

Section S: Blood Product Overview –

Prothrombin Complex Concentrate (PCC)

- OCTAPLEX® manufactured by Octapharma
- BERIPLEX® manufactured by CSL Behring

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DESCRIPTION of PRODUCT

- Each 20mL vial of PCC contains approximately 500 Units 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 20 mL vial)
- Also contains: Heparin, sodium citrate, water
- Manufactured from human plasma
- Manufacturing process includes viral inactivation (Solvent/Detergent treatment for Octaplex® and Pasteurization for Beriplex®) 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
- UH and VH both stock Octaplex® (manufactured by Octapharma) or Beriplex® (manufactured by CSL Behring) and either product will be issued depending on available inventory
- SJHC may request PCC for a specific patient. This will be sent to SJHC from UH

Date effective: December 2008

Date revised: Jan 2015

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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

CLINICAL INDICATIONS (see package insert for full list of 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 ≥ 1.5
- ❖ Use of Plasma (FFP / FP) to reverse Vitamin K antagonists (warfarin) is NOT recommended. PCC is the preferred agent for urgent reversal of Vitamin K antagonists (warfarin)
- PCC contains the Vitamin K dependent coagulation factors and therefore 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 for the approved indications listed above. 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 indicated in order and/or calculated by the BTL staff. When
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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

ADMINISTRATION of PRODUCT

- Recommend the administration of Vitamin K 10 mg IV STAT (intravenous Vitamin K is faster acting than oral Vitamin K)
- Order PCC through Cerner or call BTL requesting PCC (patient's name, PIN and approximate weight must be provided).
- Orders for either Octaplex[®] or Beriplex[®] will be interpreted as an order for PCC, and the product stocked at that site will be issued
- Preparation of the product takes approximately 10 minutes
- PCC is reconstituted, pooled and filtered in the BTL, and issued in a blood product bag.
 - A 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.
- Manufacturer's recommended maximum infusion rate:
 - 3 mL/min. for Octaplex[®] (180 mL/hr)
 - 8 mL/min for Beriplex[®] (480 mL/hr)
- 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 (INR is generally less than or equal to 1.5 post infusion), but a rebound of the INR is to be expected at about 6 hours if Vitamin K (IV) was not given

LINK to WEBSITE for PRESCRIBING INFORMATION

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For a comparison of the two Prothrombin Complex Concentrates (Octaplex[®] / Beriplex[®]) see the [Canadian Blood Services \(CBS\) website](#) and access the Prothrombin Complex Concentrate Comparison Table (pdf) under the section titled Product Comparison Tables

Octaplex[®] product insert available at:

http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/20120613_PM_Octaplex_approved.pdf

Beriplex[®] fact sheet available at:

http://www.cslobehring.ca/docs/326/671/Beriplex_Fact%20sheet-%20Final.pdf

Beriplex[®] product monograph available at:

http://www.cslobehring.ca/docs/921/921/2013-08-14_E_Beriplex_PM.pdf