

<b>Hamilton Regional Laboratory Medicine Program - HRLMP</b> (effective at Hamilton Health Sciences, St. Joseph's Healthcare and Associated Health Care Facilities)		
Initial Issue Date: Revision Date:	<b>Administration Guidelines</b>	Section: <b>Laboratory Medicine</b> Sub-Section: <i>Transfusion Medicine</i>
Title: <b>RECOMBINANT FACTOR IX</b>		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 Recombinant Factor IX

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

**Definitions:** BeneFix™ is a purified protein produced by recombinant DNA technology for use in therapy of factor IX deficiency.

<b>Other Names:</b> BeneFix™, COAGULATION FACTOR IX	<b>Date Approved:</b>	<b>Pages:</b> 1 of 4
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<p><b>INDICATIONS:</b></p> <ul style="list-style-type: none"> <li>- Control and prevention of hemorrhagic episodes in patients with hemophilia B, (congenital Factor IX deficiency or Christmas disease), including control and prevention of bleeding in surgical settings</li> <li>- Not indicated for treatment of other factor deficiencies (II, VII, X) not for treatment of hemophilia A patients with anti-VIII inhibitors, nor for reverse of coumadin overdose, nor for coagulopathy of liver disease.</li> </ul>
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## RECOMBINANT FACTOR IX

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### **DOSAGE:**

- Dependent of severity of Factor IX deficiency and clinical condition
- On average, one I.U. of BeneFix/Kg body weight increased the circulating activity of factor IX by 0.8 I.U./dL
- Formula # of factor IX I.U. required = body wt (in Kg) x desired factor IX increase (%) x 1.2 IU/Kg
- Presence of an inhibitor, dosage may be higher
- Refer to chart in package insert for dosing in bleeding episodes and surgery

	Circulating Factor IX Activity Required (%)	Frequency of Doses (hr)	Duration of Therapy (days)
Minor Hemorrhage	20-30	12-24	1-2
Moderate Hemorrhage	25-50	12-24	Approximately 2-7
Major Hemorrhage	50-100	12-24	7-10

### **SUPPLIED:**

- Single dose vials of 250, 500 or 1,000 & 2,000 I.U. per vial
- Actual Factor IX activity in I.U. is stated on label of each vial
- Do not use past expiry date

### **RECONSTITUTION AND STABILITY:**

- 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

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<b>ADMINISTRATION:</b> - Product should not be further diluted					
<b>METHOD</b>	<b>WHO/WHERE</b>	<b>DILUTION</b>	<b>HOW TO ADMINISTER</b>	<b>INFUSION PUMP</b>	<b>PRECAUTIONS AND MONITORING</b>
IV PUSH	RN	No	- Administer filtered product with an administration needle - Rate determined by patient's comfort level	No	- Observe and monitor for adverse reaction
MINIBAG/ BURETROL	RN	No	- Administer filtered product, using a buretrol or sterile bottle with a vented administration set	Yes	- Observe and monitor for adverse reaction
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:**

- May be contraindicated in patients with a known history of hypersensitivity to hamster protein.
- Because of potential risk of thromboembolic complications, caution should be exercised when administering this product to patients with liver disease, to patients post-operatively, to neonates, or to patients at risk of thromboembolic phenomena or DIC

**ADVERSE EFFECTS:**

- May get headache, fever, chills, flushing, nausea, vomiting, lethargy or manifestations of allergic reaction.

**MANAGEMENT OF ADVERSE EFFECTS:**

- Notify physician
- Notify Transfusion Medicine
- Rate of infusion should be decreased or the infusion stopped
- Epinephrine should be available for treatment of acute allergic symptoms

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**NOTES:**

- Manufactured by the Genetics Institute, Distributed by Canadian Blood Services  
Read package insert prior to administration.

**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-Benefix™, Coagulation factor IX (Recombinant), Genetics Institute Incorporated, February 2001.

**Developed By In Consultation With:**

Transfusion Medicine Operations Group  
Hemophilia Nurse Coordinator

REVIEW DATES:

REVISION DATES: