

## Section S: Blood Product Overview –

### Niastase RT<sup>®</sup> Activated Recombinant Factor VII (rFVIIa)

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*NovoNordisk (Product is NovoSeven<sup>®</sup> in US and Europe)*

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#### DESCRIPTION of PRODUCT

- Recombinant Factor VII is converted to the active form (rFVIIa) during the purification process.
- rFVIIa is free from all human plasma components
- Each package includes the vial of lyophilized rFVIIa concentrate, a vial of pre-measured diluent (histadine in water) and a package insert.

#### AVAILABILITY of PRODUCT

- Supplied by the CBS.
- Both LHSC sites stock the 1 mg, 2 mg, and 5 mg vials.

#### STORAGE of PRODUCT

- Stored at 2 - 30°C.
- Expiration date is indicated on bottle.
- Reconstituted product must be administered within 3 hours of reconstitution.

Date effective: Jan 2005

Date revised: October 2011

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#### CLINICAL INDICATIONS (see package insert for contraindications)

- Treatment of spontaneous bleeding events or prior to invasive procedures in Hemophilia A and B patients with inhibitors or in patients with acquired FVIII inhibitors. rFVIIa bypasses the need for FVIII and/or FIX (the Intrinsic Pathway) in the formation of a clot.
- There have been studies done to assess the efficacy of rFVIIa in non-hemophiliac patients; however these are off-label indications for rFVIIa use. There are no national or international consensus guidelines but there are numerous meta-analysis published that conclude that there is limited efficacy data available and increasing data regarding adverse thrombotic events associated with the use of rFVIIa in non-hemophiliac patients.

#### REQUESTS for rFVIIa

- **Licensed indications:** rFVIIa will be released as requested by ordering physician for documented cases of Hemophilia A and B patients with inhibitors or in patients with acquired FVIII inhibitors.
- **Non-licensed indications:** Requests for rFVIIa for a non-hemophilia bleeding patient are monitored by the City Wide Blood Transfusion Committee (sub-committee of the MAC). A [Request for Niastase \(rFVIIa\) form](#) must be completed and forwarded to the Blood Transfusion Lab. This form alerts the physician to the risks associated with off-label use and provides a check-list to review prior to the infusion of rFVIIa. As well as completing the Request Form, the ordering physician will also receive a post-infusion email questionnaire 1 to 2 weeks post-infusion.

#### RECOMMENDED DOSE of rFVIIa

- **Licensed indications (Hemophilia patient with inhibitor):** Dose and dose interval should be based on bleeding risk assessment. Initial dose of 90ug / kg is recommended. Dose interval may range from 2 to 6 hours.
- **Non-Licensed Indication: Adult dose** is weight based and rFVIIa will be issued by the BTL according to this weight based protocol. One-dose is usually sufficient, but it may be repeated once if coagulopathy has not resolved. Additional doses of rFVIIa are not recommended.

Patient Weight	rFVIIa dosage guideline	Vials required for dose
< or = 40 kg	2 mg	1 X 2 mg vial
41 to 60 kg	3 mg	1 X 2 mg and 1 X 1 mg vial
61 to 80	4 mg	2 X 2 mg vial
> 80 kg	5 mg	1 X 5 mg vial

**Pediatric patient:** Dosage guideline - 0.04 mg/kg

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#### ADMINISTRATION of PRODUCT

- Supplied by the BTL in original package which includes lyophilized powder and pre-measured diluent
- Using needle and syringe, remove diluent from diluent vial. Insert needle through the centre of the rubber stopper of the vial containing the powder aiming diluent against side of vial, not directly on powder, to prevent foaming.
- Do NOT shake. Swirl gently until all the powder is dissolved
- Remove reconstituted rFVIIa from vial and infuse immediately by IV push
- Step by step reconstitution and administration instructions for [NIASTASE RT](#) are available through the [Bleeding Disorders Program](#) website.

#### ADDITIONAL COMMENTS:

Given the current state of knowledge of the efficacy and safety of rFVIIa for non-licensed indications, no national or international consensus guidelines exist to guide local practices and protocols. At LHSC, individual cases should continue to be managed on a case by case basis. Consider the following:

1. All surgical options (anatomical bleeding) have been explored.
2. Coagulation corrected
  - a. INR < 1.5
  - b. PTT < 55 sec
  - c. Fibrinogen > 1.0 g/L
3. Platelets > 50.
4. Any acidosis and/or hypothermia corrected.

#### LINK to WEBSITE for PRESCRIBING INFORMATION

Product monograph available at

[http://cae.novonordisk.ca/PDF\\_Files/NiaStaseRTPMEnglish\\_2010-03-18.pdf](http://cae.novonordisk.ca/PDF_Files/NiaStaseRTPMEnglish_2010-03-18.pdf)