

## Section S: Blood Product Overview –

### Prothrombin Complex Concentrate (PCC)

Page  
1 of 3

- OCTAPLEX<sup>®</sup> manufactured by Octapharma
- BERIPLEX<sup>®</sup> manufactured by CSL Behring

DESCRIPTION of PRODUCT .....	1
AVAILABILITY of PRODUCT .....	1
STORAGE of PRODUCT .....	1
CLINICAL INDICATIONS (see package insert for contraindications) .....	2
REQUESTS for Prothrombin Complex Concentrate (PCC) .....	2
ADMINISTRATION of PRODUCT .....	3
LINK to WEBSITE for PRESCRIBING INFORMATION .....	3

### DESCRIPTION of PRODUCT

- Each 20mL vial of PCC contains approximately 500IU of prothrombin complex. This is based on the concentration of Factor IX in each vial.
- In addition to Factor IX, PCC also contains the coagulation factors II, VII, and X and Proteins C and S (see product monograph for specific amounts per 20mL vial)
- Also contains: Heparin, sodium citrate, water
- Manufactured from human plasma
- Manufacturing process includes viral inactivation (Solvent/Detergent treatment for Octaplex<sup>®</sup> and Pasteurization for Beriplex<sup>®</sup>) as well as virus removal (nanofiltration)
- Each package includes: lyophilized PCC , diluent (sterile water), transfer set with integrated filter, package insert

### AVAILABILITY of PRODUCT

- Supplied by the CBS.
- Victoria Hospital stocks Beriplex<sup>®</sup> (manufactured by CSL Behring)
- University Hospital stocks Octaplex<sup>®</sup> (manufactured by Octapharma)

### STORAGE of PRODUCT

- Stored at room temperature (must not exceed 25°C).
- Do not freeze.
- Reconstituted product should be administered **immediately**, and must be infused within 4 hours

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Page  
2 of 3

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### CLINICAL INDICATIONS (see package insert for contraindications)

- **Emergent reversal of warfarin therapy in patients:**
  - Exhibiting serious or life-threatening bleeding manifestations
  - Requiring UNPLANNED (<6 hours) procedure / intervention that may cause bleeding

**AND**

  - Having an INR  $\geq$  1.5
- **NOTE:** PCC contains the Vitamin K dependent coagulation factors and may be considered a warfarin antidote. It will not work for other coagulation disorders such as:
  - Disseminated intravascular coagulation (DIC)
  - Coagulopathy associated with liver dysfunction/disease
  - Massive transfusions
  - Reversal of anticoagulants other than Vitamin K antagonists
- **CONTRAINDICATED** in patients with known history of heparin induced thrombocytopenia (HIT)
- CAUTION should be used in patients with an increased risk of thrombosis.
- There is insufficient evidence for the use of PCC in pregnant or lactating women and pediatric patients.

### REQUESTS for Prothrombin Complex Concentrate (PCC)

- PCC will be released ONLY for the approved indications above. BTL will request information confirming appropriateness of request at time of order
- All other requests must have the approval of the Medical Director of the Blood Transfusion Laboratory (BTL) or the hematologist on call.
- NOTE: PCC is a blood product and requires transfusion consent
- **DOSE:** Weight based dose is calculated by the BTL staff. When requesting PCC, the patient's weight must be known:

Patient Weight (kg)	PCC (IU)	PCC volume (mL)
< or = 40	1000	40
41 – 60	1500	60
61 – 80	2000	80
81 – 100	2500	100
> 100	3000	120

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Page  
3 of 3

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### ADMINISTRATION of PRODUCT

- Administer Vitamin K 10mg IV STAT (intravenous is faster than oral)
- Call BTL requesting PCC. Patient's name, PIN and approximate weight must be provided. The BTL will calculate appropriate dose based on patient weight. Preparation of the product takes approximately 10 minutes
- Orders for either Octaplex<sup>®</sup> or Beriplex<sup>®</sup> will be interpreted as an order for PCC, and the product stocked at that site will be issued
- PCC is reconstituted, pooled and filtered in the BTL, and issued in a blood product bag.
  - NB: Product is pre-filtered in the BTL, therefore blood transfusion set is not required for administration.
  - An infusion guideline is attached to each bag of PCC issued
- Must be given **immediately** by IV.
- Infusion rate:
  - 3mL/min. for Octaplex<sup>®</sup>
  - 8ml/min for Beriplex<sup>®</sup>
- Flush tubing post infusion with 0.9% Sodium Chloride.
- Rarely associated with immediate allergic or thrombotic complications.
- Monitor vital signs pre, during and following infusion.
- Draw INR immediately post PCC infusion, and repeat at 6 hours.
- PCC effect is immediate (expect INR  $\leq$  1.5 within 10-60 minutes post infusion)
- Vitamin K is typically effective within 6 – 12 hours

### LINK to WEBSITE for PRESCRIBING INFORMATION

Octaplex<sup>®</sup> / Beriplex<sup>®</sup> comparison table available at:

[http://www.blood.ca/CentreApps/Internet/UW\\_V502\\_MainEngine.nsf/resources/CustomerLetters2011/\\$file/PCC-ComparisonTable.pdf](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/CustomerLetters2011/$file/PCC-ComparisonTable.pdf)

Octaplex<sup>®</sup> product insert available at:

[http://www.octapharma.com/index.php?eID=tx\\_nawsecuredl&u=0&file=uploads/media/Canadian\\_Product\\_Monograph\\_english\\_01.pdf&t=1321990305&hash=49f1d9247f10c7efce9c58731478efd3010ab108](http://www.octapharma.com/index.php?eID=tx_nawsecuredl&u=0&file=uploads/media/Canadian_Product_Monograph_english_01.pdf&t=1321990305&hash=49f1d9247f10c7efce9c58731478efd3010ab108)

Beriplex<sup>®</sup> fact sheet available at: [http://www.cslobehring.ca/docs/326/671/Beriplex\\_Fact%20sheet-%20Final.pdf](http://www.cslobehring.ca/docs/326/671/Beriplex_Fact%20sheet-%20Final.pdf)

Beriplex<sup>®</sup> product monograph available at:

[http://www.cslobehring.ca/docs/17/83/Beriplex\\_NC134547\\_eng\\_app5nov10-ar.pdf](http://www.cslobehring.ca/docs/17/83/Beriplex_NC134547_eng_app5nov10-ar.pdf)

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