Alberta Health Services

This document applies to all Covenant and AHS sites.

NiaStase RT®

Class: *Manufactured recombinant product*

OTHER NAMES: recombinant Factor VIIa, eptacog alfa (activated)

Company: Novo Nordisk

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes	Yes	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

DESCRIPTION OF PRODUCT:

- NiaStase RT® contains activated recombinant Factor VII.
- Supplied in 1.0 mg, 2.0 mg, and 5.0 mg single use vials as a white lyophilized powder with a clear, colorless histidine in water solvent, in either a vial or a prefilled syringe (as of July 2015).
- **Latex-free**

AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Hemophilia A/B patients with inhibitors to Factor VIII or Factor IX, respectively, for the treatment of bleeding episodes (including treatment and prevention of those occurring during and after surgery).
- Glanzmann's thrombasthenia with clinical refractoriness and/or platelet specific antibodies, or where platelets are not immediately available (including treatment of severe bleeding episodes and/or prevention of bleeding in surgical interventions or invasive procedures).

CONTRAINDICATIONS:

- Known hypersensitivity to any of the constituents in the preparation of NiaStase®, or to mouse, hamster, or bovine protein.

WARNINGS:

- Both arterial and venous thromboembolic adverse events have been reported after NiaStase® treatment, mostly in patients with predisposing concurrent risk factors. Caution should be exercised in: patients with the following conditions: history of coronary heart disease, liver disease, immobilized post-operatively, neonates, risk of thromboembolic phenomena, or disseminated intravascular coagulation (DIC).
- Patients with DIC, advanced atherosclerotic disease, crush injury, septicemia, or concomitant treatment with aPCCs/PCCs (activated/non-activated prothrombin complex concentrates) may have an increased risk of developing thrombotic events due to their underlying condition or concomitant treatment.

DOSE (Refer to Product Insert):

Treatment for bleeding episodes:

- Recommended initial dose = 90 mcg/kg (dose may vary depending on severity of bleed). See product insert.

Treatment for surgery:

- Recommended initial dose = 90 mcg/kg (dose may vary depending on type of surgery). See product insert.

Consult with Hematologist or bleeding disorders clinic.

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.
- Ensure that the 'Review of Niastase RT® Use' form is filled out and sent back to the Blood Bank (To be filled out once/patient/indication) where required.

Access: NiaStase RT ® can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:

- NiaStase RT®, lyophilized in single dose vial and solvent **Or** NiaStase RT® lyophilized in single dose vial and prefilled syringe with solvent (MixPro® as of July 2015)

Administration Supplies:

- Sterile plastic syringe (large enough to contain dose) or pre-filled syringe (after July 2015) compatible with luer-lock connections
- Sterile 20-26 gauge needle
- Alcohol swabs

Reconstitution: Refer to reconstitution steps with vial adapter at following link::
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-niastase-reconst-va.pdf

with syringe: http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-niastase-reconst-mixpro.pdf

Administration:

- Give immediately after reconstitution (within 3 hrs) of reconstitution. **DO NOT freeze** after reconstitution or store in syringes.
- Intended for IV bolus administration **only**.
- **DO NOT** mix with other drugs or IV solutions.
- **DO NOT** store reconstituted NiaStase RT® in syringes.
- **Administration rate:** Direct IV over 1-2 minutes, or at rate as requested by authorized prescriber or hemophilia clinic.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.
- **The most common adverse reactions are pyrexia, injection site reactions, headache, hypertension, hypotension, nausea, vomiting, pain, edema, and rash. Monitor for signs and symptoms of thrombosis.**

Side Effects - Flushing - Headache - Nausea - Itching and redness at injection site	→	**Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**Action** **STOP** infusion **IMMEDIATELY** and contact physician.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as the patient condition requires.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post.

Patients receiving product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, refer to the following link http://www.albertahealthservices.ca/lab/page4240.aspx. **Notify the transfusion service as soon as possible that an adverse reaction has occurred.**

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products procedure
- ***Recipients of blood products are to be notified in writing of the transfusion***

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-30°C. **Do not freeze**.
- Keep protected from light.
- Reconstituted product must be administered within 3 hours of reconstitution.

COMMENTS:

Date Effective: 11 Sep. 2015
Revised Date: 11 Aug 2015
Version 1.1
Approved By: TM Network
Document Number: PTMRGN00011
For questions or comments about this document, please contact Transfusion.SafetyTeam@albertahealthservices.ca

REFERENCES

NiaStase RT® product monograph
CBS Customer Letter #2015-16

LINK to WEBSITE for PRESCRIBING INFORMATION:

http://www.novonordisk.ca/