NiaStase RT

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Activated Recombinant Coagulation Factor VII Product	None

PREPARATION and ADMINISTRATION

NiaStase RT is a recombinant factor VII product that does not contain human plasma therefore blood consent is not required.

Reconstitution

Diluent: histidine solvent for injection

See pages 3-8 for reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter prior to administration.

IV Direct	Intermittent Infusion	Continuous Infusion
IV Direct is the recommended route of administration. Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Administer dose slowly over 2-5 minutes. Adapt the rate of administration to the response of each individual patient. If no indwelling IV, use the butterfly and supplies provided in the box.	**IV Bag (large volume pump)** Not Recommended **Syringe (syringe pump)** Not Recommended	**IV Bag (large volume pump)** Not applicable **Syringe (syringe pump)** Not applicable

Requirements and Monitoring

Simultaneous use of prothrombin complex concentrates should be avoided.

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Document all vitals taken.
Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Indicated:

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

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in those undergoing surgery or invasive procedures.

- In patients with congenital Factor VII deficiency, for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures.

ADVERSE EFFECTS

The most serious adverse drug reactions observed in patients receiving Niastase are thrombotic events, however the extent of the risk of thrombotic adverse events after treatment in individuals with congenital hemophilia with inhibitors is considered to be low.

The most common adverse drug reactions observed in patients with congenital hemophilia A or B with inhibitors are pyrexia, injection site reaction, headache, hypertension, hypotension, nausea, vomiting, pain, edema and rash.

If an AE is suspected: stop the infusion, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume infusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

For patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system

COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

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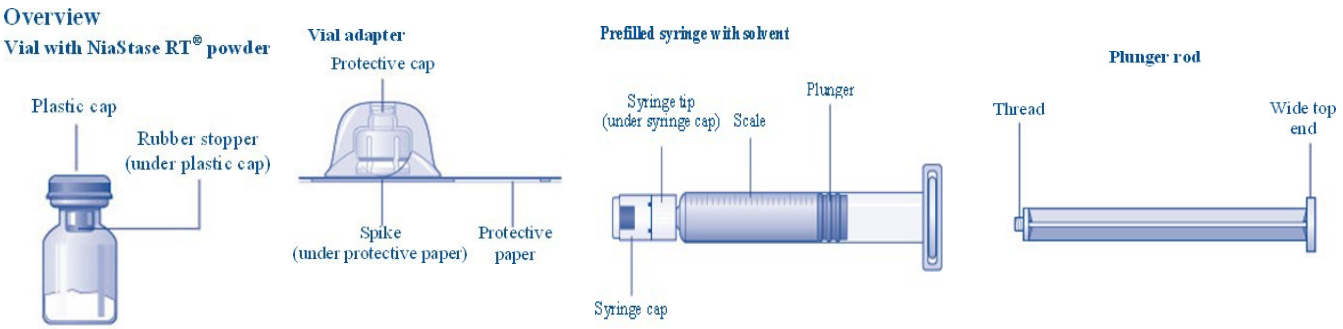
- None

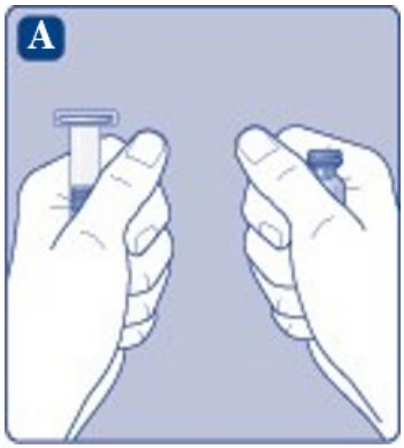
RECONSTITUTION

The diluent glass syringe will NOT fit some IV tubing. Use a plastic luer lock syringe to draw up reconstituted product for administration.

NiaStase RT® Vial Size (mg)	Volume of Histidine Solvent to be Added to NiaStase RT® Vial (mL)	Approximate Concentration of rFVIIa After Reconstitution (mg per mL)
1	1	1
2	2	1
5	5	1
8	8	1



1. Prepare the Vial and Syringe

Step A		**Check the expiry date. Put on clean gloves.** **Check the name, strength and colour** of the package, to make sure it contains the correct product. Take the vial, the vial adapter and the prefilled syringe out of the carton. **Leave the plunger rod untouched in the carton.** **Bring the vial and the prefilled syringe to room temperature** (not above 37°C). You can do this by holding them in your hands until they feel as warm as your hands. **Do not use any other way to warm** the vial and prefilled syringe**.**

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Step B		**Remove the plastic cap** from the vial**. If the plastic cap is loose or missing, do not use the vial.** **Wipe the rubber stopper** with a sterile alcohol swab and allow it to air dry for a few seconds before use to ensure that it is as germ free as possible.
2. Attach the Vial Adapter		
Step C		**Remove the protective paper** from the vial adapter. **If the protective paper is not fully sealed or if it is broken, do not use the vial adapter.** **Do not take the vial adapter out of the protective cap with your fingers.**
Step D		**Place the vial on a flat and solid surface.** **Turn over the protective cap,** and snap the vial adapter onto the vial. **Once attached, do not remove the vial adapter from the vial.**

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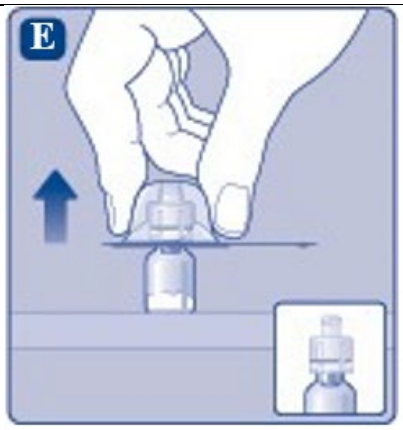
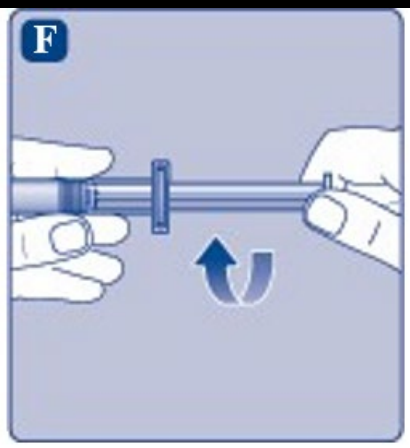
Step E		Lightly **squeeze the protective cap** with your thumb and index finger as shown. **Remove the protective cap** from the vial adapter. **Do not lift the vial adapter from the vial** when removing the protective cap.
3. Attach the Plunger Rod and the Syringe		
Step F		Grasp the plunger rod by the wide top-end and take it out of the carton. **Do not touch the sides or the thread of the plunger rod.** **Immediately** connect the plunger rod to the syringe by turning it clockwise into the plunger inside the prefilled syringe until resistance is felt.
Step G		**Remove the syringe cap** from the prefilled syringe by bending it down until the perforation breaks. **If the syringe cap is loose or missing, do not use the prefilled syringe.**

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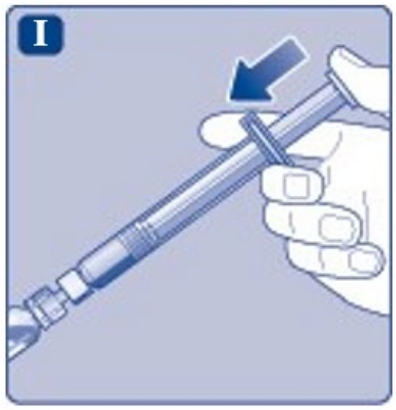
Step H		**Screw the prefilled syringe securely** onto the vial adapter until resistance is felt.
4. Reconstitute the Powder with the Solvent		
Step I		**Hold the prefilled syringe slightly tilted** with the vial pointing downwards. **Push the plunger rod** to inject all the solvent into the vial.
Step J		**Keep the plunger rod pressed down and swirl** the vial gently until all the powder is dissolved. **Do not shake the vial as this will cause foaming.** Check the reconstituted solution. If you notice visible particles or discoloration, do not use it. With the plunger rod pushed in, unscrew and **replace the glass syringe with a 10 mL plastic syringe** (with the rod pushed in).
NiaStase RT® is recommended to be used immediately after it has been reconstituted. If your dose requires more than one vial, repeat steps A to J with additional vials, vial adapters and prefilled syringes until you have reached your required dose.		

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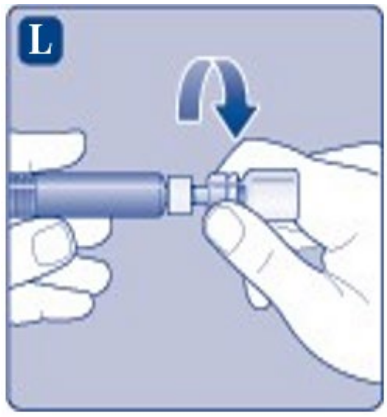
Step K		**Keep the plunger rod pushed completely in. Turn the** **syringe** with the vial upside down. **Stop pushing the plunger rod and let it move back** on its own while the reconstituted solution fills the syringe. **Pull the plunger rod slightly downwards** to draw the reconstituted solution into the syringe. If, at any point, there is too much air in the syringe, inject the air back into the vial. While holding the vial upside down, **tap the syringe gently** to let any air bubbles rise to the top. **Push the plunger rod** slowly until all air bubbles are gone.
Step L		**Unscrew the vial adapter** with the vial. **Do not touch the syringe tip.** NiaStase RT® is now ready to inject. Administer slowly over 2 to 5 minutes.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- NiaStase RT product monograph. Found at https://www.novonordisk.ca/products/our-products.html