

Hamilton Regional Laboratory Medicine Program - HRLMP (effective at Hamilton Health Sciences, St. Joseph's Healthcare and Associated Health Care Facilities)		
Initial Issue Date: Revision Date:	Administration Guidelines	Section: Laboratory Medicine Sub-Section: <i>Transfusion Medicine</i>
Title: PROTHROMBIN COMPLEX		Document Number:
<i>Approved By:</i> <i>Director, Laboratory Medicine</i> <i>Chair, Regional Transfusion Medicine Committee</i> <i>Head, Transfusion Medicine, HRLMP</i> <i>Manager, Transfusion Medicine, HRLMP</i> <i>Technical Specialist, Transfusion Medicine, HRLMP</i> <i>Chief of Nursing Practice, Hamilton Health Sciences</i> <i>Chief of Nursing Practice, St. Joseph's Healthcare</i>		Page 1 of 4

Purpose: To Establish the Indications and Administration of Prothrombin Complex

Scope: All patient care areas across HHS and St. Joseph's Healthcare

Definitions: Prothromplex- T is a concentrate prepared from human plasma and contains the coagulation factors II, VII, IX and X.

Other Names: PROTHROMPLEX-T TIM 4 (Human)	Date Approved:	Pages: 1 of 4
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INDICATIONS:

- Patients with acquired prothrombin complex deficiency primarily caused by: oral anticoagulants, severe liver disease, vitamin K-deficiency
- Control bleeding before, during and post surgery in above individuals
- Treatment of surgical bleeding in patients with single or multiple congenital deficiency of II, VII, IX or X when single factor concentrates are unavailable

DOSAGE:			
<ul style="list-style-type: none"> – Therapy must be individualized – General Rule: individual dosage regimens should be based on results of coagulation test 			
Type of Hemorrhage or Surgery	Factor IX-Level to be Achieved Initially	Factor IX-Level Maintenance Therapy	Average Duration of Treatment
Minor Hemorrhage	20%	---	Single dose usually sufficient
Major Hemorrhage	40%	20 - 40%	3 - 4 days or until wound healing
Life Threatening Hemorrhage or Major Surgery	≥ 60%	1 st post-op week: 40-60% 2 nd post-op week: 20-40%	10-14 days or until complete wound healing

SUPPLIED:
<ul style="list-style-type: none"> – Special Access Product - must obtain Emergency Drug Release - contact Transfusion Medicine – Lyophilized state should be reconstituted immediately before administration – Store product between 2°C and 8°C – Do not use past expiry date on product – Supplied in 200 IU and 600 IU vials
RECONSTITUTION AND STABILITY:
<ul style="list-style-type: none"> – Preparation (including reconstituting, filtering, and pooling if required) is performed in Transfusion Medicine – See Manufacturer’s information (package insert) for further information – Reconstituted product should be used immediately

ADMINISTRATION:					
<ul style="list-style-type: none"> – Product should not be further diluted 					
METHOD	WHOWHERE	DILUTION	HOW TO ADMINISTER	INFUSION PUMP	PRECAUTIONS AND MONITORING
IV PUSH	RN	No	<ul style="list-style-type: none"> - Administer filtered product with administration needle - Maximum rate 5 mL/min 		<ul style="list-style-type: none"> - Observe and monitor for adverse reactions
MINIBAG/ BURETROL	RN	No	<ul style="list-style-type: none"> - Administer filtered product using buretrol or sterile bottle with a vented administration 	Yes	<ul style="list-style-type: none"> - Observe and monitor for adverse reactions

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			set. -Maximum rate 5 mL/min		
PRIMARY IV BAG	N/A	N/A	N/A	N/A	N/A
IM or SC	N/A	N/A	N/A	N/A	N/A

COMPATIBILITIES/INCOMPATIBILITIES:

- No interactions with other drugs have been reported to date
- Should not be infused with other intravenous solutions
- Common venous access should be flushed with isotonic saline prior to and after the administration of PROTHROMBIN COMPLEX
- Must not be used on patients with signs of D.I.C. or hyperfibrinolysis unless it is a life threatening bleed
- Also, not used on patients with myocardial infarction, coronary heart disease and other risk factors predisposing to thrombosis
- Do not use on patients with hypersensitivity to heparin

ADVERSE EFFECTS:

- High doses of PROTHROMBIN COMPLEX have been associated with D.I.C. and thromboembolic complications
- Monitor patients closely particularly in patients with liver disease
- Replacement therapy may lead to the formation of a circulating inhibitor directed against the respective coagulation factor in rare cases
- Heparin, even small amounts, cannot be excluded as a cause of adverse reactions.

MANAGEMENT OF ADVERSE EFFECTS:

- Notify physician
- Notify Transfusion Medicine
- Discontinue infusion if suspicious signs develop where appropriate, antithrombotic therapy with heparin and/ AT III should be initiated
- Hypersensitivity reactions can be managed with antihistamines
- Severe reactions require immediate intervention following the rules of modern shock therapy
- Epinephrine should be available for treatment of severe allergic symptoms

NOTES:

- When performing clotting tests which are sensitive to heparin, in patients receiving high doses of PROTHROMBIN COMPLEX, the heparin content in the product must be taken into account
- See package insert
- Manufactured by: IMMUNO AG-VIENNA AUSTRIA

Documentation

Issue transfuse sheets or requisitions with lot numbers must be included in patient's chart. Written consent for transfusion must be obtained prior to administration.

References

Package Insert Prothrombin Complex, Human, Steam Treated, Oesterreichisches Institut Fuer Haemoderivate Ges. M.B.H. Immuno April 1994

Developed By In Consultation With

Transfusion Medicine Operations Group
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REVIEW DATES:

REVISION DATES: