Recombinant Factor VII (7) NovoSeven® RT

Plasma Derived Blood Components and Synthetic / Recombinant Products

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>FVIIa NOVOSEVEN®RT pre-filled syringe</th>
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<tbody>
<tr>
<td>SPECIFICATIONS</td>
<td>Recombinant Factor VIIa 1.0mg/ml, sodium chloride 2.3mg/ml, calcium chloride dehydrate 1.5mg/ml, glycylglycine 1.3mg/ml, polysorbate 80 0.1mg/ml, mannitol 25mg/ml, sucrose 10mg/ml, methionine 0.5mg/ml, histidine 1.6mg/ml.</td>
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<tr>
<td>VIAL SIZES</td>
<td>1mg, 2mg, use 3mL syringe solvent for reconstitution; 5mg, 8mg, use 10mL syringe solvent for reconstitution;</td>
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<tr>
<td>INDICATIONS</td>
<td>The full product information should be read prior to prescribing or administering FVIIa (<a href="#">NovoSeven®RT Product Information</a>) this can be obtained from the insert accompanying the product. <strong>Bleeding disorders</strong>: control of bleeding in congenital FVII deficiency, FVIII or FIX patients with inhibitors, Glanzmann’s Thrombasthenia, rare bleeding disorders. <strong>Critical bleeding</strong>: off label use requires approval by Haematology Specialist and Treating Consultant</td>
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<td>CONTRAINDICATIONS</td>
<td>Patients with known hypersensitivity to rFVIIa, any of the components of NovoSeven RT or to mouse, hamster or bovine proteins.</td>
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<td>CONSUMER INFORMATION</td>
<td><a href="#">NovoSeven Consumer Medical information</a></td>
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<tr>
<td>CONSENT</td>
<td>Written consent is not required. Refer to Transfusion Medicine Protocol – <a href="#">Blood product prescription and informed consent</a>.</td>
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| DOSE                           | Guided by Haematology Specialist.  
• The dose should be rounded to the nearest whole vial to minimise wastage.  
• Following intravenous injection, the time to peak concentration is 15 minutes.  
• The half life of FVIIa is 2 hours. Occasionally a second dose may be required 2-4 hours after the first dose. |
| ORDERING                       | • **Haemophilia use**: Refer to Haematology Doctor / Haemophilia nurse to phone Transfusion Medicine Unit (TMU) and request order for FVIIa.  
• **Other indications**: Requesting Specialist to phone TMU and request order. Please provide name of Haematology Consultant and treating Consultant who approved use and dose. Repeat doses will require repeat approval. |
### ADMINISTRATION

- **Pre approval**: In special circumstances pre approval may be granted in complex surgical cases. Contact Laboratory Haematologist for more information.

- Two staff to perform checks as per PNPM 2.1.2 for Checking and Administration processes. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact TMU and prescribing doctor.
- Refer to product insert for reconstitution directions *Instructions for use of NovoSeven® RT*
- Do not use Novoseven RT exhibiting particulates or discolouration.
- NovoSeven RT contains no antimicrobial preservative & should be used immediately.
- Do not mix with other intravenous solutions, intravenous medications or administer FVIIa by infusion.
- Rate: Intravenous bolus injection over a period of 2-5 minutes.

### OBSERVATIONS

FVII deficient patients should be monitored for prothrombin time and FVII coagulant activity before and after administration of FVIIa. For all other patients a full blood count and coagulation profile (APTT, INR, and fibrinogen) must be available prior to considering the use of FVIIa. The patient’s clinical condition will dictate the frequency of observations. The patient’s temperature and pH at time of FVIIa administration must be recorded in the notes. Maintain vigilance for untoward coagulation/thrombosis. Thrombogenic potential or induction of DIC is possible in conditions associated with circulating tissue factor.

### ADVERSE REACTIONS

*Clinical Trial Data*: Fever, haemorrhage, fibrinogen plasma decreased, haemarthrosis, hypertension. (Post marketing) (each <1/10000) DIC, myocardial infarction, CVA and cerebral ischaemia, arterial and venous thrombotic events. Development of inhibitors for FVII has been reported in a small number of patients after treatment with FVIIa. Any adverse reaction should be reported to the Clinical Haematologist and TMU. Refer to *Blood Products – Management and Reporting of Reactions and Adverse effects* as a guide to further treatment and management of the patient. Also refer to PNPM 3.11.1 Reporting of Allergies and Adverse Reactions.

### DOCUMENTATION

- The date and time of administration.
- Patient’s temperature and pH at time of FVIIa administration.
- Amount given.
- Place Issue label in patient Blood Product Administration Record/Transfusion Record MR616 (supplied by Transfusion Medicine Unit). This information is important should the patient have a reaction to the infusion or if there is a need to trace recipients of certain batch numbers at a later date.

### REPORTING AND AUDIT

The PMH Patient Blood Management Committee will audit the use of FVIIa.
For further information, refer to product insert
Return product to TMU immediately if no longer required.
Product should be used for intended patient (issue label) only.

References

NovoSeven Product Information http://www.novosevenrt.com/

Related policies, procedures and guidelines.

<table>
<thead>
<tr>
<th>Policy/Procedure</th>
<th>Description</th>
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<tr>
<td>Paediatric nursing practice manual, Section 2.1.2 checking and administration of medications</td>
<td></td>
</tr>
<tr>
<td>Paediatric nursing practice manual, Section 3.11.1 reporting of allergies and adverse reactions</td>
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<tr>
<td>Transfusion Medicine Protocols, Blood product prescriptions and informed consent</td>
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<tr>
<td>Transfusion Medicine Protocol, Management and Reporting of Reactions and Adverse effects</td>
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Useful resources

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<tr>
<th>Resource</th>
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<tr>
<td>NovoSeven Product Information <a href="http://www.novosevenrt.com/">http://www.novosevenrt.com/</a></td>
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File Name and Path: Recombinant Factor VII (7) NovoSeven® RT pre-filled syringe
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Reviewer / Team: Consultant Haematologist/Oncologist (Dr C Cole), Medical Scientist in Charge (J. Jensen), Transfusion Coordinator (A. Taylor)
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