## Recombinant Factor VII (7) NovoSeven® RT

### DESCRIPTION
Recombinant Factor VII (7) NovoSeven® RT pre-filled syringe

### SPECIFICATIONS
- Recombinant Factor VIIa (rFVIIa) 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.

### VIAL SIZE
- 1mg, 2mg, 5mg, 8mg

### INDICATIONS
The full product information should be read prior to prescribing or administering FVIIa NovoSeven®RT Product Information this can be obtained from the insert accompanying the product.

- **Bleeding disorders**: control of bleeding in congenital FVII deficiency, FVIII or FIX patients with inhibitors, Glanzmann’s Thrombasthenia, rare bleeding disorders.
- **Critical bleeding**: off label use requires approval by Haematology Specialist and Treating Consultant

### CONTRAINDICATIONS AND PRECAUTIONS
Patients with known hypersensitivity to rFVIIa, any of the components of NovoSeven RT or to mouse, hamster or bovine proteins.

### CONSUMER INFORMATION
NovoSeven Consumer Medical information

### CONSENT
Written consent to Blood Transfusion is not required as this is not a blood product.

### DOSE
Dose and administration must be discussed with the Consultant Haematologist.

### ORDERING
Requesting Specialist to phone TMU and request order. Please provide name of Haematology Consultant and treating Consultant who approved use and dose.
## ADMINISTRATION
- Two staff to perform checks as per the Clinical Practice Manual, *WNHS Pharmacy Medication 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 or intravenous medications.

## OBSERVATIONS
- Undertake observations as for all blood products. Vital signs (temperature, pulse, respiration, blood pressure) must be recorded on the observation chart in the medical record.
- FVII deficient patients should be monitored for prothrombin time and FVII coagulant activity before and after administration of rFVIIa.
- For all other patients a full blood count and coagulation profile (APTT, INR, and fibrinogen) must be available prior to considering the use of rFVIIa.
- The patient’s temperature and pH at time of rFVIIa 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.

## DOCUMENTATION
A record should be kept in the patient’s history of the following:
- The date and time of administration.
- Patient’s temperature and pH at time of rFVIIa administration.
- Patient’s observations and condition during the infusion.
- Amount given.
- The batch number and expiry date of each bottle used.
(place a sticker with the batch number on the Transfusion Medicine Record sheet MR735). 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.

<table>
<thead>
<tr>
<th>REPORTING AND AUDIT</th>
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<tr>
<td>• The KEMH Hospital Transfusion Committee will audit the use of rFVIIa.</td>
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<td>• The drug costs are to be borne by the department making the request for NovoSeven.</td>
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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

- Instructions for use of NovoSeven® RT
- Australian Red Cross Blood Service – Blood products and transfusion practice for health professionals. [Australian Red Cross](http://www.redcross.com.au) website

Related policies


Related WNHS policies, procedures and guidelines

- [WNHS Pharmacy Medication Checking and Administration](http://www.wnhs.com.au/policies-and-procedures/medicine-medication-checking-administration)
- Obstetrics and Gynaecology Clinical Guidelines
- [WNHS Pharmacy Medication Checking and Administration](http://www.wnhs.com.au/policies-and-procedures/medicine-medication-checking-administration)

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Document owner: Chair of KEMH Hospital Transfusion Committee
<table>
<thead>
<tr>
<th>Author / Reviewer:</th>
<th>Consultant Haematologist, Scientist in Charge Transfusion Medicine, KEMH Transfusion Coordinator</th>
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<tbody>
<tr>
<td>Date first issued:</td>
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<td>KEMH Hospital Transfusion Committee</td>
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<tr>
<td>Standards Applicable:</td>
<td>NSQHS Standards: 1 Governance, 5 Patient ID/Procedure Matching, 7 Blood Products</td>
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