

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: FACTOR IX CONCENTRATE (HUMAN)		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 3

Purpose: To Establish the Indications and Administration of Factor IX Concentrate

Scope: Applies to all Transfusion Medicine Sites at HHS and St. Joseph's Healthcare

Definitions: Immunine factor IX is prepared from pooled human plasma that has been vapor-heated and then freeze-dried.

Other Names: IMMUNINE VH	Date Approved:	Pages: 1 of 3
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INDICATIONS:		
– Therapy and prophylaxis of bleeding episodes caused by congenital or acquired Factor IX deficiency		
DOSAGE:		
– Dependent on patient's weight, level of Factor IX in patient's plasma and the type of hemorrhage or surgery		
– See package insert		
– Immunine VH dose (in IU FIX) = body weight (in Kg) x desired increase in FIX (in %) x 1.2 IU/kg		
Type of hemorrhage or Surgical Intervention	Therapeutically Necessary FIX Plasma Level (% of normal)	Period During Which it is Necessary to
Minor	30%	at least 1 day
Major	30-50%	3 to 4 days
Life Threatening	50-75%	after 7 days factor IX level may be lowered but therapy continued for at least another 7 days
– Regular determinations of the patient's factor IX plasma level are necessary for monitoring the course of therapy and calculation of appropriate maintenance doses		

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SUPPLIED:

- Purified, sterile, freeze-dried concentrate
- Store between 2°C and 8°C and use before expiry date on label
- Supplied in 160 to 240, 480 to 720 and 960 to 1440 vials sizes
- Do not use after expiration date

RECONSTITUTION AND STABILITY:

- Preparation (including reconstituting, filtering, pooling if required) is performed on Transfusion Medicine
- See Manufacturer's information (package insert) for further information
- Reconstituted product should be used immediately

ADMINISTRATION:

- Product should not be further diluted

METHOD	WHO/WHERE	DILUTION	HOW TO ADMINISTER	INFUSION PUMP	PRECAUTIONS AND MONITORING
IV PUSH	RN	No	- Administer filtered product with Administration needle - Maximum rate of infusion 2 mL/minute	No	- Observe and monitor for adverse reactions
MINIBAG/ BURETROL	RN	No	-Administered filtered using a buretrol or sterile bottle with vented administration set -Rate of 2 mL/min	Yes	- observe and monitor for adverse reactions
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 pharmacologic interactions with other drugs are currently known
- IMMUNE VH should not be mixed with other drugs as for any blood coagulation factor concentrate

ADVERSE EFFECTS:

- Hypersensitivity reactions may occur (eg.: fever, urticaria, nausea, vomiting, dyspnea, drop in blood pressure, shock)
- Infusion of Factor IX concentrate may lead to the formation of circulating antibodies that inhibit factor IX in rare cases
- Thromboembolic complications cannot be entirely ruled out (applies particularly to patients at risk for thrombosis and/or receiving high dose therapy)

MANAGEMENT OF ADVERSE EFFECTS:

- Notify physician
- Notify Transfusion Medicine
- If hypersensitivity reactions occur, infusion should be stopped
- Minor reactions may be controlled by antihistamines
- Severe hypotensive reactions should be treated following the current guidelines of shock treatment
- Epinephrine should be available for treatment of severe allergic symptoms

NOTES:

- Manufactured by: OESTERREICHISCHES INSTITUT FUER HAEMODERIVATE GES. M.B.H. (Subsidiary of IMMUNO AG - Vienna, Austria)
- Distributed by: IMMUNO (Canada) Ltd., Mississauga, Ontario

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-Factor IX concentrate (Human) Vapor Heated Immuno, Oesterreichisches Institut Fuer Haemoderivate Ges. M.B.H. Immuno AG., May 1996

Developed By In Consultation With:

Transfusion Medicine Operations Group
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REVIEW DATES:

REVISION DATES: