Other Names	• Octaplex® • Beriplex®
Description	Octaplex® and Beriplex® are manufactured prothrombin complex concentrates (PCC) that are derived from human plasma. The manufacturing process has undergone solvent / detergent treatment and / or nanofiltration for viral, bacterial and parasite inactivation and removal. Each vial contains approximately 500 IU of procoagulant vitamin K dependent factors – II, VII, IX and X, anticoagulant factors protein C, protein S, and heparin to varying degrees (see product insert for actual amounts). In addition, Beriplex®P/N also contains human antithrombin III and albumin.
Special Approvals/Authorizations	• To request this product please refer to Request for Prothrombin Complex Concentrates (PCC) form. Complete form and forward to blood bank. • Nurses and student nurses may administer prothrombin complex concentrate on the written order of the attending physician or designate.
Classification/Indications	• Emergent reversal of warfarin therapy of vitamin K deficiency in patients: • Exhibiting serious of life-threatening bleeding manifestations • Requiring UNPLANNED / URGENT (<6 hours) interventions with risk of bleeding

Contraindications	• Patients with history of heparin induced thrombocytopenia (HIT)
	
	• Not Recommended for:
	  ○ Disseminated intravascular coagulation (DIC)
	  ○ Coagulopathy associated with liver dysfunction/disease
	  ○ Massive transfusions
	  ○ Reversal of anticoagulants other than Vitamin K antagonists
	  ○ Treatment of elevated INRs without bleeding or need for surgical intervention

Supplied	Vial size is 500IU and 1000IU
Dosage	• USUAL DOSE: 1000 IU • Maximum total dose = 3000 IU

	PCC dose if INR > 5	**PCC dose if INR 3-5**	**PCC dose if INR <3**
Dose	3000 IU (120 mL)	2000 IU (80 mL)	1000 IU (40 mL)
Vitamin K1	10 mg IV co-administration is strongly recommended if reversal is required for longer than 6 hours (the half-life of PCC). The onset of action of Vitamin K1 is 4-6 h IV.		

Reconstitution/Stability	Reconstitution • Available as 500 international units prothrombin complex powder/vial. • Required supplies: • 20 mL sterile water • Transfer set with filter • Empty 250 mL IV bags may be used for reconstituted product • Reconstitution directions are included • **Do not dilute further.** • Final reconstituted concentration: 25 international units /mL. Stability • Powdered product has a shelf life of 36 months when stored in a monitor facility at 2-25°C. DO NOT freeze. • Use immediately following reconstitution.

<table>
<tr><td></td><td></td></tr>
<tr><td>Compatibilities/ Incompatibilities</td><td>• Use a separate line with a standard IV administration set (tubing with a filter is not required).
• No other drugs / solutions (including normal saline) can be co-administered in the same line while PCC is being infused</td></tr>
<tr><td>Administration, Identification</td><td>Refer to Manitoba Best Practice Guidelines
• section 2.2 Standards- Identification and Administration</td></tr>
<tr><td>Administration, Method</td><td>Infusion routes – Intravenous.
Initial infusion rate of 1 mL / min for first 5 minutes, followed by a maximum rate for remainder of the infusion.
Flush the line with normal saline following completion of the infusion.

<table><tr><td></td><td>Octaplex®</td><td>Beriplex®P/N</td></tr><tr><td>Maximal rates of infusion</td><td>3mL / min</td><td>8 mL / min</td></tr></table></td></tr>
<tr><td>Adverse Events</td><td>Refer to Manitoba Best Practice Guidelines section 2.7 for transfusion reactions.
• Common side effect specific to Prothrombin Complex Concentrate are : headache, allergic reactions, anaphylactic reactions, fever, thromboembolic complications
• Both Octaplex® and Beriplex®P/ N have been rarely associated with immediate allergic or thrombotic complications.</td></tr>
<tr><td>Resources:</td><td>National Advisory Council on Blood prothrombin complex recommendations:
http://www.nacblood.ca/resources/guidelines/PCC-Recommendations-Final-2014-05-16.pdf
Octaplex® product monograph:
http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/20120613_PM_Octaplex_approved.pdf
Octaplex® reconstitute Instructions:
http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/5625_Octa_Instruction_Sheet-ENG.pdf
Beriplex®P/N product monograph:
http://labeling.cslbehring.ca/PM/CA/Beriplex-PN/EN/Beriplex-PN-Product-Monograph.pdf</td></tr>
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