Blood product information

01.11|2017

rFVIIa Novoseven®

Recombinant Activated Factor VII

Storage: +2 to 8° C
Shelf life: Until expiry

Do not freeze vials. Store vials in its original package at suggested temperature in order to protect from light. After reconstitution, rFVIIa can be stored within the original vial at room temperature or refrigerated for up to 3 hours. Do not freeze reconstituted rFVIIa.

Contains coagulation Factor VIIa synthesised by recombinant technology. The FVII gene is cloned and expressed in BHK cells, secreted into culture media containing newborn calf serum, proteolytically activated and chromatographically purified.

Each vial contains 1000 or 2000ug of rFVIIa.

Licensed indications

- Treatment of bleeding episodes or as perioperative prophylaxis in haemophilia A or B patients with inhibitors to FVIII or FIX.
- Treatment of bleeding episodes or as perioperative prophylaxis in patients with congenital FVII deficiency.
- Treatment of bleeding episodes or as perioperative prophylaxis in patients with Glanzmann's thrombasthenia and reduced or absent response to platelet transfusion

Off-label use (Refer side-note)

- Management of profuse uncontrolled bleeding due to trauma or surgery despite appropriate attempts to achieve surgical control of bleeding, and after correction of metabolic, coagulation and platelet deficiencies.
- Severe obstetric haemorrhage requiring consideration of internal artery ligation, uterine artery embolisation, or hysterectomy in the setting of optimal blood product support.
- Severe haemorrhage refractory to local control, in patients who refuse blood products but would accept recombinant blood factors.

Off-label use in critical bleeding

A haemostatic effect has been demonstrated after the administration of rFVIIa in a number of patients after trauma and bleeding as well in patients with extensive perisurgical bleeding. There is some evidence that use of rFVIIa after appropriate correction of acidosis, coagulation and platelet parameters with blood products, reduces the total amount of blood product required as well as 30-day mortality among trauma and obstetrics patients although overall long-term mortality is unaffected. Review of multiple data sources as well as a Cochrane meta-analysis has shown that rFVIIa use for off-label indications is generally associated with only a modest reduction in total blood loss or red cells transfused and no evidence of mortality benefit.

In view of the limited available evidence for rFVIIa effectiveness in management of critical bleeding, it is difficult to recommend for or against its use, especially taking into consideration the substantial cost of the product. A decision on its use in critical bleeding in this centre requires consensus from two consultants, one of whom shall be a haematologist, and the decision clearly documented in the patient's case notes. All standard measures for the management of massive haemorrhage including adequate correction of coagulation using blood products, correction of acidosis and administration of tranexamic acid should have been undertaken. An initial dose of 90ug/kg is recommended and response assessed on clinical grounds. If severe bleeding is ongoing, a second dose of 90ug/kg may be given, if appropriate, after 1 hour but not more than 2 hours from the first dose. No further doses should be administered under any circumstances during a single bleeding episode.

Administration

- Read all instructions in package insert
- Reconstitute powder following the instructions carefully
- Give as slow bolus over 2-5 minutes

Adverse reactions and precautions

This is a recombinant product. No human serum or other proteins are used in its production or formulation.

Recombinant FVIIa should not be administered to patients with known hypersensitivity to it or any of its components i.e. mouse, hamster or bovine proteins.

The most serious adverse event associated with rFVIIa is thrombosis. The extent of risk of thrombotic adverse events in treatment of patients with haemophilia and inhibitors is not known, but is considered low. When used off-label, risks may be amplified due to DIC, crush injury, septicaemia, end stage liver disease and advanced artherosclerotic disease. Patients receiving rFVIIa should be carefully monitored for any signs or symptoms of thrombosis.