

12 PLASMA DERIVED BLOOD COMPONENTS

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

12.16 Novoseven
Section 12
Transfusion Medicine Protocols
Women's & Newborn Health Services
Perth Western Australia

12.16 NOVOSEVEN (1MG 2MG AND 5 MG)

SEE ALSO SECTION 19: THE USE OF RECOMBINANT FACTOR VIIa FOR LIFE-THREATENING BLEEDING IN MEDICAL, SURGICAL OR TRAUMA PATIENTS.

DESCRIPTION

NovoSeven RT contains activated recombinant coagulation factor VII which is structurally very similar to human plasma derived activated factor VIIa. NovoSeven is supplied as a stable sterile freeze-dried powder in single use vials.

After reconstitution with solvent each vial contains 1.0mg/mL recombinant factor VIIa (50,000 IU/mL) sodium chloride 2.3mg/mL, calcium chloride dehydrate 1.5mg/mL, glycylglycine 1.3mg/mL, polysorbate 80 0.1mg/mL and mannitol 25mg/mL sucrose 10mg/mL methionine 0.5mg/mL and histidine 1.6mg/mL.

This product is for intravenous bolus injection. It is available in 1mg, 2mg and 5mg vials.

INDICATIONS

- Control of bleeding and surgery prophylaxis in patients with inhibitors to coagulation factors VIII and IX.
- Control of bleeding and surgery prophylaxis in patients with congenital FVII deficiency.
- Control of bleeding and surgery prophylaxis in patients with Glanzmann's thrombasthenia.
- Massively transfused patients with ongoing bleeding. Where, in the opinion of two consultants, this bleeding is life-threatening despite appropriate blood component therapy to try and correct coagulopathy, pharmacologic measures such as DDAVP and anti-fibrinolytic agents, general haemostatic measures including efforts to correct hypothermia and hypocalcaemia and surgical intervention where appropriate.

CONTRAINDICATIONS

- Patients with known hypersensitivity to rFVIIa or any of the components of NovoSeven.
- Patients with known hypersensitivity to Mouse hamster or bovine proteins.

DOSE AND ADMINISTRATION

Refer to Consultant Haematologist.

NovoSeven RT must be reconstituted with the sterile solvent provided and then administered by intravenous bolus over a period of 2-5 minutes.

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

Click for → [Novoseven Consumer Medicine Information including reconstitution instructions](#) ←

For Further information on Indications see Section 19.