

Prothrombin Complex Concentrate

Clinical Information Summary*

APPLICABILITY: This document applies to all APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.

*This is a summarized version of the product monographs and should not replace the full documents. For complete information, please refer to the Octaplex® or Beriplex® P/N Blood Product Information/Monographs

DESCRIPTION:

Brand Names: Octaplex® or Beriplex® P/N

Sizes: 500 IU (with 20mL diluent) and 1000 IU (with 40mL diluent)

Contents:

- 1 vial lyophilized prothrombin complex concentrate (PCC), derived from human plasma, viral inactivated/reduced
 - Contains coagulation factors II, VII, IX, and X and Protein C and S.
 - Contains heparin and sodium citrate. Beriplex® P/N contains human antithrombin III and albumin.
- 1 vial diluent (Sterile water for injection).
- Mix2Vial™ filter transfer device.

Storage & Stability:

- Lyophilized: Store at 2 - 25°C.
- Reconstituted: Use immediately. Keep at room temperature. Do not refrigerate.

INDICATIONS:

- Emergent reversal of oral vitamin K antagonists (VKAs, e.g. warfarin) or vitamin K dependent deficiency-in patients:
 - With serious or life-threatening bleeding.
 - Requiring urgent (<6 hours) interventions with risk of bleeding.
- Treatment of severe or life-threatening bleeding for patients receiving direct oral anticoagulants (DOACs) when specific reversal agents are not available.
- Replacement of coagulation factors when plasma is unavailable, contraindicated, or refused by the patient.

CONTRAINDICATIONS:

- Patients with a history of heparin induced thrombocytopenia (HIT)
- Non-urgent anticoagulation reversal or reversal of anticoagulants other than vitamin K antagonists
- Patients with recent history of disseminated intravascular coagulation (DIC), thrombosis, myocardial infarction, or coagulopathy associated with liver dysfunction.

RECOMMENDED ADULT DOSING (see product monograph for pediatric dosing)

- **Maximum** total dose = 120 mL (3000 IU).

	VKA Reversal			Bleeding with DOAC
	INR less than 3.0	INR 3.0 - 5.0 Or Unknown	INR greater than 5.0	
Dose of PCC	40 mL (1000 IU) 60 mL (1500 IU) if ICH or epidural / spinal anesthesia	80 mL (2000 IU)	120 mL (3000 IU)	2000 IU fixed dose Or 25-50 IU/kg to a max of 3000 IU
Vitamin K1	10 mg (IV) co-administration strongly recommended if reversal is required for > 6 hours			

- INR should be reassessed 10 – 30 minutes post-dose. Additional PCC should be provided if the INR remains greater than 1.5 and bleeding continues.
- If sufficient product is not available, give the maximum dose available and consider transferring the patient to another facility for additional treatment

PATIENT MONITORING

- INR: pre-administration along with other indicated blood work, and 10-30 minutes post-administration
- Vital signs: pre-administration, on completion of dose, and as patient condition requires

ADMINISTRATION:

- Use immediately following reconstitution. No filter required. Do not dilute further.
- No other drug/solution can be co-administered in the same line while PCC is being infused.

IV Infusion Options:

- Direct IV: Slow administration
- Syringe pump: Microbore tubing required
- Mini-bags: Remove NS from mini-bag and replace with PCC. Ensure minibag is labelled per policy. Prime line with product and flush with 35mL NS
- Buretrol (In-line or 'add-a-line')
 - Option 1: Attach 500mL NS bag to buretrol line. Prime tubing with 35 mL NS (leave chamber empty) and close clamp between NS and buretrol. Add PCC to chamber for infusion, and infuse at the rate indicated

below. At the end of the PCC infusion, flush line at the same infusion rate with 35 mL NS to ensure entire dose is infused.

- **Option 2: (ER/Critical Care Units):** prime buretrol line with PCC (similar to tPA process). Infuse PCC at the rate indicated below. At the end of the PCC infusion, flush line at the same infusion rate to ensure entire dose is infused.

Infusion rates:

Octaplex ®	Initial Rate: 1mL/min (60mL/h) for first 10 minutes Max rate: 2-3mL/min (120-180 mL/h)
Beriplex ® P/N	Maximum rate: 8mL/min (480 mL/h)

- For Octaplex, Health Canada has approved more rapid infusion rates (such as 1000 IU over 5 minutes or 8mL/min) in critical (or urgent) situations

PCC Reconstitution Instructions:



Fig. 1

1. Ensure lyophilized PCC and water for injection (WFI) are brought to room temperature
2. Remove caps from the PCC and WFI and clean the rubber stoppers with an alcohol swab
3. Peel away the lid of the outer package of the Mix2Vial™ transfer set. Place the WFI vial on an even surface and hold the vial firmly.
4. Push the blue plastic cannula of the Mix2Vial™ firmly through the rubber stopper of the WFI vial in one swift motion

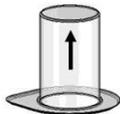


Fig. 2

5. While holding on to the WFI vial, carefully removed the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ firmly attached to the WFI vial



Fig. 3

6. Hold the PCC vial firmly on an even surface. Quickly invert the WFI vial (with the Mix2Vial™ attached). Push the transparent plastic cannula end of the Mix2Vial™ firmly through the stopper of the PCC vial and hold the downward pressure. The WFI will be drawn into the PCC vial by vacuum



Fig. 4

7. With both vials still attached, slowly rotate the PCC vial to ensure the product is fully dissolved to a clear or slightly opalescent solution. Once the contents of the PCC vial are dissolved, firmly hold both the transparent and blue parts of the Mix2Vial™. Unscrew the Mix2Vial™ into two separate pieces with the vials still attached. Discard the empty WFI vial and the blue part of the Mix2Vial™