ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

NiaStase RT®

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *recombinant Factor VIIa, eptacog alfa (activated)* ***Company:*** *Novo Nordisk* ***Class:*** *Manufactured recombinant product*

	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.**

**** Transfusion of Blood Components and Products Learning Module: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration.**

DESCRIPTION OF PRODUCT:

- NiaStase RT® is a white lyophilized powder that contains activated recombinant Factor VII.
- Supplied in 1.0 mg (50KIU), 2.0 mg (100 KIU), and 5.0 mg (250 KIU) single use vials.
- Also contains calcium chloride dehydrate, glyclyglycine, mannitol, methionine, polysorbate 80, sodium chloride, and sucrose. The solvent for reconstitution contains histidine in water for injection.
- Latex-free

AVAILABILITY

- Supplied by Canadian Blood Services.
- 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).
- Congenital Factor VII deficiency, for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery 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.
- Patients with inherent Factor VII deficiency may have pre-existing or may develop anti-Factor VII antibodies during therapy with NiaStase RT®. The clinical significance of these antibodies is unknown.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MHRP).
- Consult with Hematologist or bleeding disorders clinic
- Hemostasis evaluation should be used to determine the effectiveness of NiaStase RT® and to provide a basis for modification of the treatment schedule
- NiaStase RT® should be given as early as possible after the start of a bleeding episode. Following the initial dose, further injections may be repeated. The duration of treatment and the interval between injections will vary with the severity of the hemorrhage, the invasive procedure or surgery being performed.
- **Treatment for bleeding episodes and surgical procedures:**
  - Refer to patient's care plan or Factor First card, if available
  - If neither are available, consult with bleeding disorders clinic or transfusion medicine physician.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component 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 nursing protocol.

Access: Product can be given via CVC, PICC, or peripheral IV line

Reconstitution Supplies:

- NiaStase RT® Product (lyophilized powder)
- 10 mmol/L histidine solvent (prefilled MixPro® syringe* included with product)
- Plunger rod (included with product)
- Vial adapter (included with product)
- Alcohol swabs (not included with product)

Administration Supplies:

- Alcohol swabs
- Sterile plastic luer lock syringe, large enough to contain dose*
- Infusion set (not included with product)

***Note:** The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile 10 mL (or larger) plastic syringe with a standard luer-lock connector. Ensure the vial adapter is used when withdrawing the solution from the vial into the syringe.

Reconstitution:

- See *Prefilled Syringe with Vial Adapter Reconstitution Instructions.*

Administration:

- Give immediately after reconstitution.
- Do not use solutions that are cloudy, have deposits, or are not colourless
- Intended for IV bolus administration **only**.
- Do Not mix with other drugs or IV solutions.
- Do Not store reconstituted NiaStase RT® in syringes.
- If administered via a central venous access device, use 0.9 sodium chloride for injection to flush the line after administration, if required.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended direct IV administration over a period of 2-5 minutes, depending on the total volume.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.

Patients receiving blood 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, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- Provide patient notification documentation where required.

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) must be reported to your local transfusion service.
- The most commonly reported adverse reactions in patients receiving NiaStase® 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 the venipuncture 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

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-25°C.
- Do not freeze.
- Keep protected from light.
- Reconstituted product in its original vial is stable for 6 hours at 25°C and 24 hours at 5°C
- Do not use expired product.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments please contact: Transfusion.SafetyTeam@albertaprecisionlabs.ca

REFERENCES:

NiaStase® Product Monograph. Available from www.novonordisk.ca