

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>
<i>Title:</i> RECOMBINANT FACTOR VIIa		<i>Document Number:</i>
<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>		<i>Page 1 of 3</i>

Purpose: To Establish the Indications and Administration of Recombinant Factor VIIa

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

Definitions: NiaStase is an activated recombinant blood coagulation factor VII. NiaStase is free of all human plasma components.

Other Names: NiaStase (rFVIIa)	Date Approved:	Pages: 1 of 3
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<p>INDICATIONS:</p> <ul style="list-style-type: none"> - Hemophilia A/B patients with inhibitors for FVIII or FIX respectively for treatment of bleeding episodes (including treatment and prevention of those occurring during or after surgery) - Severe bleeding disorders (only on direction of hematologist)
<p>DOSAGE:</p> <ul style="list-style-type: none"> - Initial dose is usually 70 to 90 µg (4.5 KIU) per kg body weight, administered every 2 hours until clinical improvement is observed - Dose may vary depending on bleeding severity or surgery type - If continued therapy is required, dose interval may be increased from 2 to 6 hours
<p>SUPPLIED:</p> <ul style="list-style-type: none"> - Supplied as a white, lyophilized powder - Supplied in single dose vials with diluent - Vials contain: <ul style="list-style-type: none"> - 4.8 mg/vial (corresponds to 240 KIU/vial) - 2.4 mg/vial (corresponds to 120 KIU/vial) - 1.2 mg/vial (corresponds to 60 KIU/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

ADMINISTRATION:

- Product should not be further diluted

METHOD	WHO/WHERE	DILUTION	HOW TO ADMINISTER	INFUSION PUMP	PRECAUTIONS AND MONITORING
IV PUSH	RN OR PHYSICIAN	No	- Administer product intravenously over 2 to 5 minutes		- Observe and monitor for adverse reactions
MINIBAG/ BURETROL	RN	No	- Administered by infusion using a buretrol or sterile bottle	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:

Product is contraindicated if patient has:

- Known hypersensitivity to foreign protein
- Allergy to mice, hamsters or cattle

Patients with –DIC

- Advanced atherosclerotic disease
- Crush injury
- Septcemia; may have potential risk of developing thrombotic events with Niatase

treatment

- Product should not be mixed with infusion solution

ADVERSE EFFECTS:

- Reactions such as rash, itching, fever, nausea, headache, general discomfort, perspiration or changes in blood pressure may occur, but are rare
- Major adverse events possibly related to treatment have been reported in 7 cases (renal failure, ataxia, cerebrovascular disorder, angina pectoris, atrial arrhythmia and circulatory shock)

MANAGEMENT OF ADVERSE EFFECTS:

- Notify physician
- Notify Transfusion Medicine
- If too much is injected, consult physician
- Epinephrine should be available for treatment of severe allergic symptoms

NOTES:

- Manufactured by NovoNordisk A/S
- Distributed by Baxter Healthcare Corporation, Hyland Immuno, Glendale CA 91203

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 transfusion

References:

Package Insert-Niatase^R eptacog alfa (activated), Novo Nordisk, Canada, Inc. September 1998.

Developed By In Consultation With

Transfusion Medicine Operations Group
Hemophilia Nurse Coordinator

REVIEW DATES:

REVISION DATES: