

## Important: Please Read

### PART III: CONSUMER INFORMATION

**NiaStase RT<sup>®</sup>**  
(eptacog alfa, activated)  
**Activated Recombinant Human Blood Coagulation Factor  
VII Room Temperature Stable**

This leaflet is Part III of a three-part 'Product Monograph' published when **NiaStase RT<sup>®</sup>** was approved for sale in Canada and designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **NiaStase RT<sup>®</sup>**. Contact your doctor or Hemophilia Care Centre if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for

**NiaStase RT<sup>®</sup>** or eptacog alfa (activated) is more commonly known as activated recombinant human blood coagulation Factor VII (rFVIIa). **NiaStase RT<sup>®</sup>** is a clotting factor produced using recombinant DNA technology. **NiaStase RT<sup>®</sup>** or rFVIIa is free of all human plasma components, eliminating any possibility of contamination through the blood. **NiaStase RT<sup>®</sup>** is used in hemophilia A and hemophilia B patients with inhibitors to FVIII or FIX, respectively, for the treatment of bleeding episodes, (including treatment and prevention of those occurring during and after surgery).

##### What it does

**NiaStase RT<sup>®</sup>** is a medicine that works by activating the clotting system in the blood at the site of bleeding to prevent or eliminate the bleeding.

##### When it should not be used

###### **Pregnancy and breastfeeding**

Remember to tell your doctor or nurse if you are pregnant or are breastfeeding. Women of child-bearing potential should avoid becoming pregnant during treatment. Nursing mothers should discontinue nursing during treatment.

DO NOT use **NiaStase RT<sup>®</sup>** with any other clotting products. However, your doctor may prescribe other therapies to be used at the same time as **NiaStase RT<sup>®</sup>**.

##### What the medicinal ingredient is

Eptacog alfa, activated, contains activated recombinant human blood coagulation Factor VII (rFVIIa), which is similar to the natural human clotting Factor VIIa.

##### What the nonmedicinal ingredients are

**NiaStase RT<sup>®</sup>** contains the following nonmedicinal ingredients: calcium chloride dihydrate, glycylglycine, mannitol, methionine, polysorbate 80, sodium chloride and sucrose.

The solvent for reconstitution that comes with **NiaStase RT<sup>®</sup>** contains histidine in water for injections.

##### What dosage forms it comes in

**NiaStase RT<sup>®</sup>** comes as a freeze-dried powder available in 1.0 mg (50 KIU), 2.0 mg (100 KIU) and 5.0 mg (250 KIU) vials. The freeze-dried powder in a vial is reconstituted (dissolved) with the histidine solvent that is supplied with your **NiaStase RT<sup>®</sup>**.

#### WARNINGS AND PRECAUTIONS

##### **Serious Warnings and Precautions**

- The extent of the risk of developing blood clots after using **NiaStase RT<sup>®</sup>** is not known but is considered to be low. You may have an increased risk of developing blood clots if you have experienced a crush injury, have infection of the blood, hardening of the arteries or if you are prone to develop blood clots. If so, contact your Hemophilia Care Centre or doctor.
- Patients that lack the blood clotting factor VII (known as factor VII deficiency) can have an allergic response to **NiaStase RT<sup>®</sup>**.

BEFORE you use **NiaStase RT<sup>®</sup>** talk to your doctor if:

- you have experienced a crush injury;
- you have infection of the blood;
- you have hardening of the arteries;
- you are prone to develop blood clots.

*This information will help your doctor and you decide whether you should use **NiaStase RT<sup>®</sup>** and what extra care may need to be taken while you are on the medication.*

#### INTERACTIONS WITH THIS MEDICATION

Interactions with other drugs have not been established. Before using **NiaStase RT<sup>®</sup>**, talk to your doctor about any medicine you use.

## PROPER USE OF THIS MEDICATION

NiaStase RT<sup>®</sup> is available in three different strengths. Always check that you have the strength prescribed by your doctor. Always use an aseptic technique when injecting NiaStase RT<sup>®</sup>.

For instructions on how to prepare and administer NiaStase RT<sup>®</sup> please refer to the sections 'Preparing Your Injection' and 'Giving Your Injection' located at the end of this insert.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Tell your Hemophilia Care Centre or doctor as soon as possible if you do not feel well while you are receiving treatment with NiaStase RT<sup>®</sup>.

You may experience some redness at the injection site. This is normal. However, if you develop more severe symptoms such as: hives, itching, tightness of the chest, wheezing, or any other unusual effects, you should contact your Hemophilia Care Centre or doctor **immediately**.

Isolated cases of hypersensitivity reactions including anaphylactic reactions have been reported. Remind your doctor if you have a history of allergic reactions as you may need to be monitored more carefully.

Seek medical attention without delay, if bleeding does not appear to be adequately responding to treatment.

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or Hemophilia Care Centre		Stop taking drug and call your doctor
		Only if severe	In all cases	
Common	Redness at injection site	✓		
	Uncommon			
	Hives		✓	
	Itching		✓	
	Tightness of chest			✓
	Wheezing			✓
	Unusual effects		✓	
	If bleeding does not stop		✓	

This is not a complete list of side effects. For any unexpected effects while taking NiaStase RT<sup>®</sup>, contact your doctor.

## REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll- free telephone: 1-866-234-2345  
 Toll-free fax: 1-866-678-6789  
 By e-mail: [cadmp@hc-sc.gc.ca](mailto:cadmp@hc-sc.gc.ca)

By regular mail:  
 National AR Centre  
 Marketed Health Products Safety and Effectiveness  
 Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa, ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or Hemophilia Care Centre.*

## HOW TO STORE IT

Prior to reconstitution, keep **NiaStase RT**<sup>®</sup> powder and histidine solvent refrigerated or store between 2° to 30°C. Do not freeze. Protect powder and solvent from light. Do not use past the expiration date on the label.

After reconstitution, **NiaStase RT**<sup>®</sup> should be used immediately. If you do not use immediately after mixing, **NiaStase RT**<sup>®</sup> may be stored either at room temperature (below 30°C) or refrigerated for up to 3 hours. Do not freeze or store reconstituted **NiaStase RT**<sup>®</sup> in syringes.

**Keep all medication and supplies out of the reach of children.**

## MORE INFORMATION

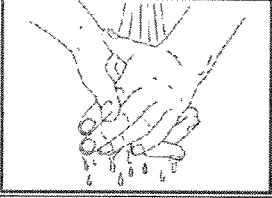
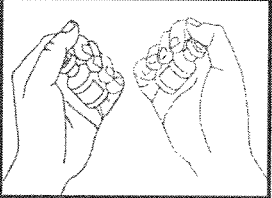
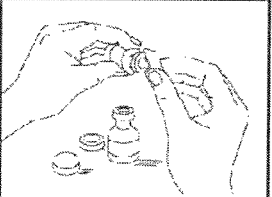
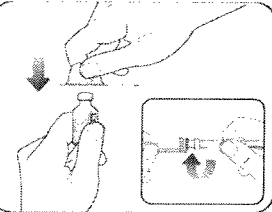
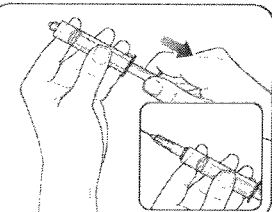
**If you still have questions or would like more information, please contact your doctor or Hemophilia Care Centre.**

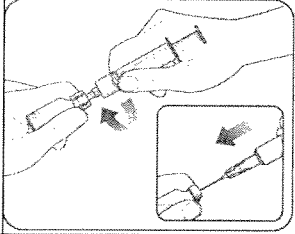
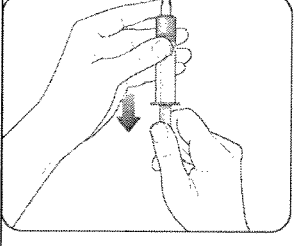
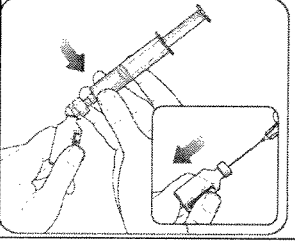
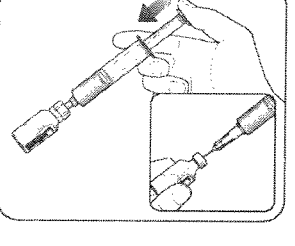
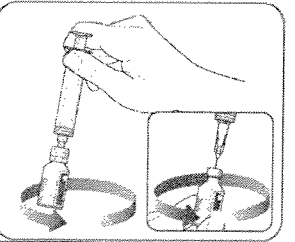
This document plus the full product monograph, prepared for health professionals can be found at:  
<http://www.novonordisk.ca> or by contacting Novo Nordisk Canada Inc., at: 1-800-465-4334

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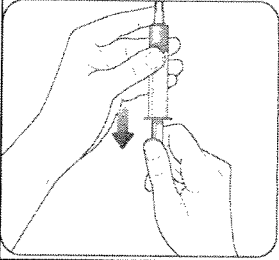
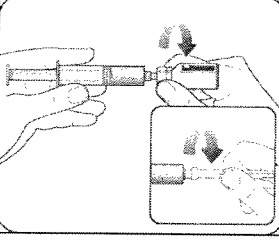
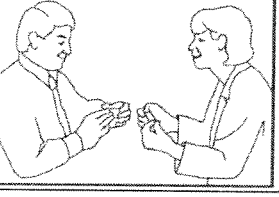
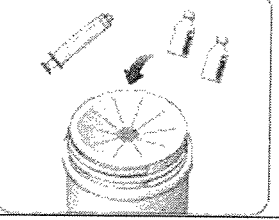
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PREPARING YOUR INJECTION		
Step 1		Wash your hands with soap and water before beginning and dry with a clean towel.
Step 2		<b>NiaStase RT<sup>®</sup></b> powder and histidine solvent vials should be at room temperature at reconstitution. If not at room temperature, hold vials to bring contents to room temperature.
Step 3		Remove the plastic caps from the two vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs, and allow them to dry prior to use.  When preparing your injection, you can either use a vial adapter or a needle. Instructions on using the vial adapter and needle are provided below.
Step 4		If using a vial adapter, remove the protective paper from the vial adapter without taking it out of the protective cap. Attach the vial adapter to the histidine solvent vial. Once attached, remove the protective cap. Take care not to touch the spike on the vial adapter.  If using a needle, remove the needle from the packaging without taking off the protective cap. Screw the transfer needle tightly onto the syringe. It is recommended to use syringe needles of gauge size 20-26.
Step 5		Pull the plunger to draw in a volume of air that is equal to the amount of histidine solvent in the solvent vial (mL equals cc on the syringe).

<p><b>Step 6</b></p>		<p>Screw the syringe tightly onto the vial adapter on the histidine solvent vial.</p> <p>If using a needle, remove the protective cap and insert the needle into the rubber stopper of the histidine solvent vial. Take care not to touch the end of the transfer needle.</p> <p>Inject the air into the vial by pushing the plunger until you feel a clear resistance.</p>
<p><b>Step 7</b></p>		<p>Hold the syringe with the histidine solvent vial upside down. If you are using a transfer needle, make sure that the needle tip is in the solvent. Pull the plunger to draw the correct amount of histidine solvent into the syringe. The correct volume of histidine solvent corresponds to the strength of <b>NiaStase RT<sup>®</sup></b> that you have been given.</p> <ul style="list-style-type: none"> <li>• Withdraw 1.1 mL of solvent, if using a 1.0 mg vial of <b>NiaStase RT<sup>®</sup></b></li> <li>• Withdraw 2.1 mL of solvent, if using a 2.0 mg vial of <b>NiaStase RT<sup>®</sup></b></li> <li>• Withdraw 5.2 mL of solvent, if using a 5.0 mg vial of <b>NiaStase RT<sup>®</sup></b></li> </ul>
<p><b>Step 8</b></p>		<p>Once the histidine solvent has been drawn, remove the empty solvent vial.</p> <p>If you use a vial adapter, tip the syringe to remove it from the vial.</p>
<p><b>Step 9</b></p>		<p>Attach the syringe with vial adapter or transfer needle to the powder vial.</p> <p>If you use a transfer needle, insert the needle through the centre of the rubber stopper of the vial containing the powder. Aim the needle against the side of the vial so that the stream of the histidine solvent runs down the vial wall.</p> <p>Push the plunger slowly to inject the histidine solvent into the powder vial. Make sure not to aim the stream of solvent directly at the <b>NiaStase RT<sup>®</sup></b> powder, as this will cause foaming.</p>
<p><b>Step 10</b></p>		<p>Keep the vial adapter or transfer needle attached to the vial. Gently swirl the vial until all the powder is dissolved into a colourless solution. Do not shake the vial as this will cause foaming. Inspect the vial solution for visible particles or discoloration. If the mixture is discoloured or contains particles, do not use it. The reconstituted product should be used immediately. If you do not use immediately after reconstitution, <b>NiaStase RT<sup>®</sup></b> may be stored either at room temperature (below 30°C) or refrigerated for up to 3 hours.</p>

## GIVING YOUR INJECTION

<b>Step 11</b>		<p>Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the syringe).</p> <p>If you are using a transfer needle, make sure that the transfer needle tip is in the solution.</p> <p>Hold the syringe with the vial upside down and pull the plunger to draw all the solution into the syringe.</p>
<b>Step 12</b>		<p>If you are using a vial adapter, unscrew the vial adapter from the empty vial.</p> <p>If you are using a transfer needle, remove the transfer needle from the vial and cover the needle with the needle cap. Twist the transfer needle off the syringe.</p>
<b>Step 13</b>		<p>Attach a suitable intravenous injection device to the syringe and inject <b>NiaStase RT<sup>®</sup></b> as instructed by your Hemophilia Care Centre or doctor. Do not store reconstituted <b>NiaStase RT<sup>®</sup></b> in syringes.</p>
<b>Step 14</b>		<p>Safely dispose of the syringe, vials, needles, any unused product and other waste materials as instructed by your healthcare professional.</p>