

## 17 WNHS POLICY FOR USE OF RECOMBINANT FACTOR VIIA FOR LIFE THREATENING BLEEDING IN MEDICAL, SURGICAL OR TRAUMA PATIENTS

Date Issued: January 2005  
Date Revised: August 2011  
Review Date: August 2013  
Authorised by: KEMH Transfusion Committee  
Review Team: KEMH Transfusion Committee

17.1 Background on Factor VIIa for life threatening bleeding  
Section 17  
Transfusion Medicine Protocols  
Women's & Newborn Health Services  
Perth Western Australia

### 17.1 BACKGROUND

Recombinant Factor VIIa (NovoSeven, NovoNordisk Australia) is the recombinant form of activated plasma coagulation Factor VII that plays a critical role in the initiation of blood coagulation. It is approved for the prevention or treatment of bleeding in patients with inhibitors to coagulation factors VIII or IX inhibitors. In these patients it has been shown to be highly effective with a very low risk of thromboembolic complications. It is also indicated for patients with rare bleeding disorders e.g. Factor VII deficiency, Glansman's Thrombaesthesia

More recently there have been a number of case reports of the effectiveness of rVIIa to treat life-threatening bleeding in

- Trauma and Surgery with persistent coagulopathy, despite appropriate blood component transfusion
- Intra Cerebral Haemorrhage
- Obstetric- PPH
- Burns
- Cardiac Surgery
- Oncology
- GI Haemorrhage
- Hepatic dysfunction

NovoSeven® RT can be stored at room temperature up to 25°C. Reconstituted NovoSeven RT should be used immediately. The final concentration after reconstitution is 1mg/ml. NovoSeven® RT is supplied in vials of 1, 2, and 5 mg with a dedicated solvent. Vials are colour-coded to match solvent vials. Vials and solvent come packaged together.

Click for additional → [Novoseven RT Manufacturer Information](#) ←

**Precautions:** Maintain vigilance for untoward coagulation/thrombosis. Thrombogenic potential or induction of DIC is possible in conditions associated with circulating tissue factor. FVII deficient patients should be monitored for prothrombin time and FVII coagulant activity before and after administration of NovoSeven. Risk of potential interaction with coagulation factor concentrates is unknown – avoid simultaneous use of prothrombin complex concentrates. Do not mix with infusion solutions or administer NovoSeven® RT by infusion.

**Adverse Reactions:** (Clinical Trials) 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 rFVIIa