

Indications and Usage

NovoSeven® RT (Coagulation Factor VIIa [Recombinant] Room Temperature Stable) is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to FVIII or FIX and in patients with acquired hemophilia; prevention of bleeding in surgical interventions or invasive procedures in hemophilia A or B patients with inhibitors to FVIII or FIX and in patients with acquired hemophilia; treatment of bleeding episodes in patients with congenital FVII deficiency and prevention of bleeding in surgical interventions or invasive procedures in patients with congenital FVII deficiency.

Important Safety Information

Warning: Serious thrombotic adverse events are associated with the use of NovoSeven® RT outside labeled indications. Arterial and venous thrombotic and thromboembolic events following administration of NovoSeven® RT have been reported during postmarketing surveillance. Clinical studies have shown an increased risk of arterial thromboembolic adverse events with NovoSeven® RT when administered outside the current approved indications. Fatal and non-fatal thrombotic events have been reported. Discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive NovoSeven® RT. Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis. Safety and efficacy of NovoSeven® RT has not been established outside the approved indications.

Please see additional Important Safety Information throughout and on page 6. Please see accompanying Full Prescribing Information.



