



octaplex® Prothrombin Complex Concentrate

Class: Manufactured blood product, derived from human plasma

OTHER NAMES:
Company: Octapharma

ROUTES	INTRAVENOUS			OTHER		
	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:

- octaplex ® is a manufactured prothrombin complex concentrate (PCC) that is derived from human plasma
- Manufacturing process includes solvent/detergent viral inactivation and a nanofiltration step
- Available in two vial sizes containing a lyophilized plasma protein preparation consisting of either approximately 500 IU or 1000 IU prothrombin complex (coagulation factors II, VII, IX, X), Protein C and S. See product insert for actual amounts. Factor IX is used to determine the concentration of the product.
- Also contains heparin and sodium citrate
- Diluent (sterile water for injection) vial size is 20 mL for 500IU, and 40 mL for 1000IU dose

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
 - vii) IgA deficient patients with anti-IgA antibodies

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 > 5
Dose of octaplex ®	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 informed consent 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: octaplex® 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 with Mix2Vial directions can be found at

<http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-reconst-inst.pdf>

Reconstitution Supplies:

- Vial of octaplex® 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 octaplex® is being infused.

Administration Rate

- Initial infusion rate of 1 mL/min (Pump rate: 60 mL/h) for first 10 minutes, followed by a maximum rate of 2-3 mL/min (Pump rate: 120-180 mL/h).

Options for IV Infusion:

- **Direct IV:** Slow administration, not to exceed 2-3 mL/min.
- **Syringe pump:** (Microbore tubing required). Not to exceed 2-3 mL/min (**Pump rate: 180 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 octaplex®. Flush line at the same rate with 35 mL normal saline at the end of octaplex® 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 octaplex® to chamber for infusion. Flush line at the same rate with 35 mL NS at the end of octaplex® 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 octaplex® (similar to tPA process). Infuse octaplex®. 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.
- **octaplex® 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 °C, DO NOT freeze.
- Use immediately following reconstitution. If not used immediately, reconstituted solution is stable and can be stored for up to 8 hours at 2-25 °C (provided sterility of product is maintained)
- Protect from exposure to light

COMMENTS:

Date Effective: 4 May 2018

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Approved By: TM Network

For questions or comments, please contact Tranfusion.SafetyTeam@ahs.ca

REFERENCES

NAC prothrombin complex recommendations at <http://www.nacblood.ca>

octaplex® product monograph SCN 174693

<http://www.octapharma.ca>