

**Important: Please Read**

**PART III: CONSUMER INFORMATION**

**NiaStase<sup>®</sup>**  
**(eptacog alfa, activated)**

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This leaflet is Part III of a three-part 'Product Monograph' published when **NiaStase<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<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<sup>®</sup>** or eptacog alfa (activated) is more commonly known as activated recombinant human blood coagulation Factor VII (rFVIIa). **NiaStase<sup>®</sup>** is a clotting factor produced using recombinant DNA technology. **NiaStase<sup>®</sup>** or rFVIIa is free of all human plasma components, eliminating any possibility of contamination through the blood. **NiaStase<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<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<sup>®</sup>** with any other clotting products. However, your doctor may prescribe other therapies to be used at the same time as **NiaStase<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 important nonmedicinal ingredients are:**

calcium chloride dihydrate, glycylglycine, mannitol, polysorbate 80, sodium chloride.

**What dosage forms it comes in:**

**NiaStase<sup>®</sup>** as a freeze-dried powder is available in 1.2 mg (60 KIU), 2.4 mg (120 KIU) and 4.8 mg (240 KIU) vials. The freeze-dried powder in a vial is reconstituted (dissolved) with Sterile Water for Injection, USP.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

- The extent of the risk of developing blood clots after using **NiaStase<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**<sup>®</sup>.

BEFORE you use **NiaStase**<sup>®</sup> talk to your doctor 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.

### INTERACTIONS WITH THIS MEDICATION

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

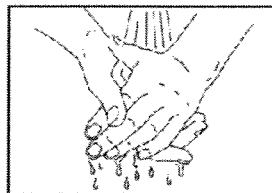
### PROPER USE OF THIS MEDICATION

**NiaStase**<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**<sup>®</sup>. For example follow the instructions for 'Preparing your injection' and 'Giving your injection'. Bring the **NiaStase**<sup>®</sup> powder and the correct volume of diluent (Sterile Water for Injection, USP - without preservative) to room temperature but not above 37°C (98.6°F). You can do this by holding the vials in your hands for a few minutes.

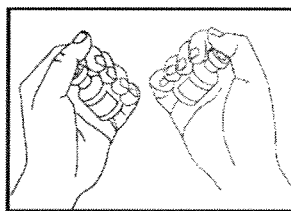
The correct volume of diluent (Sterile Water for Injection, USP - without preservative) corresponding to each strength of **NiaStase**<sup>®</sup> is as follows:

- 1.2 mg (60 KIU) per vial add 2.2 mL Sterile Water for Injection, USP
- 2.4 mg (120 KIU) per vial add 4.3 mL Sterile Water for Injection, USP
- 4.8 mg (240 KIU) per vial add 8.5 mL Sterile Water for Injection, USP

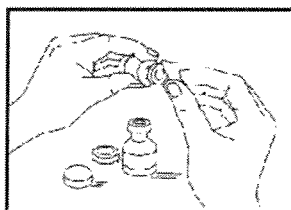
### Preparing your injection



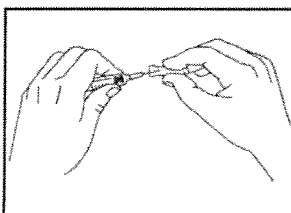
1. Wash your hands with soap and water before beginning.



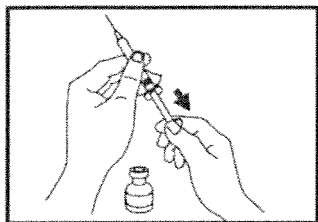
2. Hold vials to bring contents to room temperature.



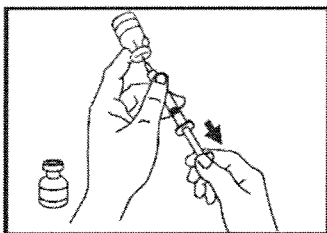
3. Remove the caps, clean stoppers with an alcohol swab, and allow to dry prior to use.



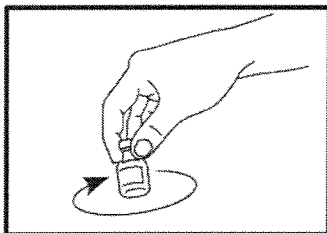
4. Attach needle to a sterile syringe and remove needle cap.



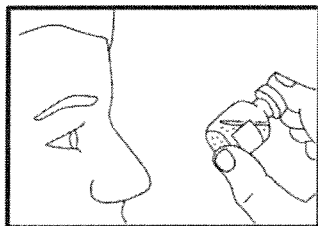
5. Admit air into the syringe and inject it into the vial containing the Sterile Water for Injection.



6. Withdraw the water and inject it into the vial containing the powder.

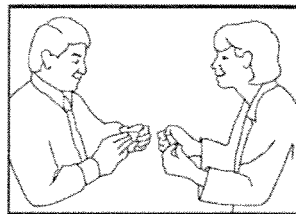


7. Gently swirl the vial until contents dissolve into a colourless solution. Do not shake the vial as this will cause foaming.

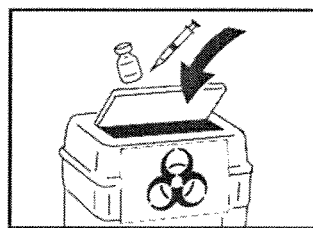


8. Inspect the vial solution for particles or discoloration. If the mixture is discoloured or contains particles, do not use it. Call your Hemophilia Care Centre or doctor.

### Giving your injection



9. Inject **NiaStase**<sup>®</sup> as instructed by your Hemophilia Care Centre or doctor. Do not store reconstituted **NiaStase**<sup>®</sup> in syringes. Use the reconstituted product within 3 hours.



10. Discard unused solution and needles in a proper container.

### **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

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

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 the drug and call your doctor
		Only if severe	In all cases	
Common	Redness at the injection site	✓		
Un common	Hives		✓	
	Itching		✓	
	Tightness of the 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<sup>®</sup>, contact your doctor.*

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.

**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**

Keep **NiaStase<sup>®</sup>** refrigerated, do not allow it to freeze.

Store in original package in order to protect from light.

Use each vial of reconstituted **NiaStase<sup>®</sup>** within 3 hours of mixing.

Do not use **NiaStase<sup>®</sup>** after the expiration date printed on the outer carton and on the vial label.

Do not store reconstituted **NiaStase<sup>®</sup>** in syringes.

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

## **MORE INFORMATION**

For further information, please refer to the leaflet '*Health Professional Information*'.

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

This document plus the full product monograph, prepared for health professionals, is available by contacting the sponsor, **Novo Nordisk Canada Inc.**, at 1-800-465-4334

This leaflet was prepared by **Novo Nordisk Canada Inc.**

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