TRANSFUSION MEDICINE PROTOCOLS

Recombinant Factor VII (7) NovoSeven® RT

This document should be read in conjunction with the Disclaimer

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	Discuss dose with Consultant Haematologist.
ORDERING	Requesting Specialist to phone TMU and request order. Please provide name of Haematology Consultant and treating Consultant approving 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 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 at time of rFVIIa administration. • Patient's observations and condition during the infusion • Amount given documented on the medication chart. • 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 or if there is a need to trace recipients of certain batch numbers at a later date.
REPORTING AND AUDIT	• The KEMH Hospital Transfusion Committee will audit the use of rFVIIa. • Drug costs for approved use are funded by the National Blood Authority. For off-label use in critical bleeding, costs are to be borne by the department making the request for NovoSeven.
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
- NovoSeven Product Information http://www.novosevenrt.com/
- Australian Red Cross Blood Service – Blood products and transfusion practice for health professionals. Australian Red Cross website
- National Safety and Quality Health Service Standards, October 2012. Standard 7: Blood and Blood Products

Related WNHS policies, procedures and guidelines

- WNHS Blood Product Prescription, Consent and Refusal
- WNHS Pharmacy Medication Checking and Administration
- Obstetrics and Gynaecology Clinical Guidelines
- WNHS Pharmacy Medication Checking and Administration

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Standards Applicable:	NSQHS Standards: 1 Governance, 5 Patient ID/Procedure Matching, 7 Blood Products		
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