

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

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

17.2 GUIDELINES FOR RECOMBINANT FACTOR VIIA

rVIIa may be considered in the following situations (each of these criteria should be met):

- Massively transfused patients with life threatening bleeding despite:
- Appropriate blood component transfusion (fresh frozen plasma, platelets cryoprecipitate), pharmacological measures (DDAVP, anti-fibrinolytic agents) and correction of hypothermia and hypocalcaemia.
- Additional surgical intervention where appropriate.

At least two Hospital Consultants (preferably Surgeon, Anaesthetist, Intensive Care Physician, Emergency Department Physician, and Haematologist) consider the condition of the patient to be such that death is likely from bleeding. This should be documented in the patient medical records.

It is highly desirable that a full blood count and coagulation profile (APTT, INR, and fibrinogen) be available prior to considering the use of rVIIa. If this is not possible then a blood sample should be taken for retrospective testing. The FBC and Coagulation profile should be repeated after the NovoSeven is administered to assess the response. The patient's temperature and pH at time of NovoSeven RT administration must be recorded in the notes

The KEMH Transfusion Medicine Unit (Blood Bank) holds a stock of two 5mg, one 2mg and eight 1mg vials. The most commonly reported dose of rVIIa used for life-threatening haemorrhage in surgical patients is 90 µg/kg body weight. To minimise wastage, the patient's weight should be quoted at the time of ordering the NovoSeven.

It is important to note that even after the use of rVIIa, transfusion of further blood components (fresh-frozen plasma, platelets, cryoprecipitate) may need to be given as appropriate.

Occasionally a second dose is required 2-4 hours after the first dose. If the Blood Bank does not have sufficient stock to cover this dose, the scientist will arrange for additional vials to be obtained from Royal Perth Hospital.

DOSE

As quoted above, the most commonly reported dose of rVIIa given to treat life-threatening bleeding in surgical patients is 90 µg/kg body weight, given as an intravenous bolus dose. The dose should be rounded to the nearest whole vial to minimise wastage.

RECONSTITUTION

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. The solution is clear and colourless after reconstitution. Do not use it if there are particles or discolouration.

Final concentration after reconstitution is 1mg/ml

Reconstituted NovoSeven RT should be used immediately.

ADMINISTRATION

NovoSeven is intended for intravenous bolus injection only and should not be mixed with infusion solutions or be given in a drip. Do not use if particulate matter or discolouration is observed. Always use aseptic technique.

The patient's temperature and pH at time of NovoSeven RT administration must be recorded in the notes

TIME TO PEAK CONCENTRATION

Following intravenous injection, the time to peak concentration is 15 minutes.

HALF-LIFE

Approximately 2 – 3 hours.

CONTRAINDICATIONS

Hypersensitivity to mouse, hamster or bovine proteins.

POTENTIAL SIDE EFFECTS

The administration of rVIIa may rarely be associated with thrombotic complications, including myocardial infarction, stroke, or venous thromboembolism.

ADVERSE EVENTS/REACTIONS

Any adverse reaction should be reported to the Clinical Haematologist

COST

The drug costs are to be borne by the Department making the request for the NovoSeven.

REPORTING AND AUDIT

The KEMH Transfusion Committee will audit the use of rVIIa.