic or thrombotic complications**.

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, and as patient condition requires.
- INR: pre-administration along with other indicated blood work, and 10-30 minutes post-administration.

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. Follow up instructions to a transfusion reaction are at http://www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products procedure.
- Recipients of blood products are notified in writing of the transfusion as per the AHS Transfusion of Blood Components and Products Policy.

STORAGE & STABILITY of PRODUCT:

- Shelf life of 36 months when stored at 2-25 ^{o}C, Do not freeze.
- Use immediately after reconstitution. **Product is only stable for 3 hours at room temperature following reconstitution.**
- **Do not** refrigerate after reconstitution.

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COMMENTS:

Date Effective: 10 Feb 2017
Revised Date: Feb 2017
Version: 1.3
Document Number: PTMGNR00029
Approved By: TM Network
For questions or comments, please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES

NAC prothrombin complex recommendations at http://www.nacblood.ca
Beriplex product monograph SCN 182605
http://www.cslbehring.ca